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U.S. ARMY CORPS OF ENGINEERS
QUALITY ASSURANCE PROGRAM PLAN

June 15, 1993

Work Performed Under Master Interagency Agreement
No. DE-AI06-90RL12074
Task Order DE-AT06-90RL121101

Prepared for
U.S. Department of Energy
Field Office, Richland

Prepared by
DEPARTMENT OF THE ARMY
Walla Walla District, Corps of Engineers
Walla Walla, Washington 99362-9265

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ASSIGNED

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Reviewer	Name/Title	Signature	Date
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CENPW Project Manager Request

Responsible Manager & Requestor	Name/Title	Signature	Date
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5. **DOE-RL Review**

Reviewer	Name/Title	Signature	Date
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DOE-RL Programmatic Review	N A INERDEL ME		9-16-91

6. **CENPW Document Clearance Approval**

Approved for Release	Name/Title	Signature	Date
CENPW Project Manager Approval	John H Jacobson Project Manager		9-16-91

U.S. Army Corps of Engineers
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APPROVAL

Chapters 1-21, Revision 0, Date 16 September 1991

Dennis L. Cannon
Chief, Hanford Program Office

Date: 16 Sep 91

Richard A. Kaden
Special Assistant for Quality Assessment

Date: 16 Sep 91

POLICY STATEMENT

It is the policy of the U.S. Army Corps of Engineers, Walla Walla District (CENPW), as a participant in the Hanford Site Environmental Restoration Remedial Action Program (ERRA), to provide a quality product in all aspects of work assigned by the U.S. Department of Energy Field Office, Richland (DOE-RL). An effective quality assurance program builds public confidence in CENPW's ability to manage the ERRA program in such a manner that provides for protection of human health and the environment.

The CENPW Quality Assurance Program Plan (CEQAPP) describes the CENPW Comprehensive Quality Assurance Program and identifies the plans, procedures, and systems CENPW will use to implement quality assurance requirements. The CEQAPP complies with the ERRA Quality Assurance Requirements Document (QARD) and was developed in relation with the CENPW Hanford Program Management Plan (HPMP). This CEQAPP is an umbrella document to be used for all work assigned to CENPW by DOE-RL Task Orders for Hanford Projects. Each Task Order for Hanford Projects will have a separate CENPW Quality Assurance Project Plan (QAPjP) or Quality Assurance Plan (QAP) prepared in accordance with the CEQAPP. The separate QAPjPs will be reviewed and approved by CENPW, and if required by the Task Order, reviewed or approved by DOE-RL.

As the Commander of CENPW, I will ensure that achievement of quality is accomplished by: (1) ensuring that management at all levels are responsible and personally accountable for achieving quality, (2) committing proper resources and budget to implement effective quality assurance activities which are responsive to program goals and performance objectives, and (3) using interdisciplinary management control systems which provide for achievement of quality in a planned and systematic manner. Therefore, I hereby endorse and establish this CEQAPP document for all CENPW work for DOE-RL.

Robert D. Volz Date 16 Sep 91

LTC. Robert D. Volz
District Commander

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GLOSSARY

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GENERAL INTRODUCTION

1. BACKGROUND

a. National Environmental Restoration Program--U.S. Department of Energy's (DOE's) stated commitment is to a 30-year goal of assessing and remediating inactive facilities and sites that were contaminated by wastes generated as a result of past operations and activities. The Environmental Restoration Program was established in 1987 to plan, execute, and control the remediation effort. This program is assigned to the DOE's Office of Environmental Restoration and Waste Management within the Office of Environmental Restoration.

b. Hanford Site Environmental Restoration Remedial Action Program--The U.S. Department of Energy Field Office, Richland (DOE-RL) is responsible for the Hanford Site Environmental Restoration Remedial Action Program (ERRA). The planning, organization, and control systems for the ERRA are described in the DOE-RL Environmental Restoration Remedial Action "Field Office Management Plan" (FOMP) for the Hanford Site. The principle regulatory compliance requirements for the Hanford Site ERRA program are derived from the statutory provisions of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 as amended by the Superfund Amendments and Reauthorization Act of 1986; the Resource Conservation and Recovery Act of 1976, as amended by the Hazardous and Solid Waste Amendments of 1984; the National Environmental Policy Act of 1969; the Hanford Federal Facility Agreement and Consent Order, hereafter referred to as the Tri-Party Agreement; the Atomic Energy Act of 1984; and, the Washington State Hazardous Waste Management Act. The Tri-Party Agreement establishes criteria, procedures and milestones for ERRA relative to waste management and environmental restoration activities at the Hanford Site.

c. Interagency Agreement--On 12 July 1990, DOE and the U.S. Army through the U.S. Army Corps of Engineers (USACE) implemented a Memorandum of Understanding to define types and levels of support that USACE will provide DOE in connection with DOE's Environmental Restoration and Waste Management Program. Pursuant to the Memorandum of Understanding, a master Interagency Agreement (IA) DE-AI06-09RL12074, dated 27 July 1990, entitled "Environmental Restoration and Waste Management Program Services," was enacted between DOE-RL and the U.S. Army Corps of Engineers, North Pacific Division. The purpose of the IA is to secure technical and management expertise from the U.S. Army Corps of Engineers, Walla Walla District (CENPW) to support waste management and environmental restoration activities at the Hanford Site. The IA establishes procedures for DOE-RL to assign work and obligate funds to CENPW through task orders for Hanford Projects.

d. Participant--CENPW is a full service organization of 645 personnel located in Walla Walla, Washington. CENPW is responsible for USACE activities located in the area generally defined by the Snake River drainage basin and the Columbia River between the Hanford Site and McNary Dam. CENPW can draw upon the extensive resources of USACE, which is composed of a staff in excess of 40,000. CENPW can also draw upon the

resources of the U.S. Army, other Department of Defense organizations, and private consultants and contractors to support work on the Hanford Site.

e. Participant Documents--As described in paragraph 9.0 and shown in figure 9-1 of the FOMP, each major participant, including CENPW, must prepare ERRA program documentation in the hierarchy indicated.

(1) Program Management Plans--As described in paragraph 9.10.1 of the FOMP, each major participant must prepare a participant Program Management Plan. CENPW has prepared the U.S. Army Corps of Engineers, Walla Walla District, "Hanford Program Management Plan."

(2) Quality Assurance Program Plan--The Hanford Site ERRA Quality Assurance Program is designed to build confidence in the DOE's ability to manage its waste in a manner which provides for protection of human health and the environment. To accomplish this objective, a number of quality assurance standards and requirements have been identified for ERRA program implementation. All of the applicable standards and requirements have been consolidated into a single document entitled the Environmental Restoration Remedial Action "Quality Assurance Requirements Documents" (QARD).

The achievement of quality is accomplished by ensuring that management at all levels is responsible and personally accountable for achieving quality and by using an interdisciplinary management control system. The management control system includes quality verification and overview activities to ensure the completeness and appropriateness of achieved quality; the adequacy, validity, and traceability of data; assurance that an activity is performed to specified requirements; and assurance that a structure, system, process, document, or component will perform its intended functions.

As described in paragraphs 2.2 and 9.10.2 of the FOMP and as shown in figure 1 of the QARD, each major participant must prepare a Quality Assurance Program Plan (QAPP) in conjunction with the Program Management Plan (PMP) and under the standards and requirements of the QARD. The QAPP will identify the applicable requirements of the QARD relative to the participant's scope of work and the PMP. Having defined the applicable standards, the QAPP establishes methods and procedures to be followed and assigns the responsibilities of key positions for implementing the identified requirements.

Additionally, for major ERRA program activities, a Quality Assurance Project Plan (QAPjP) will be prepared identifying specific quality assurance measures and requirements for that activity. As a minimum, a QAPjP will be prepared for the operable unit assessment activities and will be included as part of the task order documentation.

CENPW was assigned responsibility for preparation of the QAPP in accordance with the IA and the requirements of Task Order Number 001-PM-01-00.

2. PURPOSE

The U.S. Army Corps of Engineers, Quality Assurance Program Plan (CEQAPP) describes CENPW's comprehensive Quality Assurance Program (QAP) and identifies the plans, procedures, and systems CENPW will use to implement quality assurance requirements. The CEQAPP complies with the QARD and was developed in accordance with the Hanford Program Management Plan. The CEQAPP establishes the Special Assistant for Quality Assessment for independent quality assurance oversight of CENPW work for Hanford Projects. The CEQAPP also establishes comprehensive quality assurance requirements for management and administration, design and control of environmental data, and design and control of items and remedial actions.

3. APPLICABILITY AND RESPONSIBILITY

The CEQAPP is an umbrella document applicable for all Hanford Projects assigned to CENPW by DOE-RL Task Orders. All CENPW organizations and other organizations used by CENPW to accomplish its work are responsible for implementing the requirements in the CEQAPP that are applicable to their respective scopes of work.

For Hanford Projects with environmental data operations, CENPW will prepare a specific QAPjP in accordance with the CEQAPP and task order to detail specific line organizational elements, project management organizational elements, and interface requirements with other USACE organizations and contractors. The QAPjP will be part of the PMP and approved by the CENPW Project Review Board. When CENPW utilizes other USACE organizations or contractors to accomplish work for Hanford Projects involving environmental data operations, the specific QAPjP may be developed in phases matching the agreement or procurement process. The first phase will be development of the QAPjP for CENPW internal organization and controls with appropriate interface requirements detailed for the other USACE organizations and contractors. After completion of the agreement or procurement process, a second phase may be necessary to supplement the QAPjP with the other USACE organizations or contractor's internal organization and controls developed in accordance with the CENPW QAPjP and CEQAPP. If required by the task order, the QAPjP will be reviewed/approved by DOE-RL.

For Hanford Projects with remedial design and remedial actions, CENPW will prepare either a QAPjP if the project involves environmental data or a QAP if the project does not involve environmental data. For projects without environmental data, the QAP will be in accordance with the CEQAPP and task order and detail the organizational elements and interface requirements with other USACE organizations and contractors. The QAP will be part of the CENPW PMP and approved by the CENPW Project Review Board. The QAP will be prepared in accordance with Engineering Regulation (ER) 1110-1-71, and/or ER 1180-1-6. If required by the task order, the QAPjP or QAP will be reviewed/approved by DOE-RL.

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1.0 QUALITY ASSURANCE PROGRAM

1.1 GENERAL

The Quality Assurance (QA) program is comprised of this U.S. Army Corps of Engineers Quality Assurance Program Plan (CEQAPP), policies, procedures, and instructions necessary for implementing the program. The establishment of the program will include consideration of the technical aspects of the activities affecting quality. The program will provide control over activities affecting quality to an extent consistent with their importance in meeting the performance objectives as described in paragraph 1.4. These requirements apply to all work done for the Department of Energy, Richland Operations Office (DOE-RL) at the Hanford Facility by the U.S. Army Corps of Engineers, Walla Walla District (CENPW), and all contractors and organizations performing Hanford Project-related activities for CENPW.

1.2 ORGANIZATION

This section defines the U.S. Army Corps of Engineers (USACE), CENPW organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality and work in general. This QA program applies to all work assigned to CENPW by DOE-RL.

Effective product quality will be facilitated through clear assignment of responsibility, authority, and accountability to all levels within the CENPW organization.

1.2.1 Line Organization and Responsibility

1.2.1.1 Background. USACE is a decentralized civilian organization under the stewardship and command of military personnel at three line organizational levels: USACE Headquarters, Division Offices, and District Offices. Headquarters is responsible for all the independent Division Offices. Each Division Office is responsible for a number of independent Districts making up a regional part of the country. Each District Office is responsible for USACE activities located in a specific area generally defined by river drainage basins. The military line organization consists of the commanders of the three organizational levels.

Each of the three levels has a decentralized civilian organization, which is organized into equivalent functional elements at each level. Therefore, the line organization of USACE also has a secondary civilian chain of command for management oversight and quality verification by respective functional elements.

CENPW has established a District organization, independent of the other functional elements, to satisfy the requirements of DOE-RL and the Quality Assurance Requirements Document (QARD). This organization is called the Special Assistant for Quality Assessment. The Special Assistant for Quality Assessment fulfills the need for an independent QA organization within CENPW whose function is to provide QA planning,

monitoring, and assessment. The Special Assistant for Quality Assessment provides QA oversight of CENPW line organizations and other organizations CENPW utilizes to perform its work for DOE-RL in management, environmental data operations, remedial design and remedial actions.

Readers of this document must recognize that there are differences in Department of Energy (DOE) and USACE terminology and organizations. Some USACE terminology included in the CEQAPP, such as "QA Branch," "QA Representative," and "QA Representative Laboratory Technician," describe organizations or personnel responsible for quality achievement and quality verification. Quality assessment, in the context of the CEQAPP for Hanford Projects, is the responsibility of the Special Assistant for Quality Assessment.

1.2.1.2 USACE Organization and Responsibility. The USACE Commander maintains primary control of U.S. Army Corps of Engineers, North Pacific Division (CENPD), Commander and staff and provides management oversight and quality verification of CENPD's equivalent civilian functional elements.

1.2.1.3 CENPD Organization and Responsibility. The CENPD Commander provides primary control over CENPW's Commander and staff and maintains management oversight and quality verification over the District's equivalent civilian functional elements. The CENPD organization chart is shown in figure 1-1. The functions and responsibilities of each CENPD functional element are described in ER 10-1-3.

1.2.1.4 CENPW Organization and Responsibility. The CENPW line organization chart is shown in figure 1-2 (a-c). The District Commander of CENPW is the military District Engineer, and in his absence the military Deputy District Engineer. The District Commander also has a civilian Deputy District Engineer for Project Management who is responsible for assuring the successful accomplishment of all CENPW programs and project management objectives. The civilian line organizations under the District Commander are organized by functional elements. Each element separately reports to the District Commander. The functional elements are termed either Divisions or Offices. The Special Assistant for Quality Assessment provides QA oversight of CENPW work for Hanford Projects, per the QARD, and is independent of all other civilian line organization functional elements. All other line organization functional elements are responsible for the quality control (QC), quality achievement, and quality verification of their respective scope of involvement.

1.2.1.4.1 CENPW Management and Administration Organization--The overall management and administration line organization of CENPW for each military and civilian functional element is described in NPWOM 10-1-3. NPWOM 10-1-3 also lists the overall organizational structure, functional responsibilities, levels of authority, and lines of communication within CENPW. In general, for each CENPW functional element, the achievement of quality is the responsibility of the Division Chief of that functional element, with appropriate delegated responsibilities to the Branch Chief, and then to the Section Chief. The overall functions and responsibilities listed in NPWOM 10-1-3 will be supplemented by

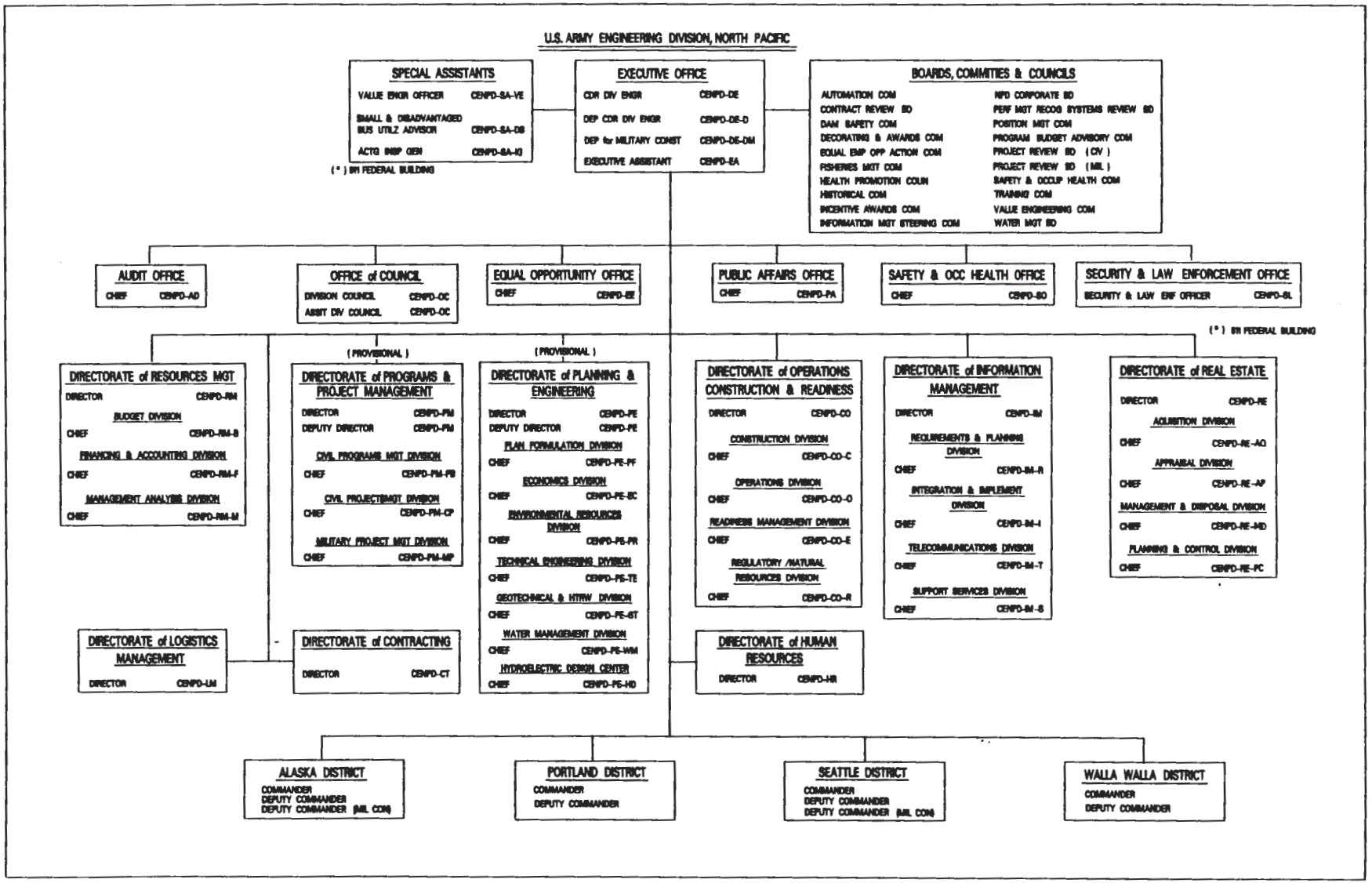

Figure 1-1. U.S. Army Corps of Engineers, North Pacific Division, Organization Chart

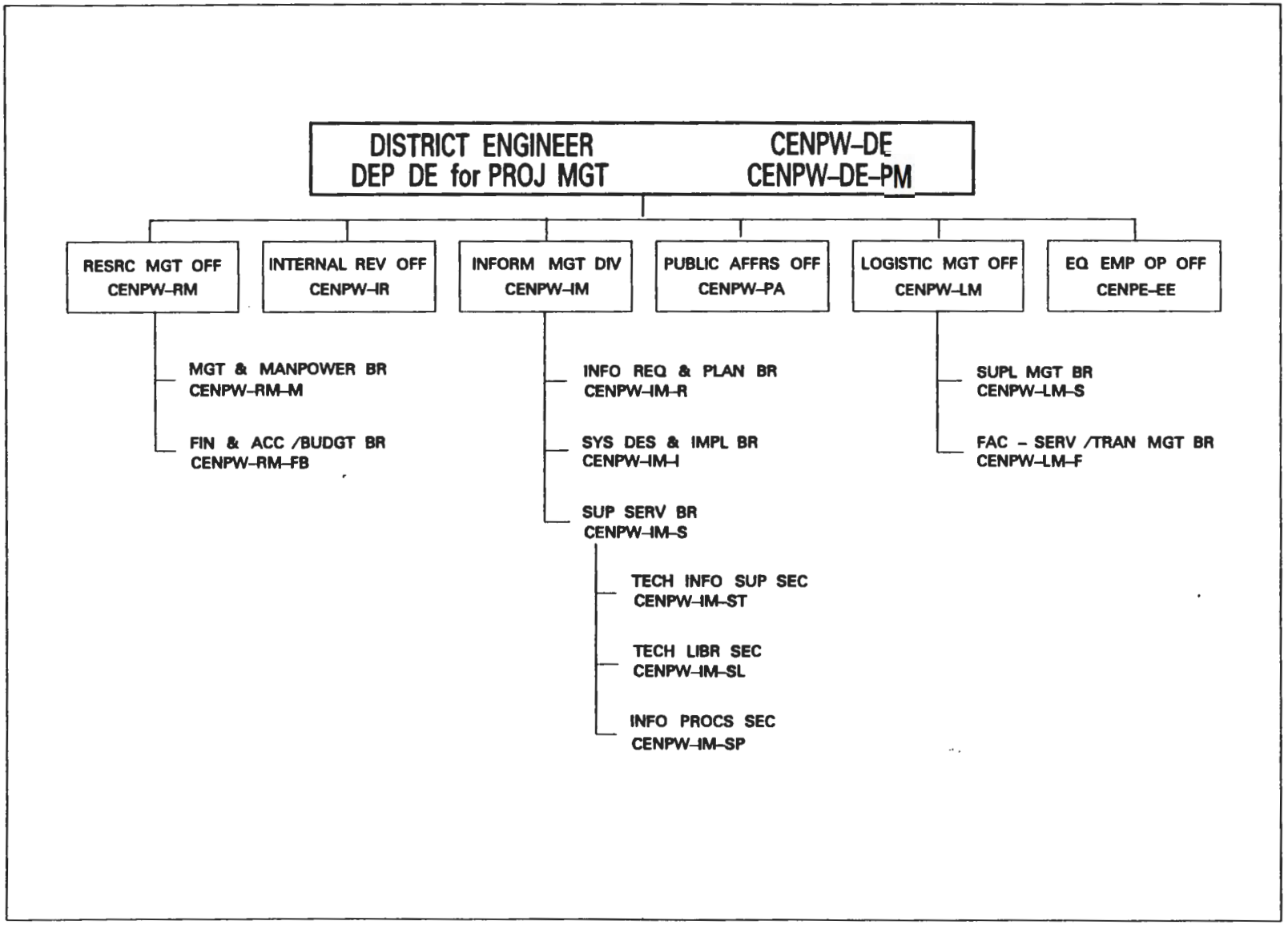

Figure 1-2(a). CENPW Line Organization Chart

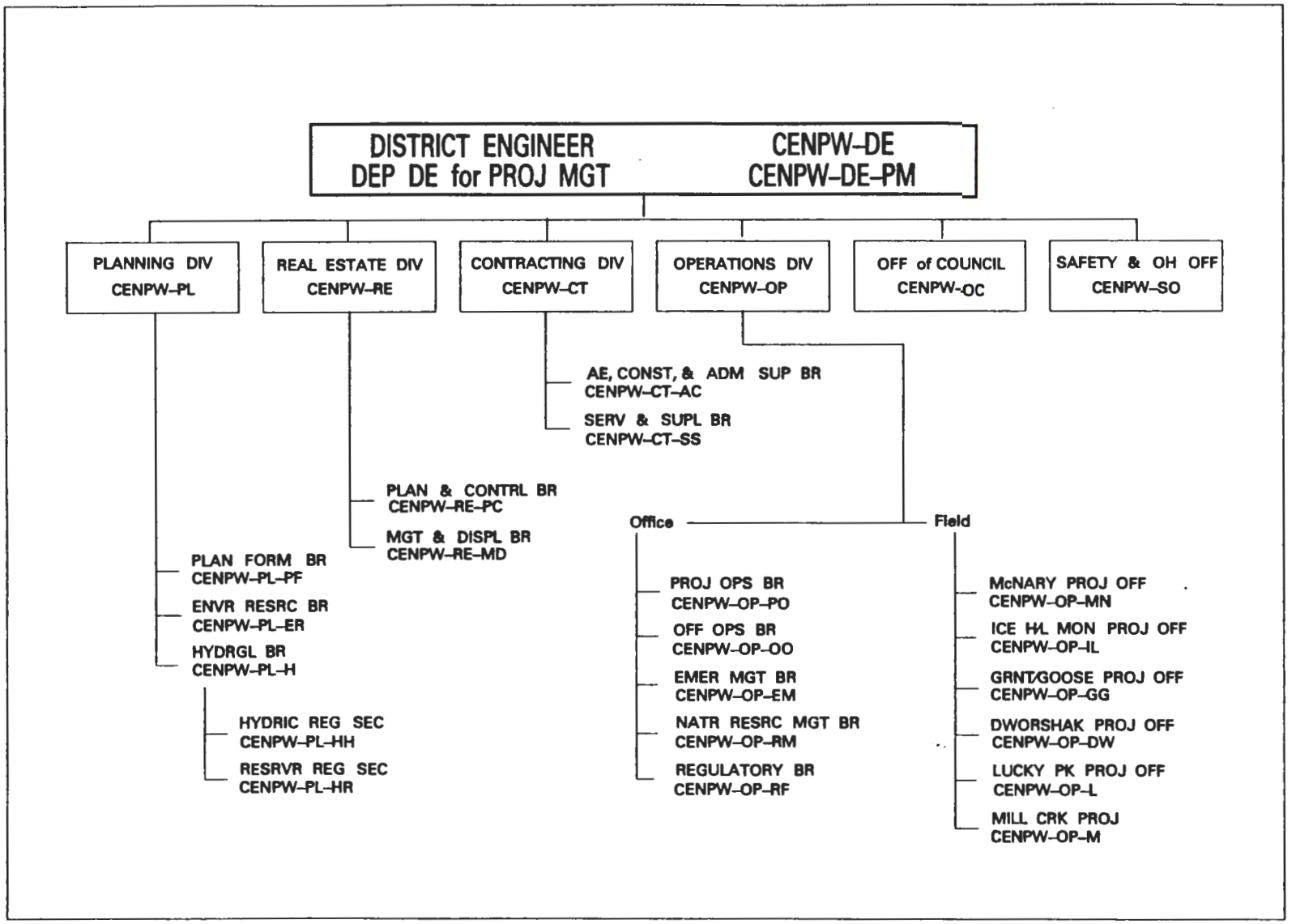

Figure 1-2(b). CENPW Line Organization Chart

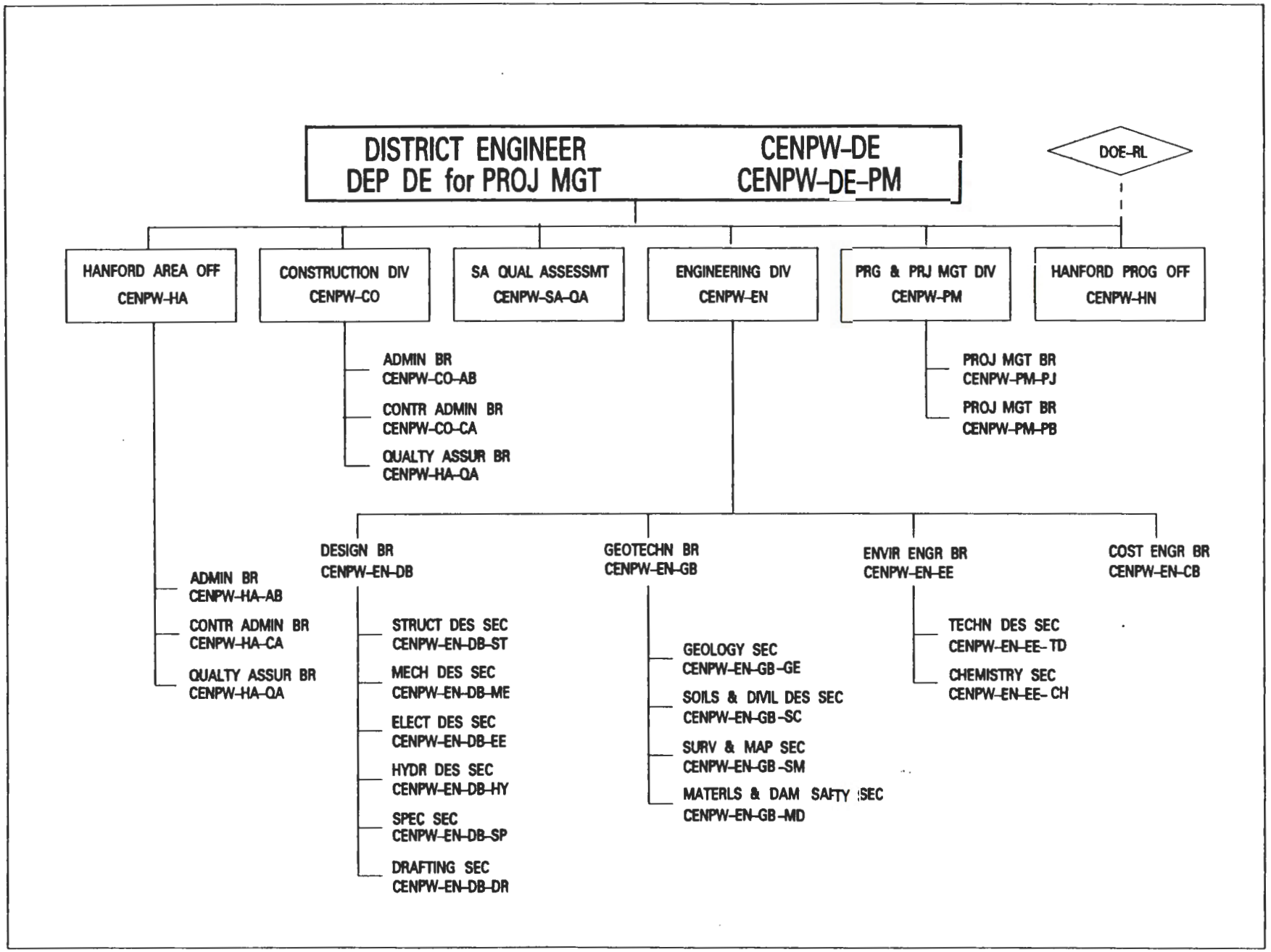

Figure 1-2(c). CENPW Line Organization Chart

the Quality Assurance Project Plan (QAPjP) or the Quality Assurance Plan (QAP) with more specific information on organizational structure, functional responsibilities, responsible individuals, levels of authority, and lines of communication of the functional elements needed for that specific project for activities affecting quality of management and administration.

1.2.1.4.2 CENPW District Commander Responsibility--The functions and responsibilities of the District Commander as defined in NPWOM 10-1-3 for activities affecting quality are supplemented by the following:

a. The District Commander will allocate the appropriate resources and make appropriate budget commitments in order to assure that effective QA activities are responsive to program needs and objectives.

b. The District Commander will assure that appropriate planning is accomplished for the performance and verification of activities affecting quality.

c. The District Commander will mandate the implementation of the QAP, through the Special Assistant for Quality Assessment, and accept the responsibility for that implementation.

d. The District Commander will commit to full implementation of the applicable requirements of the CEQAPP.

e. The District Commander will require that all organizations and personnel be responsible for quality achievement and maintenance.

f. The District Commander will require that quality achievement be checked and reverified by persons or organizations not directly responsible for performing the work.

g. The District Commander will emphasize the use of innovative measures to prevent quality problems.

h. The District Commander will participate in organizational audits/reviews.

i. The District Commander is committed to continuing quality improvement.

j. The District Commander acting as the Contracting Officer may delegate, as appropriate, to the Administrative Contracting Officer (ACO) or Contracting Officer's Representative (COR), responsibility to manage, oversee, and otherwise assure contract performance.

k. The District Commander is authorized to stop work as a result of unsatisfactory quality performance by any CENPW organization or other organization CENPW utilizes for Hanford Projects.

1.2.1.4.3 CENPW Line Organization Functional Elements Responsibility--The functions and responsibilities for the Chiefs of CENPW line organization functional elements performing activities affecting quality are defined in NPWOM 10-1-3 and are supplemented by the following:

a. Organizing and planning activities to consistently meet quality requirements.

b. Coordinating work performance with controls required by the QAP and the Special Assistant for Quality Assessment.

c. Training and qualifying personnel to achieve proficiency, maintain proficiency, and adapt to changing technology, methods, or job responsibilities.

d. Ensuring that environmental data operations, remedial designs, and remedial actions are properly documented.

e. Overseeing the quality of activities performed by the organization and providing direction and guidance for improvement.

f. Ensuring resources/budgets are effectively disbursed to complete work.

g. Ensuring implementation of appropriate QA requirements.

h. Participating in organizational audits/reviews.

i. Assigning and delegating sufficient responsibility for individual Hanford Projects to Technical Managers. The Technical Managers are not permanent positions. The Technical Manager is responsible for quality achievement and quality verification of their functional element's portion of the assigned Hanford Project. The Chief is ultimately responsible for the technical quality of the products.

1.2.1.4.4 CENPW Special Assistant for Quality Assessment Responsibility--The functions and responsibilities, as defined in NPWOM 10-1-3, for the Quality Assessment Manager include the QA responsibility of paragraph 1.2.1.4.3 and are supplemented by the following:

a. Ensuring the line organization's implementation of the QAP or QAPjP.

b. Reviewing the line organization's and Technical Managers' development and preparation of QA documents.

c. Assuring that subcontractors establish a QAP applicable to their scope of work.

d. Performing audits, surveillance, and inspections of activities affecting quality, to evaluate their effectiveness and compliance with requirements. If necessary, stopping unsatisfactory work or controlling the further processing, delivery, or installation of nonconforming materials and/or services.

e. Providing interpretations of QAP requirements.

f. Ensuring that an appropriate staff for the Special Assistant for Quality Assessment has been designated who will verify that activities that affect quality have been correctly performed, and who has sufficient authority, access to work areas, and organizational freedom to:

(1) Identify quality problems.

(2) Initiate, recommend, or provide solutions to quality problems through designated channels.

(3) Verify implementation of solutions.

g. Maintaining direct access to a responsible management level, as shown in the line organization chart, where appropriate action can be effected.

1.2.1.4.5 CENPW Delegation of Work--The District Commander and Special Assistant for Quality Assessment are responsible for establishing and executing the QAP and shall retain responsibility for any and all QA work delegated to others. QA functions delegated to others shall be described in writing.

1.2.1.5 CENPW Design and Control of Environmental Data Operations Organization. The overall Design and Control of Environmental Data Operations organization for each CENPW functional area is described in ER 1110-1-263. Engineering Division is the primary functional element in CENPW responsible for QC activities associated with environmental data operations for Hanford Projects during all project phases. Within Engineering Division, the Environmental Engineering Branch is the organization delegated responsibility for environmental data operations. The Special Assistant for Quality Assessment is the independent office responsible for QA oversight activities associated with environmental data operations for Hanford Projects during all project phases. When appropriate, the QAPjP's will also provide specific information on organizational structure, functional responsibilities, responsible individuals levels of authority, and lines of communication of the functional elements needed for that Hanford Project for activities affecting quality of environmental data operations during each phase of the project.

1.2.1.5.1 CENPW Engineering Division Responsibility--The functions and responsibilities for the Chief of Engineering Division, as defined in NPWOM 10-1-3, in performing activities affecting quality of environmental data operations during all project phases are supplemented by the following:

a. Developing, reviewing, and recommending approval/rejection of CENPW's QAPjP and QAPjP's developed by other organizations utilized by CENPW, for all CENPW Hanford Projects involving environmental data operations.

b. Identifying the minimum specifications and acceptance criteria for the environmental data that are generated.

c. Developing and adopting technical guidelines for estimating data quality in terms of precision, bias, representation, completeness, and comparability. Incorporating data quality requirements into all CENPW Hanford Projects involving environmental data operations.

1.2.1.5.2 CENPW Planning Division Responsibility--The functions and responsibilities for the Chief of Planning Division, as defined in NPWOM 10-1-3, in performing activities affecting quality of environmental data operations are supplemented by the following:

a. Environmental data operations delegated to Planning Division for Hanford Projects will comply with all requirements established by this CEQAPP.

b. Planning Division achieves and verifies the quality of environmental data operations associated with their functional work of performing preliminary social and economic investigations, including hydrological, fish and wildlife, social impact investigations; meteorological research and experimentation; preparation of project cost estimates; economic base studies; and analysis of project benefits and costs.

1.2.1.5.3 CENPW Environmental Engineering Branch Responsibility--The functions and responsibilities for the Chief of Environmental Engineering Branch, as defined in NPWOM 10-1-3, in performing activities affecting quality of environmental data operations during all project phases are supplemented by the following:

a. The Chief of the Environmental Engineering Branch works under the general supervision of the Chief of Engineering Division and is responsible for activities affecting quality of environmental data operations as delegated from Engineering Division.

b. The Chief of the Environmental Engineering Branch will delegate environmental data operations responsibilities to Section Chiefs within the Environmental Engineering Branch who are performing analysis, modeling, data summarization, data transfer, and data encoding, and will ensure that written procedures as stated in the project plans are followed to avoid loss or compromise of data.

c. The Chief of Environmental Engineering Branch will delegate quality achievement and quality verification responsibilities for all laboratory environmental data operations to a Laboratory Technical Manager permanently assigned to the Environmental Engineering Branch. The authority and responsibility associated with this title includes ensuring CENPW conforms to ER 1110-1-263. The Laboratory Technical Manager will be responsible for the quality achievement and quality verification of all activities affecting quality of laboratory environmental data operations during all project phases as follows:

(1) Developing, reviewing, and recommending for approval CENPW's QAPjP and QAPjP's developed by other organizations utilized by CENPW, for all CENPW Hanford Projects involving laboratory environmental data operations.

(2) Identifying the laboratory environmental data operations that require QA coverage, along with the minimum specifications and acceptance criteria for the data which are generated.

(3) Developing and adopting technical guidelines for estimating data quality in terms of precision (reproducibility), bias (accuracy), representation, completeness, and comparability, and incorporating data quality requirements in all CENPW Hanford Project activities involving laboratory environmental data operations.

d. The Chief of Environmental Engineering Branch will delegate quality achievement and quality verification responsibilities for environmental data operations program responsibilities for individual Hanford Projects to Technical Managers. The Technical Manager position is not a permanent organizational position. The Technical Managers will be selected from personnel within CENPW and will have responsibility for the following quality achievement and quality verification activities:

(1) Monitoring project activity to verify that it is in compliance with the established plans and manual requirements.

(2) Reviewing project plans to assure that appropriate quality requirements are included.

(3) Establishing Data Quality Objectives (DQO's).

(4) Ensuring that all data is verified.

(5) Ensuring that all design procedures discussed in chapter 4 are implemented.

(6) Ensuring that all samples are handled, stored, and shipped in a manner consistent with chapter 14 and appendix E.

(7) Ensuring that all project documents, records, photographs, and items are filed or stored in accordance with the appropriate procedures.

(8) Ensuring that all data base records and project record inventories are maintained.

(9) Developing or managing development of the technical portion of the QAPjP for all projects and tasks involving environmental data operations and related activities. Reviewing and recommending approval/rejection of all QAPjP's.

(10) Identifying the activities that require QA review, along with the minimum specifications and acceptance criteria for the activity/product which is generated.

(11) Ensuring data precision, accuracy, and completeness.

(12) Ensuring corrective actions are accomplished.

(13) Maintaining a file of qualifications and training for all persons working on the project.

(14) Coordinating with organizations performing data operation activities and ensuring that the DQO's are incorporated into the activity product.

(15) Maintaining all files documenting changes to activities/products.

(16) Maintaining files documenting nonrepresentative sample evaluations and determinations.

(17) Ensuring development and processing of the technical products, including product quality.

(18) Functioning as the primary technical interface with the Project Manager from the Hanford Project Office.

(19) Coordinating all technical disciplines in the development of technical products.

(20) Coordinating other technical functions, when needed, in the development of technical products.

(21) In concert with the Project Manager from the Hanford Program Office, communicating with DOE-RL's technical representatives.

(22) Assuring that CENPW contractors establish a contractor QC program applicable to their scope of work.

(23) Developing, reviewing, and recommending approval of the appropriate CENPW work plans and reports prepared for Hanford Projects in accordance with requirements of the Tri-Party Agreement (TPA). TPA primary documents requiring approval by DOE-RL and the regulators are shown on table 9-1 of attachment 2. The primary documents typically include CENPW's QAPjP, Sampling and Analysis Plan (SAP), Health and Safety Plan (HSP), and Standing Operating Procedures (SOP).

e. The Chief of Environmental Engineering Branch may also delegate environmental data operations responsibilities to a Field Team Leader who directs field operations for Hanford Projects ensuring that all field activities are carried out in accordance with

appropriate written procedures, the work plans, and the CEQAPP. The Field Team Leader is primarily responsible for documenting field activities. This is not a permanent organizational position.

1.2.1.6 CENPW Design and Control of Items and Processes Organization (Remedial Design). The CENPW line organization for Design and Control of Items is the same as described in paragraph 1.2.1.5 above. The CENPW line organizations and responsibilities specifically used for QC of remedial design is as required by Engineering Circular (EC) 1110-1-71. The Special Assistant for Quality Assessment is the independent element responsible for QA oversight of CENPW remedial designs. When appropriate, the overall functions and responsibilities listed in the NPWOM 10-1-3 will also be supplemented in the QAPjP or QAP for specific information on organizational structure, functional responsibilities, responsible individuals levels of authority, and lines of communication of the functional elements needed for that project for activities affecting the quality of remedial designs.

The primary line organizational functional element responsible for remedial design activities for Hanford Projects will be Engineering Division with appropriate branches and sections delegated the responsibility as the lead technical element. Also, the organization will be as required by EC 1110-1-71. The designated Technical Manager in each functional element will be principally responsible for day-to-day line organization activities to ensure quality achievement and verification. Design work will be performed by technical personnel within Engineering and Planning Divisions as requested and directed by the Technical Manager. Additional support will be provided by contractors or other USACE organizations as outlined in paragraph 1.2.3.

Section Chiefs are responsible for assigning individuals with the appropriate training and experience to perform design work on projects requested by the Technical Manager. Section Chiefs will also be responsible for producing validation procedures for data reduction and computer analyses. Data transcription and computations performed within the section will be checked by personnel assigned by the Section Chief.

1.2.1.7 CENPW Design and Control of Items and Processes Organization (Remedial Action). The CENPW line organization for design and control of items is the same as described in paragraph 1.2.1.5. During remedial actions, Construction Division is the primary functional element in CENPW responsible for QC of remedial actions. The Special Assistant for Quality Assessment is the independent element responsible for QA oversight of remedial actions. When appropriate, the overall functions and responsibilities listed in NPWOM 10-1-3 will also be supplemented in the QAPjP or QAP for specific information on organizational structure, functional responsibilities, responsible individuals, levels of authority, and lines of communication of the functional elements needed for that Hanford Project on activities affecting quality of remedial actions.

1.2.1.7.1 CENPW Construction Division Responsibility--During the remediation phase of the Environmental Restoration Remediation Action (ERRA) program, the CENPW Construction Division will become the primary line organization functional element

responsible for QC activities. The CENPW line organizations and responsibilities specifically used for QC of remedial actions is as required by ER 1180-1-6. The Technical Manager will be selected from personnel within CENPW Construction Division and/or the Hanford Area Office and will have responsibility for the quality achievement and verification activities of remedial actions. The Technical Manager position is not a permanent organizational position. The Technical Manager will provide continuity to the other line organizations by participating in project meetings and reviews. The functions and responsibilities defined in NPWOM 10-1-3 for the Chief of Construction Division performing activities affecting quality of remedial actions are supplemented by the following:

a. Organizing and planning activities in order to meet quality requirements.

b. Coordinating environmental data operations, remedial design, and remedial actions with the controls required by project documents, other line organizations, the QAP, and the Special Assistant for Quality Assessment.

c. Training and qualifying personnel to achieve proficiency, maintain proficiency, and adapt to changing technology, methods, or job responsibilities.

d. Ensuring that work performance is properly documented.

e. Defining and implementing effective corrective action for quality problems.

f. Monitoring the quality of activities performed by the organization, and providing direction and guidance for improvement.

g. Ensuring that resources/budgets are most effectively distributed to complete work.

h. Assuring implementation of appropriate QA requirements.

i. Participating in organizational audits/reviews.

1.2.1.7.2 CENPW Hanford Area Office Responsibilities--Within Construction Division, the Hanford Area Office is the line organization functional element delegated by Construction Division with the responsibility for remedial actions. The Hanford Area Office organization and responsibilities specifically used for QC of remedial actions is as required by ER 415-1-260 and ER 1180-1-6. The functions and responsibilities defined within NPWOM 10-1-3 for the Chief of the Hanford Area Office (Resident or Area Engineer) performing activities affecting quality of remedial actions are supplemented by the following:

a. The Chief of the Hanford Area Office performs under the general supervision of the Chief of Construction Division and is responsible for activities affecting quality of remedial actions as delegated from Construction Division. The District Commander, as the Contracting Officer, may designate in writing the ACO and/or COR authority and responsibility to the Chief of the Hanford Area Office to manage, oversee, and otherwise assure contract performance.

b. Overseeing the implementation of plans provided to the remedial action contractor as contained in CENPW's Remedial Action Work Plan for a Hanford Project.

c. The Chief of the Hanford Area Office will delegate remedial action program responsibilities for individual Hanford Projects. Additional support may be provided by contractors or other USACE organizations as outlined in paragraph 1.2.3. The Chief of the Hanford Area Office will also be the Technical Manager for that functional element and will have responsibility for the following quality achievement and quality verification activities:

(1) Coordinating the implementation of Remedial Action Work Plan(s) with Technical Managers, including the Environmental Engineering Branch Technical Manager.

(2) Coordinating environmental data operations during remedial actions with the Environmental Engineering Branch Technical Manager and Laboratory Technical Manager.

(3) Coordinating with the Environmental Engineering Branch Technical Manager and Laboratory Technical Manager to determine DQO's needed for manifesting, transporting, storing, and disposing of hazardous waste, radioactive waste, and/or mixed waste.

(4) Coordinating with Engineering Division for technical support during remedial actions on quality-related activities such as review of contractor submittals, shop drawings, evaluation of changed conditions and design issues, and other technical matters.

d. When appropriate, Section Chiefs are responsible for assigning individuals with the appropriate training and experience to perform remedial action work on projects requested by the Chief of the Hanford Area Office. Section Chiefs will also be responsible for producing validation procedures for data reduction and computer analyses. Data transcription and computations performed within the section will be checked by personnel assigned by the Section Chief.

1.2.2 Project Management Organization and Responsibility

1.2.2.1 Background. The previously described civilian line organization evolved when most USACE projects were built for USACE to own and operate. A typical project was managed sequentially and individually by each civilian functional element. The project would typically progress through the following functional elements: from planning to real estate to engineering to contracting to construction to operation. Each line organization functional element well served the management of the project, with appropriate reviews by other functional elements as the responsibility for management of the project changed between functional elements. In recent years, the number of projects built by USACE for other customers has increased. Accordingly, the senior leadership of USACE has recognized the need to modify management of projects for all customers.

USACE has issued ER 5-7-1 to focus USACE leadership on the successful completion and delivery of quality projects to customers within budget and on schedule. The stated

goals of the new project management system are to: improve USACE management performance while addressing the concerns and expectations of our customers; increase accountability for scope, quality, cost, budget, and schedule; and improve project management continuity. This project management system accomplishes these goals by creating a new civilian project management functional element and system. The system retains the existing civilian functional elements; however, the new project management functional element utilizes personnel from each appropriate existing line functional element to form a matrix type organization for management of the project. The following paragraphs describe the project management system and the activities affecting quality.

1.2.2.2 USACE Organization and Responsibility. USACE project management provides primary leadership over CENPD's Commander and secondary management oversight and quality verification over CENPD's equivalent civilian project management functional elements. The functions and responsibilities of each USACE project management element is described in ER 5-7-1.

1.2.2.3 CENPD Organization and Responsibility. CENPD project management provides primary command over CENPW's military commander and secondary management oversight, and quality verification over CENPW's equivalent civilian project management functional elements. The CENPD organization chart is shown in figure 1-1. The functions and responsibilities of each CENPD project management functional element is described in ER 5-7-1 and ER 10-1-3.

1.2.2.4 CENPW Organization and Responsibility. The overall management and administration line organization of CENPW for project management functional elements in CENPW is described in ER 5-7-1 and NPWOM 10-1-3. They also list the overall organizational structure, functional responsibilities, levels of authority, and lines of communication within CENPW line organizations and project management organizations. Primary responsibility for the project management system is in the CENPW Programs and Project Management Division (PPMD). The project management system is also organized into two organizations. The first is the CENPW Project Review Board (PRB) led by the Deputy District Engineer for Project Management and composed of members from various line organizational elements who are the Chiefs of the Divisions or Offices involved in the project as shown in figure 1-3. The function and responsibility of the CENPW PRB is to review and approve all the CENPW Program Management Plans (PMP's) and any changes to the CENPW PMP's. The second organization is the project specific organization called the CENPW Project Manager/Technical Managers Team led by a Project Manager from the Hanford Program Office and composed of members from various line organizational functional elements who are Technical Managers for the specific project as shown in figure 1-4. The function and responsibility of the CENPW Project Manager/Technical Managers Team is to develop, implement, execute, and monitor the PMP. The Special Assistant for Quality Assessment provides oversight of Project Management activities.

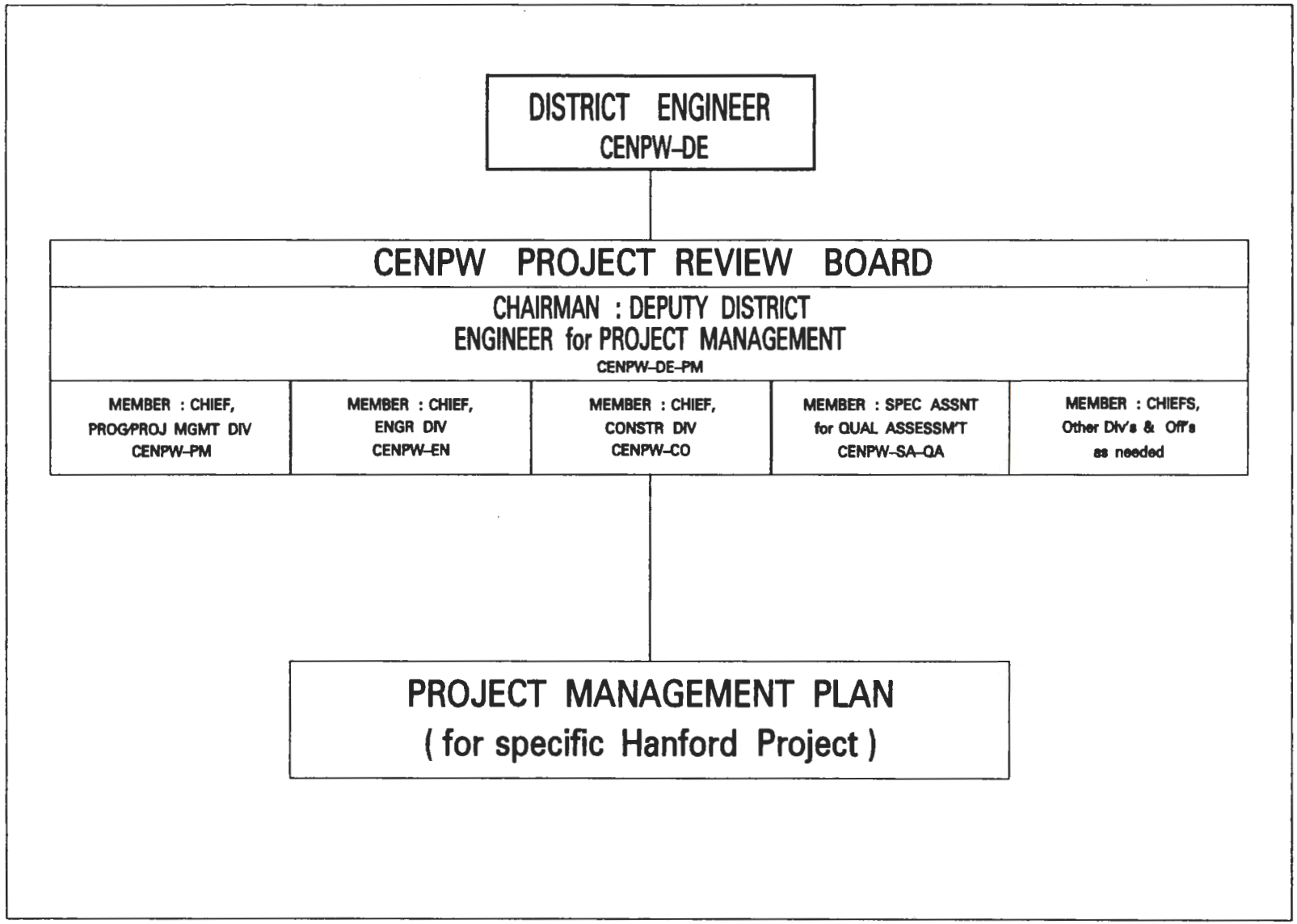

Figure 1-3. Project Management Review Board Organization Chart

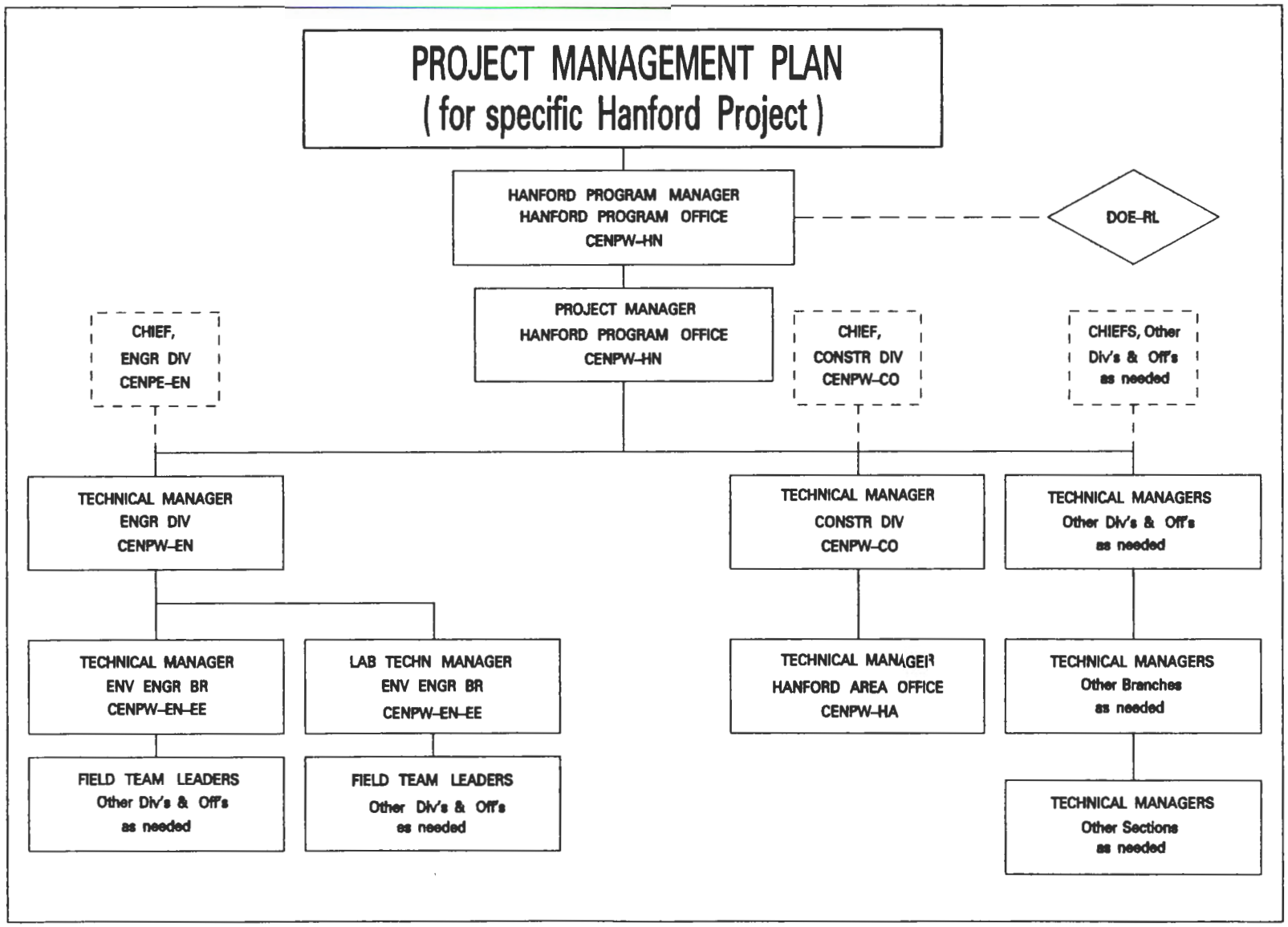

Figure 1-4. CENPW Project Manager/Technical Managers Organization Chart

The PMP for a Hanford Project is the primary tool that establishes and measures performance of the management and control of the project from initiation through operation. The PMP contains scope, quality, schedule, budgets, performance, and interface with customers. Budgets are developed using the work breakdown structure format. The PMP documents customer's expectations and changes to quality requirements for the project. In accordance with ER 5-7-1, the PMP will be endorsed by DOE-RL and approved by the CENPW PRB.

In general, for each CENPW organizational functional element, the achievement and verification of quality is the responsibility of the Division Chief of that functional element, with appropriate responsibilities delegated to the Branch Chief and Section Chief under the Division Chief. For each DOE-RL Task Order for Hanford Projects, CENPW will prepare a separate QAPjP or QAP, as appropriate, in accordance with the CEQAPP to detail specific project management organizational elements and personnel needed for that Hanford Project.

1.2.2.4.1 District Commander Responsibility--The District Commander has primary responsibility for assuring successful accomplishment of all programs and project management in CENPW. The District Commander approves all programs and CENPW PMP's (including specific QAPjP or QAP) for Hanford Projects.

1.2.2.4.2 Deputy District Engineer for Project Management Responsibility--The Deputy District Engineer for Project Management and the Chief of Programs and Projects Management Division is a dual assignment. The incumbent collaborates with the District Commander in planning, developing, coordinating, advising, and directing the activities of the CENPW PRB and PPMD. He/she provides organizational leadership in establishing a work environment conducive to the effective utilization of the District's human and financial resources to accomplish assigned projects and tasks. The Deputy District Engineer for Project Management delegates appropriate authority and responsibility to the Hanford Program Manager and the Project Manager for each project. See ER 5-7-1 for specific responsibilities.

1.2.2.4.3 PPMD Responsibility--The PPMD provides staff leadership in establishing District management policies and procedures to manage scope, quality, cost, project budget, project schedule, and to define related interfaces, roles, and responsibilities. See ER 5-7-1 for specific responsibilities.

1.2.2.4.4 Hanford Program Manager Responsibility--The Hanford Program Manager is responsible for the Hanford Program Office and is under the general supervision of the Deputy District Engineer for Project Management. The Hanford Program Manager is responsible for the general supervision of Project Managers for Hanford Projects to ensure quality achievement and verification of DOE-RL quality requirements in all Project Management Plans. The Hanford Program Manager is the primary point of contact and interface onsite with DOE-RL. See ER 5-7-1 for specific installation project manager responsibilities.

1.2.2.4.5 Project Manager Responsibility--Project Managers in the Hanford Program Office are responsible for management of individual Hanford Projects to ensure quality achievement and verification of DOE-RL quality requirements in all Project Management Plans. The Project Manager is the primary point of contact and interface onsite with DOE-RL for each individual Hanford Project. See ER 5-7-1 for specific Project Manager responsibilities.

1.2.2.4.6 Project Manager/Technical Manager Team Responsibility--The Project Manager/Technical Manager Team is responsible for establishing, implementing, and executing the Project Management Plan for each Hanford Project. The Team is also responsible for ensuring quality achievement and verification of DOE-RL quality requirements. The Team determines DOE-RL technical and quality requirements through meetings onsite with appropriate DOE-RL technical counterparts and documents them in the CENPW PMP and QAPjP or QAP. The Technical Managers are responsible for development of quality products under the supervision of their line organization functional element Division Chief. The Project Manager has the authority and responsibility to question technical products.

1.2.3 Multiple Organizations

1.2.3.1 Interface with Other USACE Organizations. All the work CENPW performs on Hanford Projects will be reviewed by CENPD as outlined in CENPD-EN-TE letter dated October 1990, Subject: Review and Coordination of Work Performed by USACE for DOE's Environmental Restoration and Waste Management Program (Records Control Symbol: CENPW-EN-14). CENPD will review all scopes of work for Architect-Engineer (A-E) contracts, scopes of work for support by other USACE organizations, work plans, QAPjP's, SAP, HSP, PMP, Community Relations Plans (CRP), remedial investigation reports, feasibility study reports, draft Record of Decision documents, remedial design, remedial design plans and specifications, remedial action plans, and any other documents produced during the conduct of work assigned to CENPW by DOE-RL via task orders for Hanford Projects.

The Project Manager for each individual Hanford Project will be responsible for interfacing with CENPD and ensuring that reviews are accomplished concurrently with review by DOE-RL and that all reviews are completed prior to utilization of the document for its intended purpose.

CENPW may utilize other USACE organizations, and contractors of those organizations, in performing work assigned to CENPW for Hanford Projects. Overall QA of all products produced or activities accomplished by any USACE organization other than CENPW will be the responsibility of CENPW and the Special Assistant for Quality Assessment.

1.2.3.2 Interface with Contractors.

1.2.3.2.1 Contractor Management and Administration--CENPW may utilize contractors in performing work assigned to CENPW for Hanford Projects. All contractors will be required to establish a QAP and QC program in accordance with the executive summary. All dealings with contractors will be through CENPW Contracting Officer, ACO, or COR. CENPW Technical Managers and Project Managers will deal with contractors to the extent authorized in writing by the CENPW Contracting Officers. Overall quality of all products produced or activities accomplished by any contractor utilized by CENPW will be the responsibility of CENPW and the CENPW Special Assistant for Quality Assessment.

1.2.3.2.2 Contractor Environmental Data Operations--The contractor's environmental data operations shall comply with the contractor's contract documents and with CENPW's CEQAPP and QAPjP for the specific Hanford Project. The Project Manager/Technical Manager Team is responsible for quality verification of the contractor's environmental data operations during all phases of the project. The Laboratory Technical Manager in Environmental Engineering Branch is responsible for quality verification of the contractors laboratory environmental data operations. The Technical Manager and Laboratory Technical Manager will be responsible for monitoring the contractor's activities to ensure compliance with the QAPjP. The CENPW Assistant for Quality Assessment is responsible for the quality assessment of the contractors environmental data operations and laboratory environmental data operations during all phases of the project. CENPW may utilize USACE or other independent contractors/laboratories to assist the Special Assistant for Quality Assessment in performing quality assessment activities.

1.2.3.2.3 Contractor Remedial Design--The contractor's remedial design shall comply with the contractor's contract documents and with CENPW's CEQAPP and QAPjP or QAP for the specific Hanford Project. The Technical Managers in Environmental Engineering Branch and other designated branches and sections are responsible for quality verification of the contractor's remedial design. The Technical Manager will be responsible for monitoring the contractor's activities to ensure compliance with the QAPjP or QAP. The Special Assistant for Quality Assessment is responsible for the quality assessment of the contractors remedial design. The CENPW may utilize USACE or other independent contractors/laboratories to assist the Special Assistant for Quality Assessment in performing quality assessment activities.

To ensure compliance with the requirements of the contract documents, contractors will be responsible for all activities necessary to manage, control, and document work. Contracts awarded by CENPW will include all applicable QA requirements defined in this CEQAPP and any applicable QAPjP or QAP requirements related to the specific Hanford Project. Contractors will be required to provide Contractor Quality Control Plans (CQCP's) for approval by CENPW in accordance with EC 1110-1-71. Those plans shall provide a detailed description of the contractor's policies and procedures to ensure that adequate QA/QC exists for work done by the contractor's organization, suppliers, subcontractors, technical laboratories, and consultants. Contractors will be responsible for performing those

QC activities necessary to ensure that the contracted product meets the quality requirements of the contract.

1.2.3.2.4 Contractor Remedial Action--The contractor's remedial action shall comply with the contractor's contract documents and with CENPW's CEQAPP and QAPjP or QAP for the specific Hanford Project. The Chief of the Hanford Area Office is responsible for quality verification of the contractor's remedial action to ensure compliance with the CEQAPP and QAPjP or QAP. CENPW Special Assistant for Quality Assessment is responsible for quality assessment of the contractor's remedial action. The CENPW may utilize USACE or other independent contractors/laboratories to assist the Special Assistant for Quality Assessment in performing quality assessment activities.

To ensure compliance with the requirements of the contract documents, contractors will be responsible for all activities necessary to manage, control, and document work. Contract documents awarded by CENPW will include all applicable QA requirements defined in this CEQAPP and any applicable QAPjP or QAP requirements related to the specific Hanford Project. Contractors will be required to provide CQCP for approval. Those plans shall provide a detailed description of the contractor's policies and procedures to ensure that adequate QA/QC exists for work done by the contractor's organization, suppliers, subcontractors, technical laboratories, and consultants. Contractors will be responsible for performing those QC activities necessary to ensure that the contracted product meets the quality requirements of the contract.

1.2.3.2.5 Hanford Area Office Responsibility--The functions and responsibilities as defined in NPWOM 10-1-3 for the Chief of the Hanford Area Office performing quality achievement and verification activities affecting quality of contractor remedial actions are supplemented by the following:

a. Assumes overall responsibility for the QAP during the remedial action, including establishment of the three-phase inspection system required by ER 1180-1-6 for preparatory, initial, and followup inspections.

b. Reviews and approves CQCP.

c. Reviews the QAP with Hanford Area Office Quality Assurance Representative(s) (QAR) to ensure that all QAR personnel understand their responsibilities. Revises QAP as necessary.

d. Conducts preconstruction conference and CQCP coordination meetings to achieve mutual understanding of CQCP roles and responsibilities. Prepares minutes of those meetings to document attendance, topics discussed, and agreements reached.

e. Ensures that the QAR assigned to this remedial action prepares QAR reports, as necessary, and reviews CQCP reports for accuracy and completeness.

f. Ensures that contractor QC staff implements the three-phase inspection systems and provides 24-hour notice to QAR prior to conducting preparatory and initial inspections on definable features of work identified as important to schedule and quality.

g. Ensures that QAR attends preparatory and initial inspections.

h. Calls and conducts meetings, as necessary, to discuss remediation activities, CQCP effectiveness, safety, and any potential material, workmanship, or scheduling problems with the contractor.

i. Ensures that CQCP is provided by the contractor for all subcontractor and material suppliers activities.

j. Interprets the contract requirements and provides recommendations to the Chief of Construction Division concerning disputes, CQCP effectiveness, contractor progress payments, and contractor performance evaluations.

k. Adopts and maintains a deficiency tracking system on the project to ensure that all deficiencies are identified and corrected.

l. Assures that the QAR assigned to the remedial action receives all necessary training. Onsite training sessions will be held prior to beginning each phase of the work to review contract requirements that pertain to that phase of work (including referenced codes and standards), contract modification, and testing requirements.

m. Reviews and monitors Submittal Registers to ensure timely submittal and approval of material and equipment requiring approval prior to their installation on the project.

n. Refers technical questions or problems to appropriate personnel in Construction Division and/or Engineering Division for resolution.

o. Monitors job progress with photographs and Memorandums for Record. Meets with the contractor to agree on progress payments and makes recommendations to Chief, Construction Division concerning retention and payments for material.

1.2.3.2.6 Hanford Area Office QA Representative Responsibility--The onsite Hanford Area Office QAR performing quality achievement and verification activities affecting quality of contractor remedial actions will have the following responsibilities:

a. Reviews CQCP and QAP to become familiar with his or her role and responsibilities.

b. Attends preconstruction conference and CQCP coordination meetings.

c. Actively participates in preparatory and initial inspections scheduled by CQCP personnel. Informs Section Chief when contractor is not prepared to start a phase of work according to the preestablished schedule.

d. Writes QAR reports, which include personnel and operating equipment onsite, weather data, work performed, CQCP/QAR inspections performed and results, any causes for contractor delay, controversial matters, any instructions given to the contractor, and safety items.

e. Ensures that CQCP reports are submitted and reviews them for accuracy and completeness. CQCP reports must include records of all preparatory and initial inspections and their results.

f. Assures that the contractor has approved shop drawings and submittals before starting a phase of work.

g. Ensures that all contractor work is in strict compliance with the contract requirements through preparatory, initial, and followup inspections.

h. Ensures that CQCP performs and reports all tests required by the contract.

i. Arranges for QA Representative Laboratory Technician (QARLT) tests as necessary to ensure contract compliance and in accordance with the QAP Test Schedule.

j. Reports to the appropriate Section Chief on any potential changes or claims against the contract.

k. Advises the appropriate Section Chief on resolution of field construction problems and of any field conditions that may affect timely completion of the work.

l. Interprets the contract requirements and refers technical questions to the appropriate Section Chief for resolution.

m. Maintains a deficiency tracking system to record and monitor all construction deficiencies until they are corrected.

n. Monitors changed work and potential claim areas for assessment of labor and equipment required.

o. Reports to the appropriate Section Chief any failure of the CQCP to perform satisfactorily as evidenced by lack of preparatory and initial inspections, failure to obtain approval of submittals, absence from site while work is underway, and failure to obtain contract compliance.

1.2.3.2.7 Hanford Area Office QARLT Responsibility--For nonenvironmental data operations, the onsite Hanford Area Office QARLT performing quality achievement and

quality verification activities affecting quality of contractor remedial actions will have the following responsibilities:

a. Reviews CQCP and QAP to become familiar with his or her role and responsibilities.

b. Reviews contract documents prior to the start of work to become familiar with CQCP and QAP testing required and to ensure that proper testing equipment is available. Makes arrangements for other laboratory facilities needed to conduct required tests.

c. Reviews CQCP test results for contract compliance and advises Section Chief on acceptability of data.

d. Conducts QAP tests in accordance with the QAP Test Schedule, determined in advance for each project or as requested by the Section Chief. Reports results of QAP tests to the Section Chief.

e. Inspects contractor's plant, equipment, and laboratory as requested by the Section Chief to determine its compliance with applicable standards and its ability to conduct analyses to the specifications of the contract.

1.2.3.2.8 Remedial Action Contractor Quality Control Representative (CQCR) Responsibility--The onsite CQCR performing quality achievement and verification activities affecting quality of contractor remedial actions will have the following responsibilities:

a. The CQCR is part of the remedial action contractor's CQCP organization. The CQCR responsibilities are defined in the contract documents and in the CQCP.

b. The CQCR maintains a comprehensive QC program to control remedial action activities and certify contractor compliance with contract requirements.

1.2.3.3 Interface with Other Participant. CENPW may utilize the services of the other organizations participating with DOE-RL at the Hanford Site. If another participant's services are utilized, the work performed will be under their DOE-RL approved QAP and Quality Assurance Program Plan (QAPP).

1.2.4 Stop Work Authority

The District Commander and the Quality Assessment Manager will be authorized to stop work as a result of unsatisfactory quality performance within any CENPW organization or any other organization CENPW utilizes for Hanford Projects. Stop work orders will also be consistent with appendix O of NPWOM 385-1-1.

Each CENPW line organization chief will also be authorized to stop work in their organizations in response to nonconformance, deficiency, or unsatisfactory conditions discovered as a result of QA or audit activities. Resumption of work will not take place until

the discrepancy has been addressed and the individual who stopped work has approved corrective action.

The CENPW Contracting Officer, ACO, and COR will have the authority to stop all or part of the work of contractors in response to their failure to comply with the QC requirements of a contract. When continuation of work has the potential of further degradation of quality or will prevent implementation of required corrective actions, the ACO and COR will prohibit contractors from performing any work until satisfactory corrective action is taken.

Should any employee encounter a situation or event that poses an imminent or immediate danger, they may stop work as authorized in DOE-RL letter dated 12 July 1991, Subject: Health and Safety Responsibilities at Hanford.

1.3 GRADED QA PROGRAM

The QA requirements and procedural controls shall be selectively applied. The requirements selected, and the degree of their application to each item and activity, shall be consistent with the following factors:

a. Consequence of failure.

b. Importance of data relative to meeting performance objectives.

c. Complexity of design or fabrication distinctions.

d. Reliability of the process.

e. Reproducibility of results.

f. Degree of functional product demonstration.

g. Degree of standardization.

h. History of quality.

i. Impact on schedule or cost in the event of failure.

j. Need for special controls or processes.

1.4 PLANNING ELEMENTS

1.4.1 Project Planning Documents

For environmental data methods/protocols, the QAP consists of the CEQAPP and project-specific planning documents that include the following:

1.4.1.1 Work Plan. Work plans will be prepared for implementing all environmental data methods/protocols. They will describe the nature and complexity of the work to be performed and include a schedule and technical performance baseline specified as a function of the environmental data and remediation activities or phases being accomplished for a project.

1.4.1.2 Field Sampling Plan. A field sampling plan will be prepared that describes the objectives of the sampling efforts; phase of sampling; ultimate use of the data; sampling protocol and procedures; and types, locations, and frequency of samples to be taken.

1.4.1.3 QAPjP. A QAPjP will be prepared for each specific project or continuing operation (or group of similar projects or continuing operations) by the program participant. The QAPjP will describe, in specific terms, the policies, organization, objectives, functional activities, and specific QA/QC activities designed to achieve the data quality goals of the specific project(s) or continuing operation(s). The QAPjP will follow the format described by Environmental Protection Agency (EPA) in the most current version of QAMS/005/80.

1.4.1.4 HSP. An HSP will be prepared to identify potential health and safety problems. The plan will describe the specific health and safety requirements that are unique to the specific project, based on the project location and conditions.

1.4.1.5 Community Relations Plan. The DOE-RL CRP will be referenced as the applicable document.

1.4.2 DQO's Integration with Work Plan

The DQO design inputs will be incorporated into work plans for each environmental data operation and environmental monitoring program. The Technical Manager will be responsible for coordination among the organizations participating in the data operation and incorporation of the DQO's into the work plan. This is described in paragraph 10.2.

1.4.3 Scoping

During the scoping process, planning will be coordinated among individuals and contractors involved with the project to identify and document the following information, as a minimum:

a. The program/task scope, objectives, and the types of actions that may be required to address site problems.

b. Whether interim actions are necessary, or appropriate, to mitigate potential threats, prevent further environmental degradation, or to effect rapid, significant reduction of risk.

c. The optimal sequence of site actions and investigative activities.

This information will be used in the development of project planning documents.

1.4.4 Design and Planning Input

Applicable inputs, such as mission objectives; performance requirements; risk analyses; existing data; regulatory requirements, including applicable or relevant and appropriate requirements (ARAR's); codes; standards; and contract requirements, will be identified and documented and their selection reviewed and approved by the Technical Manager. The following will be determined, as a minimum:

a. Identification of what the task measurement system is to accomplish.

b. Identification of engineering data required for design.

c. Identification of the specific scientific and technical information to be collected and analyzed.

d. Identification of the field and laboratory testing equipment to be used.

e. Identification of methods and/or procedures for field, laboratory, and engineering sampling, testing, and analysis activities.

f. Identification of preliminary remedial action objectives and likely response actions for the site.

g. Identification of preliminary ARAR's expected to be applicable to the environmental data operations.

h. Assignment of analytical requirements for sample analysis.

i. Identification of QA records required and data to be collected.

1.4.5 Relationship Between Documents

Work plans will be the primary project planning documents governing the conduct of environmental data operations. Work plans, SAP's, QAPjP's, HSP's, and CRP's may be issued separately or as an integral part of the overall work plan. These plans will be prepared, reviewed, and approved prior to the start of the environmental data operation (see chapter 5). Appendix A describes the contents to be included in each plan.

1.4.6 Document Cross-Referencing

When specific QA/QC protocols or other requirements for the QAPjP are addressed in the work plan, the QAPjP may then reference the page number and location in the plan where the descriptions occur (QAPjP Locator Page). However, the work plan will include a QAPjP locator page immediately following the table of contents, listing each item required for the QAPjP and stating the section and page in the QAPjP where it is specified. If information required for the QAPjP is not applicable to the specific work plan, "N/A" will

be inserted next to the appropriate item on the locator page, and the reason for its nonapplicability will be stated briefly in the appropriate subsection of the QAPjP itself. However, specific routine procedures to be used to assess data precision, accuracy, and completeness of specific measurement parameters involved, will always be included.

When relevant QAPjP procedures are not addressed in the work plan, the schedules for their development will be indicated.

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2.0 PERSONNEL TRAINING AND QUALIFICATIONS

2.1 PERSONNEL QUALIFICATIONS

CENPW will ensure that personnel performing activities affecting quality have the required education, training, and experience to effectively perform assigned tasks. CENPW will analyze each job position to determine the quality affecting task responsibilities of the position. The analysis will identify minimum education, training, and experience prerequisites for each position involved in the performance or verification of activities that affect quality.

Standard requirements for professional occupations are defined in Office of Personal Management Handbook X-118, "Qualification Standards for Positions Under the General Schedule." The method of evaluation and selection of candidates for these positions is described in appendix C, of NPDR 690-1-335. This method increases the probability that only qualified personnel fill professional positions.

Personnel training requirements are systematically administered by the CENPW Personnel Office through the Training and Development Unit, Human Resources Office in coordination with the individual's line manager. The Safety and Occupational Health Office will maintain a data base of all individuals having received Hanford Project-specific training.

2.1.1 Personnel Qualifications for Managers

Qualifications for personnel who perform leadership and management functions during environmental data operations, remedial design, and remedial actions are defined below:

a. Project Manager--A Baccalaureate Degree in an Engineering- or Science-related subject. The Project Manager should have a minimum 2 years of experience with management of environmental projects. It is recommended the following courses be taken:

Course Name	Course Length	Course Number
Safety and Health Compliance for Managers	24 hours	EPA 165.8
Hazardous/Toxic and Radioactive Waste Overview	28 hours	PROSPECT 350
Implementation of Hazardous and Toxic Waste Environmental Laws and Regulations on USACE Projects	28 hours	PROSPECT 356
Risk Assessment Guidance for Superfund	28 hours	EPA 165.6

b. Technical Manager--A Baccalaureate Degree in an Engineering- or Science-related subject. The Technical Manager should have a minimum 2 years of experience with environmental data operations and/or management of environmental projects. It is recommended the following courses be taken:

Course Name	Course Length	Course Number
Sampling for Hazardous Materials	24 hours	EPA 165.9
Air Surveillance for Hazardous Materials	32 hours	PROSPECT 404
Safety and Health Compliance for Managers	24 hours	EPA 165.8
Hazardous/Toxic and Radioactive Waste Overview	28 hours	PROSPECT 350
Hazardous Material Treatment Technologies	32 hours	EPA 165.3
Implementation of Hazardous and Toxic Waste Environmental Laws and Regulations on USACE Projects	28 hours	PROSPECT 356
Risk Assessment Guidance for Superfund	28 hours	EPA 165.6

c. Field Team Leader--A Baccalaureate degree in Engineering or a related science subject is desirable. It is recommended the Field Team Leader take either the courses listed below, or possess the equivalent experience or training to these courses plus 6 months experience (minimum participation in six sampling events).

Course Name	Course Length	Course Number
Implementation of Hazardous and Toxic Waste Environmental Laws and Regulations on USACE Projects	28 hours	PROSPECT 356
Air Surveillance for Hazardous Materials	32 hours	PROSPECT 404

d. Hazardous Waste Coordinator--It is recommended that the Hazardous Waste Coordinator take either the courses listed below or possess the equivalent or training to these courses.

Course Name	Course Length	Course Number
Sampling for Hazardous Materials	24 hours	EPA 165.9
Hazardous Waste Site Shippers	24 hours	WHC 02006S

2.1.2 Personnel Qualifications for Environmental Data Operations

Personnel performing environmental data operations affecting project quality will have the education, training, and experience necessary to meet the minimum requirements specified in this chapter. The Technical Manager is responsible for reviewing the job descriptions and training history of all individuals working on each project to ensure the training requirements are met in coordination with the individual's line organization supervisor. If requested, contractors and other USACE organizations will supply CENPW with the qualification and training records for their personnel working on the project.

2.1.3 Personnel Qualifications for Remedial Design and Remedial Actions

Personnel performing remedial design and/or remedial actions will have the education, training, and experience necessary to meet the minimum requirements specified in this chapter. The Technical Manager or Resident Engineer is responsible for reviewing the job descriptions and training history of all individuals working on each project to ensure the training requirements are met in coordination with the individual's line organization supervisor. If requested, contractors and other USACE organizations will supply CENPW with the qualification and training records for their personnel working on the project.

2.1.4 Personnel Qualifications for Inspection and Test Personnel

Personnel performing inspections and testing will have the education, training, and experience necessary to meet the minimum requirements specified in this chapter and ER 350-7-1. The Technical Manager is responsible for ensuring that personnel selected for performing inspection and test activities have the experience or training commensurate with the scope, complexity, or special nature of the activities. The QAPjP or QAP will contain specific qualification requirements for individual task orders. On-the-job training shall be included in the qualification program, with emphasis on first-hand experience gained through actual performance of inspections and tests. Training and qualification requirements for personnel performing nondestructive examination are outlined in appendix D. Technical Managers may want to certify all inspection and test personnel as shown in appendix D, paragraph 4. Contractors and other USACE organizations will supply CENPW with the qualification and training records for their personnel working on the project.

2.2 INDOCTRINATION AND TRAINING

Personnel performing or managing activities affecting product quality will be identified by the Technical Manager. The personnel will receive supplemental training as listed in paragraph 2.3 as directed by the Technical Manager in the QAPjP or QAP. All personnel involved in the Hanford Project will receive the indoctrination outlined in paragraph 2.2.1.

2.2.1 Indoctrination

Personnel will be indoctrinated in the following subjects as they relate to the functions to be performed:

a. General criteria, including, but not limited to: governing manuals, Hanford Federal Facility Agreement and Consent Order (Tri-Party Agreement), applicable codes, standards, regulations, and procedures.

b. Applicable QA program elements.

c. Job responsibilities and authority.

d. QA/QC.

2.2.2 Training

Training will be provided, as needed, in order to:

a. Achieve initial proficiency.

b. Maintain proficiency.

c. Adapt to changes in technology, methods, or job responsibilities.

2.2.3 General Training

Training, as outlined in NPWOM 385-1-1, will be provided for all personnel.

2.3 SUPPLEMENTAL TRAINING

Section Chiefs will schedule supplemental training, as defined in this paragraph, for all personnel involved in the Hanford Project. The Technical Manager will be responsible for defining the need for supplementing the general training of personnel involved with each task order. The need will be based on an individual's previous training, experience, or academic qualifications and complexity of the work. The following typical listing of supplemental training may be used as a guide:

a. Radiation Protection:

Course Name	Course Length	Course Number
Implementation of Hazardous and Toxic Waste Environmental Laws and Regulations on USACE Projects	28 hours	PROSPECT 356
Radiation Safety at Superfund Sites	40 hours	EPA 165.11

b. Groundwater Studies:

Course Name	Course Length	Course Number
Groundwater Hydrology	36 hours	PROSPECT 124

c. Sampling Activities Related to Hazardous Material:

Course Name	Course Length	Course Number
Safety and Health Compliance for Managers	24 hours	EPA 165.8
Sampling for Hazardous Materials	24 hours	EPA 165.9
Hazardous Waste Site Shippers	24 hours	WHC 02006S

2.4 INDOCTRINATION AND TRAINING RECORDS

Records of completed indoctrination and training will be established and maintained by the CENPW Personnel Officer (Training and Development Unit, Human Resources Office) and the Special Assistant for Quality Assessment. These records will include, as appropriate:

a. Certificate of course completion or attendance sheets.

b. Records of course content, including date(s) of training and the name of the instructor(s).

c. Training logs.

d. Personnel training records.

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3.0 QUALITY IMPROVEMENT

3.1 DETECTION AND CONTROL OF NONCONFORMING ITEMS

This section establishes the CENPW QAP requirements for identifying and controlling nonconforming items. Items that do not conform to specified requirements will be controlled to prevent inadvertent delivery, installation, or use. Controls will provide for identification, documentation, evaluation, and segregation when practical, including disposition of nonconforming items, followed by notification to affected organizations.

3.1.1 Scope

These requirements apply to all work done for DOE-RL at the Hanford Facility by CENPW and all contractors or organizations performing Hanford Project related activities for CENPW.

3.1.2 Method of Identification

Nonconforming items will be marked, tagged, or otherwise identified so that the end use of the item will not be effected. The identification will be legible and easily recognizable.

3.1.2.1 Exceptions. If identifying each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, will be identified.

3.1.3 Segregation

When practical, nonconforming items will be segregated by placing them in a clearly identified and designated holding area until they are properly dispositioned. When segregation is impractical or impossible because of physical conditions, such as size, weight, or access limitations, other precautions will be employed to preclude inadvertent use of a nonconforming item.

3.1.4 Disposition

3.1.4.1 Control. Nonconforming characteristics will be reviewed, and recommended dispositions of nonconformances will be proposed and approved in accordance with procedures in NPWOM 715-1-8. Further processing, delivery, installation, or use of a nonconforming item will be controlled pending an evaluation and an approved disposition by authorized personnel.

3.1.4.2 Responsibility and Authority.

3.1.4.2.1 Delivery Orders--CENPW personnel involved in the execution of task orders are responsible for identifying nonconformances and initiating corrective action for delivery order items. Any nonconformance will be reported to the COR, who will contact the

Contracting Officer at the earliest time possible. The contractor will then receive a written notification of nonconformance and be requested to submit a written plan outlining how the situation will be corrected.

3.1.4.2.2 Service Contracts--CENPW personnel involved in the execution of task orders are responsible for identifying nonconformances and initiating corrective action for service contracts. Contract clauses enforcing compliance are contained on page 243 of Federal Acquisition Regulation (FAR) 52, "Uniform Contract Clauses."

3.1.4.2.3 Remedial Action Contracts--Nonconformance control for Remedial Action Contracts is outlined in ER 1180-1-6. The Deficiency Tracking System, as noted in paragraph 15.1.7.3, directs how the item is to be segregated and, after review, what its disposition will be. The entire process will be verified by QA review.

3.1.4.3 Personnel. Personnel performing evaluations, in order to determine a disposition, will have demonstrated competence in the specific area they are evaluating, display an adequate understanding of the requirements, and have access to pertinent background information.

3.1.4.4 Disposition. The disposition of nonconforming items (*i.e.*, use-as-is, reject, repair, or rework) shall be identified and documented in project files by the Technical Manager.

Technical justification from Engineering Division for the acceptability of a nonconforming item, dispositioned repair, or use-as-is, will be documented and included in the project files. Nonconformances to design requirements dispositioned as use-as-is or repair shall be subject to the same design control measures as in the original design. The as-built records, if such records are required by chapter 6, will reflect the accepted deviation.

3.1.4.5 Reworked Items. Reworked items will be examined in accordance with applicable procedures and with the original acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.

3.1.5 Event Reporting

Nonconformances will be evaluated for event reporting requirements in accordance with DOE Orders 5000.3B, 5484.1, and 5480.4.

3.1.6 Nonrepresentative Environmental Data Samples

Samples whose representation is in question due to such factors as aging, deterioration, damage, contamination, or identity uncertainty will be controlled. These controls will be in accordance with those for nonconforming items. The section directing the work will determine whether the nonconforming data is usable and will document the evaluation process and final determination. The documentation will be maintained by the Technical Manager in the project files.

3.1.7 Criteria for Identifying Nonconforming Conditions

Circumstances to document nonconforming conditions for environmental data operations may include, but are not limited to, the following:

a. When QC limits are exceeded.

b. When assessments of data quality indicate that DQO's are not being realized.

c. When interlaboratory comparisons indicate that bias or imprecision is, or may be, present.

d. When instruments, standards, or reagents used to produce data are found to be out of calibration or otherwise deficient.

e. When required conditions for analysis and/or measurement (such as temperature, humidity, or voltage control) have deviated from minimum levels possibly affecting the results.

f. When errors are discovered in data transfer, reduction, or reporting.

g. When applicable requirements of a QAPjP, approved procedure, or CEQAPP are not met.

3.2 CORRECTIVE ACTION

This section describes CENPW's QAP requirements for corrective action. Conditions that have a potential for compromising product quality will be promptly and effectively corrected. The underlying causes and the full extent of conditions negatively impacting product quality will be determined and corrected in order to prevent their recurrence. The corrective action methods must be performed and documented in a manner allowing their use as evidentiary data.

3.2.1 Scope

These requirements apply to all work done for DOE-RL at the Hanford Facility by CENPW and all contractors or organizations performing Hanford Project-related activities for CENPW.

3.2.2 Corrective Action Program

CENPW's corrective action program should ensure that conditions adverse to quality are identified promptly and corrected as soon as practicable. In the case of a significant condition adverse to quality, the root cause of the condition will be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality will be documented and reported to appropriate

levels of management. Followup action is taken to verify implementation of this corrective action. Conditions adverse to quality may include, but are not limited to, the following:

a. Failure to implement major elements of the QA program.

b. Failure to implement corrective action in response to inspection, surveillance, and audits.

c. Nonconformance of items or services.

A copy of all Corrective Action Requests, Corrective Action Responses, and Trend Analyses will be retained in the project files by the Technical Manager. The originals will be included in the contract files.

3.2.2.1 Corrective Action Requests. A Corrective Action Request memorandum to the ACO or COR will be used to initiate and direct the appropriate corrective action required when intervention by upper level of management is necessary to assure correction of conditions adverse to quality. The memorandum will document the quality deficiencies and recommend appropriate corrective action. The memorandum will be directed to the Special Assistant for Quality Assessment for review and approval. The appropriate functional division chief will determine the specific nature and extent of corrective action to be taken.

3.2.2.2 Corrective Action Response and Closeout. Corrective Action Requests and action required as the result of audits, surveillance, and management assessments will require written response from the Technical Manager, through the Project Manager, which identifies the following:

a. Root cause of the deficiency.

b. Corrective action to resolve the condition and preclude the recurrence of the problem.

c. Completed activities that may be impacted by the condition adverse to quality. The results of this investigation will be reported to SAQA.

The Corrective Action Response will be approved by the chief of the appropriate functional division. Engineering Activities Surveillance and QA management assessments by CENPD will check CENPW files for both the Corrective Action Requests and Corrective Action Responses and verify that the proper corrective action was taken.

3.2.3 Reporting and Resolution of Significant Conditions Adverse to Quality

Significant conditions adverse to quality will be identified, reported, and corrected with the following requirements:

a. Specific criteria will be developed in the QAPjP or QAP to identify significant conditions adverse to quality.

b. Management information, including lessons learned from significant conditions adverse to quality, shall be routinely disseminated to all appropriate personnel.

c. Existing, developing, or potentially out-of-control quality conditions will be promptly reported to the chief of the appropriate functional division for evaluation and action.

d. Upon discovering or receiving notification that a significant condition adverse to quality exists, the following actions will be taken:

(1) Timely response to remedy the specific condition.

(2) Determination of root cause factors.

(3) Appropriate action to preclude recurrence, including review, evaluation, and revision of controls and SOP's.

(4) Assessment and documentation of impact on completed work.

3.2.4 Recurring Significant Conditions Adverse to Quality

For recurring quality problems where corrective actions have not been effective, the chief of the appropriate functional division, as needed, will:

a. Determine the events leading to the quality problem's occurrence.

b. Develop an understanding of the technical and work activities associated with the quality problem(s).

c. Determine the extent to which similar quality problems (or precursors to the problem) have been recognized by the responsible organization, assess the effectiveness of any corrective actions that were taken, and recognize any generic implication and/or impact on completed work.

d. Consider stopping work associated with the applicable activity in accordance with paragraph 1.2.4.

e. Recommend actions that can be taken by the responsible organization as defined in the QAPjP to preclude recurrence.

3.2.5 Trend Analysis

The Special Assistant for Quality Assessment will analyze audit reports, surveillance reports, quality deficiency reports, and Corrective Action Requests and Responses to identify significant quality trends. This analysis within CENPW will be performed at least quarterly. It will be supplemented with the twice yearly Engineering Activities Surveillance by CENPD that will analyze documents which report conditions adverse to quality and corrective actions to determine the extent of quality deficiency trends and to identify their root causes. The results of these reviews will be submitted through the COR to the appropriate functional division chiefs for appropriate corrective action.

4.0 PROCUREMENT

4.1 PROCUREMENT PLANNING

Procurement activities for various types of contracts, as required, such as "fixed-price," "cost-plus," and negotiated contracts will be planned and documented in accordance with NPWOM 715-1-8 to ensure a systematic approach to the procurement process.

Due to the restrictions described in the Competition in Contracting Act of 1984, the planning process, in which the minimum requirements are set, is critical to the QA process. Planning will be accomplished as early as practical and no later than at the start of those procurement activities that require control, to ensure compatibility and a uniform approach to the procurement process. Planning will provide for integration of the following:

a. Procurement document preparation, review, and change control.

b. Selection of procurement sources.

c. Bid evaluation and award.

d. CENPW control of contractor's performance.

e. Appropriate oversight for the items or services being procured depending upon the complexity, scope, or importance of the required items or services.

f. Control of nonconformances.

g. Corrective action.

h. Acceptance of the item or service.

i. QA records.

During this planning phase, it is the responsibility of CENPW contracting personnel to analyze the technical requirement(s) and resolve comments and questions. CENPW personnel writing specifications must have technical qualifications appropriate to fully comprehend the complexity of the task requiring the purchase of items or services.

The QA oversight responsibility for the requirements and/or specifications rests with the Special Assistant for Quality Assessment. CENPW's Office of Counsel, higher headquarters, other divisions, and separate offices may also perform reviews resulting in comments and questions requiring resolution coordination by the Contracting Office.

4.2 CONTRACTOR SELECTION

The selection of contractors will be based on an evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents. The evaluation will be conducted by CENPW's Chief of Contracting Division, Office of Counsel, and all relevant technical staff for the Contracting Officer. The evaluation will include a determination of the prospective contractor's responsiveness and responsibility. Measures for evaluating and selecting procurement sources, and the results thereof, will be documented and will include one or more of the following:

a. Evaluation of the contractor's history of providing an identical or similar product that performs satisfactorily in actual use. The contractor's history will reflect current capability.

b. Contractor's current QA records supported by documented qualitative and quantitative information that can be objectively evaluated.

c. Contractor's technical and quality capability as determined by a direct evaluation of the contractor's facilities and personnel and the implementation of their QA program.

4.3 BID EVALUATION

Bid evaluation will determine the extent of conformance to the procurement documents. This evaluation will be performed by individuals or organizations designated to evaluate the following subjects, as applicable to the type of procurement:

a. Technical requirements.

b. QA requirements.

c. Contractor's personnel.

d. Contractor's production capabilities.

e. Contractor's management information system.

f. Contractor's subcontracting plan.

g. Contractor's past performance.

h. Contractor's current work load and percent of plant capacity currently being used.

i. Alternates.

j. Exceptions.

4.3.1 Resolution of Unacceptable QA Conditions

The contract will not be awarded until all unacceptable quality concerns are resolved to the satisfaction of CENPW. This requirement may be fulfilled either by:

a. The resolution of all unacceptable quality concerns to the satisfaction of CENPW.

b. The contractors binding declaration to resolve unacceptable quality concerns in a timeframe acceptable to CENPW.

4.4 CONTRACTOR QC PERFORMANCE

CENPW will establish measures to interface with the contractor and to verify the contractor's performance. The interface measures are described in ER 1180-1-6 and ER 415-1-302 and include:

a. Establishing an understanding between CENPW and the contractor of the provisions and specifications of the procurement documents.

b. Requiring the contractor to identify planning techniques and processes to be utilized in fulfilling procurement document requirements.

c. Reviewing contractor documents generated or processed during activities fulfilling procurement requirements.

d. Identifying and processing necessary change information.

e. A contract requirement establishing the method of document information exchange between CENPW and the contractor.

f. A contract requirement establishing the extent of source surveillance and inspection activities.

These verification activities will be conducted as early as practicable. CENPW's verification activities, however, will not relieve contractors of their responsibilities for verification of quality achievement.

A prework conference and QA/QC coordination conference will be conducted prior to allowing the contractor to start contract work. These conferences will be the first opportunity to develop a mutual understanding between CENPW and the contractor concerning how the QA/QC system will function (see paragraph 1.2.1.1). Negotiated contracts (negotiations), A-E service contracts, and delivery orders will require initial meetings to define the scope of the project, project costs, and provide an opportunity to discuss contractor QC items. The terms "negotiated contracts (negotiations)" and "delivery orders" are defined in NPWOM 715-1-8.

All contracting activities initiated by CENPW for the Hanford Site will be documented per NPWOM 715-1-8. Contract records will be maintained at CENPW offices in Walla Walla.

4.5 CONTENT OF PROCUREMENT DOCUMENTS

Procurement documents issued at all tiers of procurement will include the provisions in paragraphs 4.5.1 through 4.5.6, as deemed necessary by CENPW. CENPW will specify the provisions that apply to each procurement in the applicable procurement document.

4.5.1 Scope of Work

A statement of the scope of the work to be performed by the contractor will be shown in the procurement document.

4.5.1.1 Technical Requirements. Technical requirements will be specified in the technical provisions portion of the procurement document. Where practical, standard guide specifications will be used or incorporated into the work. Where necessary, these requirements will be specified by reference to specific methods, drawings, specifications, codes, work plans, standards, regulations, procedures, or instructions (including revisions) that describe the items or services to be furnished. The procurement documents will include, as necessary, control of special processes, identification of tests, inspections, and CENPW acceptance requirements for monitoring and evaluating the contractor's performance.

4.5.2 QAP Requirements

Procurement documents will require that the contractor have a documented QC program that implements all applicable requirements of this CEQAPP. The extent of the program will depend upon the type and use of the item or service being procured. The procurement documents will require the contractor to incorporate the appropriate QC program requirements of this CEQAPP in subtier procurement documents.

4.5.2.1 Justification of Participant's QAP. CENPW may permit some or all contractors to perform under the jurisdiction of this CEQAPP provided the scope of the activity is addressed. When these circumstances apply, the procurement documents will specify those portions of this CEQAPP's policies and procedures that are applicable to the contractor's work effort.

4.5.3 Right of Access

At each tier of procurement, the procurement documents will provide for access to the contractor's facilities and records for audit and inspection by CENPW or its authorized representatives.

4.5.4 Documentation Requirements

At all tiers, the procurement documents will identify the documentation required to be submitted by contractors for information, review, or approval by CENPW. The time of submittal will also be established. When CENPW requires the contractor to maintain specific QA records, the retention times and disposition requirements will be specified in accordance with chapter 6.

4.5.5 Nonconformances

The procurement documents will include CENPW's requirements and procedures for reporting and approving disposition of nonconformances as described in chapter 16.

4.5.6 Spare and Replacement Parts

The procurement documents will require the identification of appropriate spare and replacement parts or assemblies and the appropriate delineation of the technical and QA-related data that are required for ordering these parts or assemblies. The technical and quality requirements will be equal to or better than the original. If QA or technical requirements of the original item cannot be determined, an engineering evaluation will be conducted by qualified individuals to establish the requirements. The evaluation will consider the interchangeability, function, and safety of the item and will be documented.

4.6 CONTROL OF PROCUREMENT DOCUMENTS

All purchase/service requirements that are necessary to assure adequate quality will be included or referenced in documents for procurement of items and services. Procurement documents will require contractors to have a QC program that complies with all applicable requirements of this CEQAPP.

4.7 PROCUREMENT DOCUMENT REVIEW

A review of the procurement documents, and changes thereto, will be made to assure that documents transmitted to the prospective contractor(s) include appropriate provisions to assure that items or services will meet the specified requirements. Review(s) will be performed and documented to provide objective evidence of satisfactory accomplishment of such review(s) prior to contract award. Responsibilities for review and approval of procurement documents are defined in NPWOM 715-1-8. Changes made as a result of the bid evaluations, precontract negotiations, or additional technical data will be incorporated into the procurement documents.

4.8 PROCUREMENT DOCUMENT CHANGES

Procurement document changes, or contract modifications, will be made in accordance with the FAR, Defense Federal Acquisition Regulation Supplement (DFARS), Army Federal Acquisition Regulation Supplement (AFARS), Engineer Federal Acquisition

Regulation Supplement (EFARS), ER 1110-2-1200, and NPWOM 715-1-8. Contract modifications will be subject to the same degree of control as utilized in preparing the original documents.

4.9 ACCEPTANCE OF ITEMS OR SERVICES

The COR will write a report accepting, fully or in part, the items or services and submit the report to the Contracting Officer for approval. Acceptance shall be based upon criteria included in the contract specifications.

4.9.1 Methods of Acceptance

Methods used by CENPW to judge the acceptability of an item or related service may be a Supplier Certificate of Conformance, source verification, receiving inspection, performance testing, or a combination thereof.

4.9.1.1 Certificate of Conformance. When a Certificate of Conformance is used, the following minimum criteria will be met:

a. The certificate will identify the purchased items or equipment, such as by the purchase order number.

b. The certificate will identify the specific procurement requirements met by the purchased items or equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of the specific requirements or by providing, onsite, a copy of the purchase order and the procurement specifications or drawings with a suitable certificate. The procurement requirements identified will include any approved changes, waivers, or deviations applicable to the subject material or equipment.

c. The certificate will identify any procurement requirements that have not been met, with an explanation and the means for resolving the nonconformances.

d. The certificate will be signed or otherwise authenticated by a person who is responsible for this QA function and whose function and position are described in the contractor's QA program.

e. The certification system and the administrative procedures for review and approval of the certificates will be described in the contractor's QA program.

f. Means shall be provided to verify the validity of Certificates of Conformance and the effectiveness of the contractor's certification system. Methods utilized for verification may include any or all of the following:

(1) Audits performed by CENPW.

(2) Independent testing or inspection of items and/or services.

(3) Source verification activities at the item's point of manufacture.

4.9.1.2 Receiving Inspection. Receiving inspections will be performed to verify, by objective evidence, such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness. Documentation for purchased items and services will be provided by the contractor, as necessary, to verify conformance to specified requirements, taking into account source verification, audit activities, and the demonstrated quality performance of the contractor. Receiving inspections will be coordinated with the review of contractor documentation when procurement documents require contractor documentation to be furnished prior to receiving inspection. A receiving report will be completed and submitted to the COR. The report will indicate that all or a specific portion of an order was received and whether the order meets specifications. At a minimum, one copy of the report will be provided to CENPW Contracting Division for review and filing.

4.9.1.3 Performance Testing. When performance testing is used, performance test requirements and acceptance documentation will be specified.

4.10 ACCEPTANCE OF SERVICES ONLY

In certain cases involving procurement of services only, such as third-party inspection; engineering and consulting services; and installation, repair, overhaul, or maintenance work, CENPW will accept the service by employment of any or all of the following methods:

a. Technical verification of data produced.

b. Surveillance and/or audit of the activity.

c. Review of objective evidence for conformance to the procurement document requirements such as certifications and stress reports.

4.11 CONTROL OF CONTRACTOR NONCONFORMANCES

CENPW control of contractor nonconformance is described in chapter 3.

The contractor shall establish and document methods for the disposition of items and services that do not meet procurement documentation requirements in the contractor's QAPjP. These methods will include provisions for:

- Evaluation of nonconforming items.

- Submittal of a nonconformance notice to CENPW by the contractor, as directed by CENPW. These submittals shall include a contractor-recommended disposition of the nonconforming item or service and a technical justification for the recommendation.

Nonconformance, for the purposes of this document, shall include, but not be limited to, the following:

- Violation of a technical or material requirement.
- Violation of a CENPW-approved contractor document.
- Identified nonconformance not resolvable by continuation of the original manufacturing process or by rework.
- Failure to meet the original requirement even though the item can be restored to a condition so that the capability of the item to function is unimpaired.

CENPW will perform a technical review of contractor's recommendations and provide written approval/disapproval of the proposal. CENPW will verify contractor implementation of the submitted recommendation per paragraph 4.9. Records of contractor-submitted nonconformances will be maintained at CENPW offices.

4.12 COMMERCIAL GRADE ITEMS

Where the design utilizes commercial grade items, the following requirements are an acceptable alternative to other requirements of this chapter, except as noted in paragraph b. below.

a. Commercial grade items are identified in an approved design output document. Alternate commercial grade items may be applied, if the cognizant design organization provides verification that the alternate commercial grade items will perform the intended function and will meet design requirements applicable to both the replaced items and their application.

b. Source evaluation and selection, where determined necessary by CENPW based on complexity and importance to safety, will be in accordance with paragraph 4.1.

c. Commercial grade items, or their equal, will be identified in the purchase order by the manufacturer's published product description (*e.g.*, catalog number).

d. After receipt of a commercial grade item, CENPW will determine that:

(1) Damage was not sustained during shipment.

(2) The item received was the item ordered.

(3) Inspection and/or testing is accomplished, as required by CENPW, to assure conformance with the manufacturer's published requirements.

(4) Documentation, as applicable to the item, was received and is acceptable.

5.0 DOCUMENTS

5.1 DOCUMENT PREPARATION, REVIEW, APPROVAL, AND ISSUANCE

The preparation, review, approval, and issuance of instructions, procedures, plans, and drawings that specify quality requirements or prescribe activities affecting quality will be controlled to assure that correct documents are being utilized. Such documents, including changes thereto, will be reviewed for adequacy and approved for release by authorized personnel.

5.2 DOCUMENT CONTROL SYSTEM

The document control system will, at a minimum, identify all documents requiring control and the parties responsible for the preparation, review, approval, and issuance of documents. Such parties will be identified in approved project-specific work plans provided by CENPW or any organization or contractors performing activities for CENPW. The approval process is outlined in the executive summary. The approved project-specific work plans will contain document control protocols for all aspects applicable and relevant to the project.

The document control system will be established and implemented in accordance with written procedures or instructions; the procedures or instructions may include, but are not limited to, those listed below:

a. Identifying documents to be controlled and their specified distribution.

b. Identifying assignment of responsibility for preparing, reviewing, approving, and issuing documents.

c. A review of documents for adequacy, completeness, and correctness prior to approval and issuance.

5.3 TECHNICAL AND QA CONCURRENCE

Procedures for the review, approval, and issuance of program documents, and changes thereto, shall be established to assure that technical adequacy and appropriate QA requirements are included prior to issuance. The QA organization shall review and concur with the QA aspects of these documents. Program documents shall also be reviewed for technical adequacy by an individual or organization other than the person who generated the document, but who has a technical understanding of these documents. The reviewing organizations shall have access to pertinent background data or information on which to base its approval. The responsibility for QA oversight will reside with the Special Assistant for Quality Assessment.

5.4 DOCUMENT CHANGES

Document changes shall be controlled, reviewed, and approved. Minor changes, such as editorial comments, may be reviewed and approved by the Technical Manager in concert with the Project Manager. All other changes should be considered "major," and reviewed and approved by the same organizations or individuals who performed the original review.

6.0 RECORDS

6.1 RECORDS SYSTEM

A records system will be established at the earliest practicable time consistent with the schedule for accomplishing work activities and will be in compliance with the requirements of AR 25-400-2, The Modern Army Record Keeping System (MARKS). The records system will be defined, implemented, and enforced in accordance with these written procedures.

6.2 GENERATION OF RECORDS

The applicable Hanford Project work plans, design specifications, procurement documents, implementing procedures, or other similar documents will specify the QA records to be generated, supplied, or maintained. Documents that are designated to become records will be legible, accurate, complete, and appropriate to the work accomplished.

6.3 RECORDS VALIDATION

Documents will be considered valid (complete) records only if initialed, signed, or otherwise authenticated and dated by the person originating the document or if the document is clearly identified as a statement by the reporting individual or organization. These records may be originals or reproduced copies.

CENPW will maintain a list that contains the signature and initials of the personnel authorized to authenticate records.

6.4 RECORDS IDENTIFICATION, INDEXING, AND DISTRIBUTION

6.4.1 Identification

The MARKS records and/or indexing system will provide sufficient information to permit identification of the record and the item(s) or activity(s) to which it applies.

6.4.2 Indexing

The records will be indexed. The indexing systems will include, as a minimum, record retention times and the location of the record within the records system.

The title of each MARKS number will be on the office list and, when needed for clarity, a brief description of the actual documents included under that number will be included.

6.4.3 Distribution

The records will be distributed, handled, and controlled in accordance with written CENPW procedures.

6.5 RECORD CLASSIFICATION

Records will be classified as lifetime, nonpermanent, or post-closure by CENPW, as stated in the Interagency Agreement (IA), as follows:

a. Lifetime Records. Lifetime records are those that meet one or more of the following criteria:

(1) Records of significant value in demonstrating capability for safe operation.

(2) Records of significant value in maintaining, reworking, repairing, replacing, or modifying an item.

(3) Records of significant value in determining the cause of an accident or malfunction of an item.

(4) Records providing required baseline data for in-service inspections.

(5) Records used for disposal facility licensing or permits.

(6) Records used to identify and assess the performance capabilities of those engineered and natural barriers important to waste isolation.

(7) Records of computer programs and mathematical models needed to perform ongoing correlations between performance assessment predictions and actual test results, and data collection and analysis.

(8) Records of significant value in exercising the retrieval option for the waste package.

(9) Records needed during decommissioning and closure of the waste disposal facility.

b. Nonpermanent Records. Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements, but need not be retained for the life of the item because they do not meet the criteria for lifetime or post-closure records.

c. Post-closure QA records are those that meet one or more of the following criteria:

(1) They are maintained to prevent actions that could impair the long-term isolation of the waste.

(2) They are maintained to preserve information that would prevent inadvertent human intrusion, such as the nature and hazard of the waste and the locations of the hazardous waste area, boreholes, and boundaries of the controlled area.

(3) They are maintained to provide information relevant to post-closure monitoring and assessment of performance of the waste disposal facility.

(4) They are maintained to preserve, for future generations, information regarding the geologic setting relevant to mitigation of releases of radioactive and nonradioactive hazardous substances or materials.

(5) They would be of significant value after decommissioning and closure of a stabilization site or waste disposal facility.

6.6 RECORDS RETENTION

QA records will be retained in accordance with MARKS requirements as follows:

a. Upon completion of CENPW's work on any task related to an operable unit or remedial action site, all records related to that task will be transmitted to the Hanford Operations and Engineering contractor for storage. CENPW will receive and record notice of receipt from the storage area.

b. The retention period for nonpermanent QA records will be established in writing by CENPW in accordance with the IA.

c. Post-closure QA records are required to be maintained for periods of several hundred years and in a manner that would permit future generations to maintain them longer, if desired, using present available technology.

d. Lifetime, post-closure, and nonpermanent records generated in accordance with the TPA will be maintained for a period of 10 years after termination of the subject task order. After CENPW's work is complete on any task order, it will not store records concerning its work related to any operable unit or remedial action site. Inactive records will be transmitted to the Hanford Operations and Engineering contractor for storage.

Occupational sampling, monitoring, and medical records will be kept for 75 years in accordance with DOE Order 1324.2A.

6.7 CORRECTED INFORMATION IN RECORDS

Records may be corrected in accordance with MARKS procedures that provide for appropriate review or approval by the originating organization. The correction will include the date and the identification of the person authorized to issue such correction and will not obliterate the corrected data.

6.8 STORAGE OF RECORDS

6.8.1 Storage Procedure

The records will be stored at CENPW's facility in Walla Walla, Washington, and in the Federal Records Center in a facility that meets the requirements of MARKS. CENPW's storage procedure is stated in Walla Walla District, Hanford Office Memorandum (NPW-H-OM) 25-1-1. This procedure includes:

a. A description of the storage facility.

b. The filing system to be used.

c. A method for verifying that the records received are legible and in agreement with the transmittal document.

d. A method for verifying that the records are those designated.

e. The rules governing access to and control of the files.

f. A method for maintaining control of and accountability for records removed from the storage facility.

g. A method for filing supplemental information, as described in paragraph 6.9, and disposing of superseded records.

6.8.2 Preservation

Records will be stored in a manner approved by CENPW in accordance with the requirements of MARKS. In order to preclude deterioration of the records, the following requirements will apply:

a. Provisions will be made in the storage arrangement to prevent damage from moisture, temperature, and pressure.

b. Records will be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers.

c. Provisions will be made for special processed records (*i.e.*, radiographs, photographs, negatives, microfilm, magnetic material, *etc.*) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity.

6.8.3 Access

A list will be maintained that designates those personnel who will have access to the files. Measures will be established to preclude the entry of unauthorized personnel in the storage area. These measures will guard against larceny and vandalism.

All employees or their designated representatives will have the right of access to relevant exposure and medical records in accordance with 29 CFR 1910.20.

6.8.4 Replacement, Restoration, or Substitution

Measures will be taken to provide for replacement, restoration, or substitution of lost or damaged records.

6.8.5 Storage Facilities

Records will be stored in facilities constructed and maintained in a manner that minimizes the risk of damage or destruction from natural disasters, such as winds, floods, or fires; environmental conditions, such as high and low temperatures and humidity; and infestations of insects, mold, or rodents.

6.8.6 Single Filing for Design/Construction Records

The Technical Manager will establish a project file for an individual phase of the design/construction. The Technical Manager will maintain a listing (index) of who created a file and where it is being maintained. The files covering particular parts of the design/ construction will be maintained by the lead engineer, as prescribed in this chapter. Upon completion of each phase of the design/construction, the Technical Manager will gather the original files and transfer them to the Environmental Data Management Center, managed by the DOE-RL, Operations and Engineering Contractor. NOTE: This method is not in compliance with the requirements of NQA-1.

6.8.7 Temporary Storage

Temporary storage of records will be in accordance with AR 25-400-2. The records will be stored in a 1-hour fire rated container. The container will bear an Underwriters Laboratory label (or equivalent), certifying 1-hour fire protection or be certified by a person competent in the field of fire protection.

6.8.8 Retrieval

Storage systems will provide for retrieval of information in accordance with planned retrieval times, based upon the record type. Records maintained by a contractor at this facility or other location will be accessible, upon request, to CENPW or its designated alternate (*e.g.*, the DOE-RL Environmental Restoration Division).

6.8.9 Disposition

Prior to transfer, records accumulated at various locations will be made accessible to CENPW or its agent directly or through the procuring organization. The custodian will inventory the submittals, acknowledge receipt, and process these records in accordance with MARKS.

6.9 ENVIRONMENTAL DATA COLLECTION, DESIGN, CONSTRUCTION, AND TESTING RECORDS

The requirements for establishing and maintaining a QA records system during environmental data collection, design, construction, and testing activities will be in accordance with this chapter and with the design QA record requirements amplified by the following section. Typical QA records are listed in appendix C.

6.9.1 Environmental Data Collection Records

Each Technical Manager involved in environmental data collection will ensure that all data items/elements used and produced by CENPW, its contractors, and other USACE organizations are maintained in accordance with paragraphs 6.1 through 6.8 of this CEQAPP.

6.9.2 Design QA Records

Design documentation and records, which provide evidence that the design and design verification processes were performed in accordance with the requirements of the CEQAPP, will be collected, stored, and maintained in accordance with documented procedures.

6.9.3 Construction QA Records

In addition to QA records generated by CENPD, QA records will be generated by CENPW Construction Division. CENPW Construction Division QA reports are completed daily for all days of contract work. QA and QC records are maintained by Construction Division and will comply with paragraphs 6.1 through 6.8 of this CEQAPP.

6.10 TRANSFER AND CONTROL OF COMPUTER DATA FILES

Data files will be stored on a hard disk drive of the CENPW Local Area Network (LAN) server. This system will allow storage and retrieval of data from a central source by all individuals having personal computer stations within appropriate functional elements requiring access to the data file for performance of data operations. This system will reduce the number of data transcriptions and transfers that could introduce error in the data. Other District personnel performing data operations will have access to this data through the LAN system within approximately 2 years. To avoid confusion over responsibility for maintaining the files and which files are current, files containing original data are listed on the Environmental Document Tracking System. Access to those files is controlled by access

code and only designated individuals may alter information contained within the files. Persons having access to alter files are listed in the Environmental Document Tracking System data base. To avoid loss of data resultant from hard disk crash, a tape system will be used to back up the LAN server drive daily. The tape unit will also be used to transfer large files of data (such as mapping data) from Hanford to CENPW, or vice versa, as needed. Removable hard disks from the tape unit are copied and the copies stored offsite. The CENPW LAN server is located in the computer complex and will be relocated into the Halon-protected Control Processing Unit and backup room.

6.11 PREVENTION OF LOSS OF ELECTRONIC DOCUMENTS

All electronic documents for DOE-RL work will be generated, used, and stored on mainframe and/or mini-computer and/or microcomputer file servers located in the headquarters complex computer center at CENPW and CENPD. No electronic data will be generated, used, or stored on floppy disks, work-station hard disks, or other work-station media for more than the duration of 1 working day without being transferred to the computer room systems. Computer room systems are located in fireproof, restricted access locations with noninterruptable power supplies and are backed up daily, weekly, and monthly. Backups are stored locally and offsite for maximum redundancy.

6.12 CONTRACT DOCUMENTS

Contract documents will include a listing of the drawings complete with revision number. Distribution of contract documents will be performed from a master list of plan holders. Any modifications will include a list of revised drawings with revision identification and distribution will be from the master list.

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7.0 COMPUTER SOFTWARE

7.1 GENERAL

This chapter describes the minimum documentation and configuration control requirements for existing computer software that has been procured for use by CENPW and all contractors and organizations performing Hanford Project-related activities for CENPW. Generally, all computer software packages used by CENPW are purchased commercially and will not be developed for use in ERRA work.

7.2 SCOPE

These requirements apply to all work done for DOE-RL at the Hanford Facility by CENPW and all contractors and organizations performing Hanford Project-related activities for CENPW.

7.3 SOFTWARE PROCUREMENT

All procurement of software is done in accordance with the FAR, DFARS, AFARS, EFARS, and NPWOM 715-1-8. All computer software programs are treated as corporate assets by CENPW.

7.3.1 "Off-the-Shelf" Software

CENPW will place "off-the-shelf" software, public domain, government supplied, free, or otherwise previously acquired developed software, as required, under the configuration controls of this chapter before use. CENPW will perform and document an evaluation to:

a. Determine the software's adequacy to support its operations and maintenance.

b. Identify the activities to be performed and documents that are needed for the software to be placed under configuration control. This determination will be documented and will identify, as a minimum:

(1) User application requirements.

(2) Test plans and test cases required to validate the software applicability.

c. Provide the user documentation (*i.e.*, manual, guide, *etc.*) that specifies and describes the required data and control inputs, options, program limitations, and other activities/items necessary for successful execution of the software. All error messages will be identified and corrective action described. A method of describing user identified errors/problems to the developer/owner will be established.

After the specified activities have been evaluated, reviewed, and approved, the software will be placed under configuration control. Alternatively, CENPW may obtain the above documentation from the supplier or perform a review of the documentation at the supplier facility to determine software acceptability. The onsite review must meet the requirements of paragraphs a., b., and c. above.

7.3.2 Commercial Word Processing Software

The latest version or upgrade of commercial word processing, data base management, and/or spreadsheet programs will be used by CENPW and all contractors and organizations performing Hanford Project activities. These programs will not be placed under the configuration controls of this chapter.

7.4 SOFTWARE VALIDATION

The software validation documentation will describe the results of reviews and tests that validate the software against specific requirements. In addition, software validation will also summarize the acceptability or confidence in the software to perform its intended function.

7.5 SOFTWARE CONFIGURATION CONTROL

The software control document or configuration baseline will prescribe the methods used for identification and marking of the software items, including the software, the software validation documentation, and the user documentation. The software configuration control documentation will identify the methods used for controlling changes to each of the software items as well as for recording and reporting change implementation status. The software configuration control document will identify the organizations/individuals within CENPW responsible for controlling changes to the master and controlled copies of the software, including physical access and change testing.

7.5.1 Configuration Identification

Control documents will be uniquely identified to assure positive control of revisions and to provide traceability between software documentation and the computer program version.

Approved software changes received subsequent to a control document will be added to the control document. A software configuration control document will define the most recent approved software configuration.

A labeling system for configuration items will be implemented, which will:

a. Uniquely identify each configuration item.

b. Identify changes to configuration items by revision.

c. Provide the flexibility to uniquely identify each configuration of the revised software available for use.

7.5.2 Configuration Change Control

Changes to software will be formally documented. This documentation will contain a description of the change, the rationale for the change, and the identification of the effected control document.

The change will be formally evaluated and approved by CENPW, even if it was developed by a contractor or organization performing Hanford Project activities for CENPW. Only authorized changes will be made to the software baseline. Software verification activities will be performed for the change, as necessary, to ensure the change is appropriately reflected in software documentation, and to ensure that the document traceability is maintained.

Changes to software will be subject to the same level of approval, verification, and validation as the original software. For example, where changes to previously verified computer programs are made, verification will be required for the change, including evaluation of the effects of the change on the model or program to show that it produces the correct solutions for the encoded mathematical model within defined limits. The encoded mathematical model will also produce a valid solution to the physical problem associated with the particular application.

Information concerning approved changes will be transmitted to all affected organizations.

7.5.3 Configuration Status Accounting

The information that is needed to manage software will be documented. This information will identify the approved configuration, the status of proposed changes to the configuration, the status of approved changes, and information to support the functions of identification and configuration control.

7.5.4 Physical Media Control

The control of physical media assures that the stored data or software is physically retrievable and cannot be lost or compromised by day-to-day operations or by catastrophic events. Typical media may include, but is not limited to, magnetic disks, large-scale integrated circuits, punch tape(s), program cards, magnetic tapes, laser disks, compact disks, and computer listings.

The physical media on which the software is stored must be controlled so that the software is not damaged, altered, or degraded. Backup copies of the program shall be maintained so that a single event will not cause a complete loss of software or data output from the program.

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8.0 MANAGEMENT ASSESSMENTS

8.1 GENERAL

Management assessments of organizations implementing and executing the QA program will be performed annually, documented, and reported to the District Commander. These management assessments will be conducted by an office outside of CENPW (*i.e.*, CENPD or Missouri River Division) and will provide a means for determining and taking necessary corrective actions regarding, as applicable:

a. The effectiveness of the system of management controls that are established to achieve and assure quality.

b. The adequacy of resources and personnel in order to achieve and assure quality.

c. Status of, or changes to, the QAPP or QAP.

d. Significant QA problems, accomplishments, and recommendations.

e. Results of performance and system audits conducted by CENPW.

f. Summary of QA training.

8.2 COMMUNICATIONS

CENPW, at all management levels, will utilize existing communication channels to provide timely, routine, and wide dissemination of information pertinent to quality performance such as:

a. The status of development and implementation of QAPjP elements.

b. Status of resolution of significant quality problems.

c. Quality management practices and improvements.

d. Overall performance trend analysis results.

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9.0 INDEPENDENT ASSESSMENTS

9.1 PREPARATION

9.1.1 Audit Plan

The Audit Officer will develop and document an audit plan for each audit. This plan will identify the audit scope, requirements, Audit Team personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists.

9.1.2 Audit Preparation

Audit preparation will include review of pertinent background information, procedures, and technical documents so that Audit Team members are familiar with the work being audited.

Audit planning will include a review of past audit results, if conducted, to determine the nature of problems that have occurred. When recurring problems are found, the Audit Team will review corrective actions that have been taken and attempt to determine whether the corrective actions were effective in preventing recurrence.

9.1.3 Personnel

Personnel who are selected and assigned to the Audit Team will be independent of any direct responsibility for performance of the activities they will be auditing. Audit Team personnel will have sufficient authority and organizational freedom to make the audit process meaningful and effective.

9.1.4 Selection of Audit Team

An Audit Team will be identified by the Audit Officer prior to the beginning of each audit. This team will contain one or more Audit Team members and will include a Certified Lead Auditor as the Audit Team Leader. Audit Team members need not be from CENPW. The Audit Officer organizes and directs the audit, coordinates the preparation and issuance of the audit report, and evaluates responses. The Audit Officer will ensure that the Audit Team members are prepared prior to initiation of the audit.

Audit Team members selected to participate in audits of the technical considerations will have appropriate technical expertise or at least 2 years experience in the work being audited.

9.1.5 Auditor Training and Qualification Requirements

Audit activities will be performed by qualified audit personnel in accordance with the requirements in appendix B.

9.1.6 Audit Notification

Organizations to be audited will be notified, in writing, of the audit 2 weeks prior to the audit. This notification will be in writing and include such information as the date, scope, and schedule of the audit, and the names of the Audit Officer and team members.

9.2 AUDIT PERFORMANCE

QA audits will be required to:

a. Determine that an effective QA program has been developed and documented by the A-E and Remediation Contractor.

b. Verify whether QA program elements, items, processes, work areas, or records, as appropriate, conform to specified requirements as documented by CENPW.

c. Assess the effectiveness of controls and verification activities.

d. Report audit findings to the Audit Officer, who will inform the CENPW District Engineer and the organization who should take corrective action.

e. Verify that corrective action has been planned, initiated, or completed by all applicable organizations.

f. Address technical considerations that verify the quality of the items, services, and activities, as well as programmatic compliance.

9.3 REPORTING

The final audit report will be signed and issued by the Audit Officer, and will include the following information, as appropriate:

a. A description of the audit scope.

b. Identification of the Audit Team members.

c. Identification of persons contacted during audit activities.

d. A summary of audit results, including a statement on the effectiveness of the QA program elements that were audited.

e. A description of each reported adverse audit finding and/or reportable event in sufficient detail to enable corrective action to be taken by the audited organization.

9.3.1 Audit Findings

Audit findings of a common nature will be grouped in the audit report, whenever possible, so that related or systematic breakdowns in the quality programs are identified. Findings will be categorized based on their relative importance to safety and remediation to indicate their degree of safety or environmental significance.

9.3.2 Event Report

Audit findings will be evaluated for event-reporting requirements in accordance with DOE Orders 5000.3B, 5484.1, and 5480.4, and DOE-RL Order 5000.3A.

9.3.3 Issuance of the Audit Report

The audit report will be issued within 30 days and include a required date for a response by the audited organization when a response is necessary. The audit report will be distributed to the CENPW District Commander and the audited organization.

9.4 AUDIT RESPONSE

The management of the audited organization will investigate adverse audit findings, determine root cause, schedule corrective action (including measures to prevent recurrence) and respond to the report in writing. The response will be no later than the requested date unless an extension has been agreed upon between the Audit Officer and the audited organization. It will clearly state the corrective action(s) taken to prevent recurrence. In the event that corrective action cannot be taken immediately, the response will include a scheduled date for initiation and completion. The adequacy of audit responses will be evaluated by the Auditing Officer, who may request a concurrent evaluation by the CENPW District Commander. The audited organization will report periodically on the status of corrective actions taken until completed.

Followup action will be taken by the Audit Officer or the CENPW District Commander to verify:

a. A timely, written response to the audit report.

b. Adequacy of the response.

c. That corrective action has been accomplished as scheduled.

9.5 SCHEDULING

Internal and external QA audits will be scheduled by the Audit Officer in a manner that provides coverage and coordination of ongoing QA program activities. Audits will be scheduled at a frequency commensurate with the status and importance of the activity and will be included in the cost estimate for the applicable task order.

The audit schedule will be periodically reviewed and revised as necessary to assure that coverage is maintained current. Regularly scheduled audits will be supplemented by additional audits of specific subjects, when necessary, to provide adequate coverage.

9.6 AUDIT RECORDS

Audit records will include audit plans, audit reports, written replies, and closure records.

10.0 DESIGN CONTROL

10.1 DESIGN INPUT AND DATA OBJECTIVES

Design inputs are those criteria, parameters, bases, or other design requirements upon which the final design or activity is based. These inputs may include design bases, performance requirements, regulatory requirements, codes, standards, environmental conditions, regulations, and/or risk assessments. All applicable design inputs and objectives shall be identified and documented and their selection reviewed and approved by the responsible design organization(s).

Where appropriate, criteria determining the goal of an activity (including the usefulness and/or reliability of the activity) or the use of an item (including the operation and maintenance of the item) shall be reviewed prior to initiating any design process/activity.

All applicable design inputs, including any subsequent changes to approved inputs, shall be specified, documented, approved, and correctly incorporated in a timely manner to provide a consistent basis for making design decisions, verifying designs, and evaluating any design changes.

10.2 DESIGN PROCESS CONTROL

This procedure applies to all design activities that affect new or existing facilities, systems, equipment, and environmental activities (such as monitoring, facility permits, hazardous waste site studies, and site remediation). It should be noted that in the following paragraphs, the terms process, plans, and activities are often used interchangeably depending on the implied context of the section.

10.2.1 DQO's Development

The important process of project planning assures that each step of the data gathering operation is done with appropriate care (*i.e.*, yields data that is sufficient in quantity and quality) and that the data fulfills both the regulatory requirements and the objective parameters. The procedure requires step-by-step planning with the results incorporated into the SAP, the QAPjP, and, in more general terms, the work plan for the activity(s). (See appendix A, for the requirements of these plans.) At a minimum, the following steps will be used to define the DQO's (*i.e.*, design inputs) for the environmental data measurement activities/protocols.

10.2.1.1 Define Regulatory Requirements. The knowledge of the ultimate goal will usually specify the target parameters. Typically, Federal, State, and/or local governments have established maximum concentration limits (MCL's) for a series of contaminants. These MCL's vary, depending upon the land use and the regulatory agency. Therefore, the ultimate data use and the relevant regulations (such as MCL's) define the project goal. The planning process begins by defining the regulatory requirements consistent with the land use objective.

The boundaries that define the area of contamination and timeframe in which data will be collected, must also be described. Within each site, there may exist smaller units that require further definition with respect to identification of receptor populations, current/future land uses, and critical timeframe. These are defined as the smallest area (*i.e.*, site boundary) for which a separate decision and/or strategy will apply. There may also be additional social/political and/or contractual issues to consider.

10.2.1.2 State the "Problem." (*e.g.*, a series of contaminants whose presence and/or concentrations must be determined and, if present, reduced to a specific concentration dependent upon the regulatory requirements). The initial investigative efforts will identify all contaminants, their locations (*e.g.*, surficial, subsurface, and/or groundwater), and their respective concentrations within each media. The results of this determination will include a complete description of what is known or expected at the site (*e.g.*, a summary of available information about soil, groundwater, and known contamination, including potential significant exposure pathways and information sources). In addition, a list of alternative actions to address the problem will be identified. Such actions may include further study, no action, or immediate action. These determinations are generally presented in remedial investigation and/or feasibility study reports.

Once the contamination is defined, both spatially and chemically, a strategy must be designed to remediate the site to full compliance within the regulatory framework.

10.2.1.3 Identify Inputs Affecting the Decision. Generally, contaminant concentration relative to MCL's (or, in some circumstances, a risk assessment) define the goals to achieve regulatory compliance. The decision concerning the type, quantity, and quality of data gathered must be sufficient to determine if the site is in compliance (or <u>when</u> the site is in compliance during the remediation process). Typically, a list of known or suspected contaminants is developed (with concentrations, if known) against a parallel list of the allowable concentrations of the contaminants. In addition, quantitative and qualitative statements of the acceptable level of total uncertainty will be included for each contaminant. Discussion of apportionment of error associated with environmental data operations is presented in paragraph 10.2.3.

Additional "inputs" or considerations that impact the ability to attain the project goals can be divided into three categories; practical, political, and regulatory:

- <u>Practical Limitations</u>. The availability of resources and current waste management capabilities are two important considerations. Other factors include site-specific conditions (*i.e.*, how the site geology will impact sampling operations), contaminant specific constraints (*i.e.*, volatility or toxicity of the samples/area), and seasonal conditions.

- <u>Political Climate</u>. The site is located within a region having a unique political climate. The planning process should take into account such topics as labor agreements, politically active groups, and potentially changing land use goals.

- Regulatory Framework. It must be recognized that the regulatory target may not be stationary. Many of these projects will require decades to complete. During that period, the regulations may change. Although it is not possible to predict what the regulations will be in the future, it may be possible to build some flexibility into the plan that would allow for fine-tuning of the plan during implementation.

10.2.1.4 Identify a Process (Method/Protocol) that Addresses the Problem and Defines the Domain of the Decision. All the information in the former categories is utilized to develop specific plans, items, and/or activities. These plans include contingencies at predicted decision-making branch points and describe the appropriate offices empowered to make the decisions. Logic statements will describe the potential actions to be taken and the circumstances requiring the actions. If ARAR's or risk-based criteria are to be used, the logic statement will address the threshold levels that are of potential concern.

10.2.1.5 Optimize Design for Obtaining Data or Items. Optimization involves review of the existing plan(s), items(s), or activity(s) to minimize cost and time elements to provide the most efficient plan or activity design. For example, the most efficient SAP will, in addition to protecting the public health and the environment, achieve the desired data in the shortest period of time in the most cost-effective manner.

10.2.2 Apportionment of Measurement Error

In delineating the design measurement methods/protocols (*i.e.*, the DQO's), a measurement error will be assigned to each major source of error in the data operation. The cumulative errors from this will "sum" to the overall level of uncertainty.

The total error will be apportioned among the following sources of measurement error, as a minimum:

a. Sample collection.

b. Sample handling/storage.

c. Laboratory analyses (human and instrumental).

d. Data analyses.

e. Data handling.

f. Site characteristics.

Based on the total amount of error allowable in the measurement system, precision and bias estimates will be established for each error source.

These precision and bias allowance estimates will become the basis for establishing the number and location of samples to be taken and the selection of laboratory analytical methods to be used. The constraints on uncertainty will establish the range of true values in the data operation where either a correct or incorrect value can be tolerated (*i.e.*, the impact of false-negative and/or false-positive error will be evaluated). The potential consequences of incorrect decisions based on such data must be identified and evaluated.

10.2.3 Risk Assessment

Risk assessments will be conducted in conjunction with the development of the logic statement in the DQO process. The risk assessment should characterize the known and potential threats to human health and the environment posed by hazardous substances. At the planning stage, risk assessments will address any known or suspected hazard through all program levels. All sources and pathways of contamination are considered.

It is probable that the contaminant data confidence level will increase during the Remedial Investigation/Feasibility Study (RI/FS) and remediation process. The risk assessment will be updated periodically as directed by the most current EPA (and Ecology) methodology in order to minimize the risk assessment error.

10.2.4 DQO's Integration With Design Documents

For each environmental data operation, monitoring program, or activity, the DQO design outputs will be integrated into the design documents. For example, work plan development will be coordinated among organizations participating in the environmental data measurement activities by the Technical Manager (for those issues pertaining to technical matters) and by the Hanford Program Manager or Project Managers for other issues.

10.2.5 General Design Process

The responsible design organization, as designated in chapter 2, shall prescribe and document the design activities to the level of detail necessary to permit the design process to be carried out in an acceptable manner and to permit verification that the design or activity meets requirements.

Design documents shall be adequate to support the design, construction, operation, and/or environmental activities.

Appropriate quality standards shall be identified and documented and their selection reviewed and approved. Changes from specified quality standards, including the reasons for the changes, shall be identified, documented, approved, and controlled.

Design methods, materials, parts, equipment, and processes that are essential to the function of the structure, system, component, or environmental activity shall be selected and independently reviewed for suitability of application.

Applicable information derived from experience (*e.g.*, prior similar designs, design standards or methods, lessons learned, *etc.*), or as set forth in reports or other documentation, shall be made available to cognizant design personnel.

The final design (approved design output documents and approved changes thereto) shall relate to the design input by documentation in sufficient detail to permit design verification. Also, all components of items and/or protocols for activities being designed shall be identified. Where special safety items or techniques may affect the environment or safety and health of the public, these items shall also be identified in the design output documents.

10.2.6 Design Analyses

Design analyses shall be performed and documented in a planned and controlled manner.

10.2.6.1 Data Transfer, Reduction, and Validation. Design analyses, including data transfer, reduction, and validation controls, will be established to ensure data transfer is error free, to ensure no information is lost in transfer, and to ensure that the input is completely recoverable from the output. Examples of data transfer include copying raw data from a field notebook into a computerized data form or copying from computer tape to disk. All processes that change either the form of expression or quantity of data, values, or number of data items (data reduction) will be controlled in accordance with written procedures that allow for the validation of the conversion process.

Validation of the data reduction process will also be addressed. The procedures will describe the maintenance and validation of all appropriate records. The reviewer needs to check the validity of the conversion process against a prescribed methodology for all processes. For each major measurement parameter, including all pollutant measurement methods/protocols, the following will be described:

a. Data reduction scheme for the collected data, including all equations used to calculate the concentration or value of the measured parameters and reporting units.

b. The principal criteria used to validate data integrity during collection and reporting of data.

c. The methods used to identify and treat irregular sampling areas and/or materials.

d. The data flow or reporting scheme utilized from raw data collection through storage of validated analytical results. Typically, a flowchart fulfills this requirement.

e. The identification of key individuals who will handle the data in this reporting scheme. (Generally, personnel from the section performing environmental work.)

10.2.6.2 Data Interpretation and Design Analyses. The section performing calculations or using computer software that interprets data and/or analyzes designs will perform its activities in a planned, controlled, and documented manner. The section will be responsible for preparing documentation that includes the purpose, method, assumptions, inputs, references, and units so that a technically qualified person may review, understand, and verify the calculation(s) without recourse to communicate with the originator. Calculations will be legible, complete, and in a form suitable for reproduction, filing, and retrieval. Calculations will be identifiable by subject, originator, reviewer, and date. Calculation documentation will include the following:

a. Definition of the objective of the interpretation/analysis.

b. Definition of inputs and their sources.

c. A listing of applicable references.

d. Results of literature searches or other background data.

e. Identification of assumptions and indications of the assumptions to be verified as the design proceeds.

f. Identification of any computer calculation, including computer type, algorithm [or sample calculation (with units)], program name, revision, input (with units), output (with units), evidence of program verification, and the basis of application to the specific problem.

g. Signatures and dates of review and approval by appropriate qualified personnel.

10.2.6.3 Computer Programs. Computer programs may be used for design analysis without individual verification of the program for each application, provided paragraphs a. and b. below, have been met:

a. The computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed.

b. The encoded mathematical model has been shown to produce a valid solution, over the range of application, to the physical problem associated with the particular application.

In addition, computer programs shall be controlled to assure that changes are documented and approved by authorized personnel. Where changes to previously verified computer programs are made, verification shall be required for the change, including evaluation of the effects of these changes on requirements in paragraphs a. and b. above.

10.2.6.4 Report of Evaluation and Analysis. All field activities and investigations will be documented in reports. A report of the analysis and evaluation of the investigation,

environmental aspects of the site, and the basic data supporting all conclusions and recommendations will be documented. Sufficient information will be provided to allow for independent analyses and evaluations (technical or peer review) for design verification. All data reported will be accompanied by a calculation of precision and accuracy. Where appropriate, a statement relative to the completeness and representation of such data will also be included.

10.2.7 Technical Reviews

CENPW and its contractors will conduct technical reviews of all documents and/or data following current standards, principles, and practices. CENPW technical reviews are usually directed by CENPW or CENPD Division Chiefs and separate Office Chiefs, as appropriate. These chiefs, or their designees, who have applicable technical expertise and who are independent of the originator of the work, perform the review. Comments are returned to the Technical Manager who assimilated the work or document. The Technical Manager is responsible for justification, incorporation, resolution, and documentation of all technical review comments.

10.2.8 Peer Reviews

When a more extensive or complex issue exceeds the current state-of-the-art procedures and/or standards, it may be expedient to conduct an in-depth peer review. Especially where uncertainty exists, the peer review will provide a detailed review of assumptions, calculations, extrapolations, alternate interpretations, methodologies, acceptance criteria, conclusions, and other material or data that is critical to the work. The Technical Manager is responsible for identifying the need for and scope of the peer review. As with the technical review, appropriately qualified persons, independent of the originator of the work, will be identified by the Technical Manager or the applicable CENPW or CENPD division or office chief. As with the technical review, the Technical Manager is responsible for justification, incorporation, resolution, and documentation of all peer review comments.

10.3 DESIGN CHANGE CONTROL

Changes to approved design documents and/or items such as plans, field changes, and nonconformances dispositioned as use-as-is or repair will be justified and subject to design control measures commensurate with those applied to the original design. These measures will include assurance that the DQO's for the documents, plans, or items are still valid. Minor changes that have no adverse effect on technical adequacy of the design, plan, or activity may generally be approved by the Technical Manager. This is expanded on in paragraph 7.6. Where a significant design change is necessary because of an incorrect or inadequate design, the original design procedure will be restarted. Modifications to the entire procedure may be pursued and approved by the same affected groups or organizations that reviewed and approved the original document. All changes will be documented and include a justification of the change. The Technical Manager will maintain a file documenting any changes in the project file in concert with the Project Manager.

10.4 DESIGN INTERFACE

Design interfaces shall be described between the participating organizations and controlled in QAPjP, and the design efforts shall be coordinated among the participating organizations. Interface controls shall include the assignment of responsibility and the establishment of procedures among the participating organizations for the coordination, review, approval, release, distribution, revision, and documentation of design interfaces.

10.5 QUALIFICATION OF DATA WITH INDETERMINATE QUALITY

Data to be used, which were not collected under the control of a QA program in accordance with this document, will be qualified for its intended use. This may include data collected from such sources as previous investigations, studies, professional journals, technical reports, and symposia proceedings. Evaluation of this data will be based upon both technical and QA programmatic criteria. Factors to be considered, when available and measurable, include:

a. Qualifications of personnel or organizations generating the data.

b. Technical adequacy of the equipment and procedures used to collect and analyze the data.

c. Environmental conditions under which the data were obtained.

d. Quality and reliability of the measurement control program by which the data were generated.

e. Extent to which data demonstrate properties of interest (*e.g.*, physical, chemical, geologic, or mechanical).

f. Extent to which conditions generating the data may partially meet requirements of this document.

g. Prior uses of the data and associated verification processes.

h. Prior technical, peer, or other professional reviews of data and the results.

i. Extent and reliability of the documentation associated with the data.

j. Extent and quality of corroborating data or confirmatory testing results.

k. Degree to which data generating processes were independently audited.

l. The importance of the data in showing that the product meets the performance objectives.

The organization using such data will be responsible for evaluating its accuracy, precision, completeness, representation, and comparability. The process will be documented and the records filed with the Data Verification Records. Acceptable qualification methods include the following: technical or peer reviews, corroborating data, confirming testing (either alternate methods or replication), or demonstrating that the data were collected under a QAPP equivalent to the document.

10.6 VERIFICATION METHODS

Design adequacy shall be verified in accordance with approved processes and by one or more of the following:

a. The performance of design reviews.

b. The use of alternate calculations.

c. The performance of qualification tests.

10.6.1 Requirements

The responsible design organization, as indicated in section 1.2, shall identify and document the particular design verification method(s) used and establish the requirements for performance of verification reviews. The results of design verification shall be clearly documented with the identification of the verifier clearly indicated. The responsibility for implementation of the design verification method(s) will be identified in the project-specific work plans. The responsibility for QA oversight will belong to the CENPW Special Assistant for Quality Assessment.

Design verification or review shall be performed by any qualified, competent individual(s) or group(s) other than those who performed the original design. They may be from the same organization. This verification may be performed by the originator's supervisor, provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design, or provided the supervisor is the only individual in the organization competent to perform the verification. Cursory supervisory reviews do not satisfy the intent of a design verification.

Verification shall be performed in a timely manner and generally completed prior to relying upon the system, component, or structure to perform its function and/or prior to implementing the activity/protocol. In those cases where this timing cannot be met, such as when insufficient data exists, the unverified portion of the design or activity shall be identified and controlled.

10.6.2 Extent

The extent of the design verification or review required is a function of the complexity of the design or activity, the degree of standardization, the state of the art, and the similarity with previously proven designs, activities/protocols, and/or items.

Where the design has been subjected to a verification process performed in accordance with the requirements of this plan, the verification process need not be duplicated for identical designs, activities, or protocols. However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application. Known problems affecting the standard or previously proven designs and their effects on other features shall be considered. The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design.

10.6.2.1 Changes. Where changes to previously verified designs, activities, *etc.*, have been made, reverification of that design or activity shall be completed.

10.6.2.2 Methods. Acceptable verification methods include, but are not limited to, any one, or a combination of, the following.

a. Design Reviews. Design reviews provide assurance that the final design is acceptable and satisfactory. These reviews may combine professional, peer, or technical reviews or be separate. Where applicable, the following shall be addressed:

- Were the design or environmental data operation inputs correctly selected?
- Are assumptions necessary to perform the design or data operation activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are completed?
- Was an appropriate design or DQO method used?
- Were the design or DQO inputs correctly incorporated into the design?
- Is the design or DQO output reasonable compared to design or DQO inputs?
- Are the necessary design and DQO input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions?
- Were the design and DQO processes, steps, and results adequate?

b. Alternate Calculations. Alternate calculations are calculations or analyses that are made using alternate methods to verify accuracy of the original calculations or analyses. The appropriateness of assumptions, input data used, and the computer program or other calculation method used shall also be reviewed.

c. Qualification Testing. Where design adequacy is to be verified by qualification tests, the tests shall be identified. The test configuration shall be clearly defined and documented. Testing shall demonstrate adequacy of performance under conditions that

simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means. Test results shall be documented and evaluated by the responsible design organization to assure that test requirements have been met. If qualification testing indicates that modification(s) to the item are necessary to obtain acceptable performance, the modification shall be documented and the item modified and retested, or otherwise verified, to assure satisfactory performance. When tests are being performed on models or mockups, scaling laws shall be established and verified. The results of model test work shall be subject to error analysis, where applicable, prior to use in the final design.

10.7 DOCUMENTATION AND RECORDS

Design documentation and records which provide evidence that the design and design verification processes were performed in accordance with the requirements of design control procedures shall be collected, stored, and maintained in accordance with documented procedures. The documentation shall include not only final design documents, such as drawings and specifications and revisions thereto, but also documentation that identifies the important steps, including sources of inputs, that support the final design. After modification or extensive repair on equipment or systems, there shall be determination that as-built conditions are accurately and completely shown on the drawings, specifications, engineering change notices, and other equipment/systems descriptions.

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11.0 PROCESS CONTROL

11.1 CONTROLLED PROCESSES

The requirements for processes affecting the quality of data operations shall be established within work plans, QAPjP's, SAP's, procedures, or other appropriate means. These means shall assure that process parameters are controlled, specific environmental conditions are maintained, prerequisites are established, and required verifications are performed. Examples of controlled processes include:

a. Environmental monitoring and measuring activities.

b. Sample collection.

c. Sample analysis.

d. Geophysical logging.

e. Drilling.

f. Welding.

11.2 SPECIAL PROCESSES

11.2.1 Identification of Special Processes

It is the responsibility of the Field Team Leader or Technical Manager supervising the work to identify which portion of its activities involve the use of special processes and to adhere to the approved procedures for the control of processes.

11.2.1.1 Criteria for Special Processes. Criteria for determining if an environmental data operation process control activity is a special process shall be defined. Examples of such criteria include the following:

a. When direct inspection of the process control or its results cannot be performed.

b. Results from the activity (*i.e.*, the product) cannot be tested to determine acceptability.

c. Process critical parameters exist which, if changed, require qualification of personnel, procedures, and/or equipment.

d. Personnel qualifications or training requirements are in excess of those normally required.

11.2.1.2 Listing of Special Processes. A listing of activities considered by CENPW to be special processes shall be established and maintained. Examples of such activities might include, but are not limited to:

a. In situ vitrification.

b. Soil treatment (*e.g.*, neutralization/detoxification).

c. Soil flushing.

11.2.2 Controlled Conditions for Special Processes

The requirements necessary for the qualification and accomplishment of special processes shall be described or referenced in work plans, QAPjP's, or SAP's. These requirements shall include:

a. Proper use of equipment.

b. Identification of parameters to be controlled.

c. Calibration requirements.

d. Prerequisites for the special process.

e. Personnel qualification requirements.

f. Health and safety considerations.

g. Requirements for documenting evidence of acceptable accomplishment of the special process.

h. Procedure qualification.

11.2.2.1 Training and Qualification of Personnel. Personnel performing special process activities will be trained and qualified in the actual working procedure. This training and qualification shall meet the requirements as described in chapter 2.

11.2.2.2 Acceptance Criteria. The requirements of applicable codes and standards, including acceptance criteria for the special process, shall be specified or referenced in the work plans, QAPjP's, or SAP's.

11.2.3 Qualifications of Personnel, Procedures, and Equipment

Technical Managers will describe, within the QAPjP, the methods for the qualification of personnel, procedures, and equipment.

11.3 PROCESS RECORDS

11.3.1 QA Records

Records will be maintained for currently qualified personnel, processes, equipment, and procedures of each special process. These records will be maintained in accordance with chapter 6.

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12.0 MATERIAL CONTROL

12.1 CONTROLS

These requirements apply to all work done for DOE-RL at the Hanford Facility by CENPW and all contractors or organizations performing Hanford Project-related activities for CENPW.

12.2 METHOD OF IDENTIFICATION

Nonconforming items will be marked, tagged, or otherwise identified so the end use of the item will not be effected. The identification will be legible and easily recognizable.

12.2.1 Exceptions

If identifying each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, will be identified.

12.3 DISPOSITION

12.3.1 Control

Nonconforming characteristics will be reviewed and recommended dispositions of nonconformances will be proposed and approved in accordance with procedures in NPWOM 715-1-8. Further processing, delivery, installation, or use of a nonconforming item will be controlled pending an evaluation and an approved disposition by authorized personnel.

12.3.2 Responsibility and Authority

12.3.2.1 Delivery Orders. CENPW personnel involved in the execution of task orders are responsible for identifying nonconformances and initiating corrective action for delivery order items. Any nonconformance will be reported to the COR, who will contact the Contracting Officer at the earliest time possible. The contractor will receive a written notification of nonconformance and will be requested to submit a written plan outlining how the situation will be corrected.

12.3.2.2 Service Contracts. CENPW personnel involved in the execution of task orders are responsible for identifying nonconformances and initiating corrective action for Service Contracts. Contract clauses enforcing compliance are contained on page 243 of FAR 52, "Uniform Contract Clauses."

12.3.2.3 Remedial Action Contracts. Nonconformance control for Remedial Action Contracts is outlined in ER 1180-1-6. The deficiency tracking system, as noted in paragraph 15.1.7.3, directs how the item is to be segregated and, after review, what its disposition will be. The entire process will be verified by QA review.

12.3.3 Personnel

Personnel performing evaluations, in order to determine a disposition, will have demonstrated competence in the specific area they are evaluating, display an adequate understanding of the requirements, and have access to pertinent background information.

12.3.4 Disposition

The disposition of nonconforming items (such as use-as-is, reject, repair, or rework) shall be identified and documented in project files by the Technical Manager.

Technical justification from Engineering Division for the acceptability of a nonconforming item (dispositioned repair or use-as-is) will be documented and included in the project files. Nonconformances to design requirements dispositioned as use-as-is or repair shall be subject to the same design control measures as in the original design. The as-built records, if such records are required by chapter 6, will reflect the accepted deviation.

12.3.5 Reworked Items

Reworked items will be examined in accordance with applicable procedures and with the original acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.

13.0 CONTROL OF MEASURING AND TEST EQUIPMENT

13.1 REQUIREMENTS

The procedures for the control of measuring and test equipment (M&TE) will be supplied in approved project-specific work plans provided by CENPW or any organization or contractors performing activities for CENPW. The approval process is outlined in the executive summary. These approved project-specific work plans will cover control of M&TE protocols for all aspects applicable and relevant to the project. The responsibility for implementation of the protocols will be identified in these approved project-specific work plans. The responsibility for QA oversight will reside with the Special Assistant for Quality Assessment.

The requirements defined in this chapter are applicable to M&TE used for all applications. Supplemental requirements that are specifically applicable to sampling and analyses of environmental samples are addressed in appendix E.

13.2 METHODOLOGIES

The methodologies described in the project-specific work plans will include, but are not limited to, those listed below.

13.2.1 Selection of M&TE

The range, accuracy, and precision of M&TE should be commensurate with test and/or measurement requirements.

13.3 DOCUMENTATION

The minimum requirement for documentation is to maintain complete records allowing for traceability of the status of M&TE (and personnel performing M&TE activities) through all phases of testing, operation, maintenance, and/or calibration and standardization in a manner allowing use of these records as evidentiary data. These records shall be retained, stored, and maintained in accordance with procedures described in chapter 6.

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14.0 HANDLING, STORAGE, AND SHIPPING

14.1 REQUIREMENTS FOR HANDLING, STORING, AND SHIPPING

Requirements shall be established for the control of handling, storage, cleaning, packaging, preservation, and shipping of items to prevent damage or loss and to minimize deterioration. These instructions, drawings, specifications, shipment instructions, or other pertinent documents will be handled as discussed in chapter 6.

14.2 SPECIAL EQUIPMENT AND PROTECTIVE ENVIRONMENTS

When required for particular items, special equipment (such as containers, shock absorbers, and accelerometers) and special environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels) shall be specified, provided, and their existence verified.

14.3 SPECIFIC PROCEDURES

When required for critical, sensitive, perishable, or high-value articles, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.

14.4 TOOLS AND EQUIPMENT

Special handling tools and equipment shall be used. Special handling tools and equipment shall be inspected and tested in accordance with procedures at specified time intervals to verify that the tools and equipment are adequately maintained.

14.5 OPERATORS OF SPECIAL EQUIPMENT

Operators of special handling and lifting equipment will be experienced or trained in the use of the equipment, as defined in the project-specific work plans.

14.6 MARKING AND LABELING

Instruction for marking and labeling for packaging, shipping, handling, and storage of items will be established, as necessary, to identify, maintain, and preserve the item adequately, including indication of the presence of special environments or the need for special controls.

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15.0 INSPECTION AND TEST CONTROL FOR ENGINEERED ITEMS

15.1 INSPECTION, VERIFICATION, AND VALIDATION

This section describes CENPW's QA requirements for inspection, verification, and validation activities for environmental data operations, remedial design, and remedial actions. Inspections will be performed by a Technical Manager or Resident Engineer to ensure that work has been properly performed and to provide verification of quality.

The responsibility for QA oversight will reside with CENPW's Special Assistant for Quality Assessment.

15.1.1 Inspection Measures

15.1.1.1 Environmental Data Operations and Remedial Design. Planning and design control processes are used in CENPW's Engineering Division. Project Managers work through the Technical Manager to ensure the scope of work is clear and covers all aspects of the proposed project. The specific procedures are outlined in ER 415-1-11, ER 1110-2-1200, and ER 1110-345-100.

15.1.1.2 Remedial Actions. Activities or controls that ensure quality during remedial actions will be managed by the CENPW Construction Division through the Hanford Area Office. Remedial actions will be managed in accordance with ER 1180-1-6 and ER 415-1-302.

15.1.2 Personnel

Inspections will be performed by personnel who are not directly associated with the work being inspected (*e.g.*, supervisor, workers involved with performance of the activity, or workers reporting to supervisors of the activity). Oversight of these inspections is performed by the Special Assistant for Quality Assessment. All personnel involved will be qualified as outlined in chapter 2.

15.1.3 Inspection Hold Points

Mandatory inspection hold points will be established during the formulation of work plans, QAPjP's, and remedial action contract documents. When such hold points are established, work may not proceed without the specific consent of the COR or QAR. These hold points will be indicated in all documents and will be covered in preconstruction conferences.

15.1.3.1 Waiver of Specified Hold Point. When a waiver of a specific hold point is accepted, the waiver shall be documented on the document controlling the activity by the COR or QAR assigning the hold point before work can be continued beyond the specified hold point. This waiver becomes part of the project files.

15.1.4 Inspection Planning

Planning for inspection activities will be accomplished and documented via inspection procedures, instructions, and checklists that will provide for the following:

a. Identification of characteristics and activities to be inspected.

b. A description of the method of inspection.

c. Identification of the individuals or groups responsible for performing the inspection operation.

d. Acceptance or rejection criteria.

e. Identification of required procedures, drawings, specifications, and revisions.

f. Inspector or data recorder.

g. Specifications necessary for M&TE, including accuracy requirements.

h. Records for object evidence of inspection results.

15.1.5 Requirements

The protocols for inspection, verification, and validation will be furnished in approved project-specific QAPjP's provided by CENPW or any organization or contractors performing activities for CENPW. The approval process is outlined in the executive summary. The responsibility for implementation of the protocols will be identified in these project-specific QAPjP's.

15.1.6 Methodologies

The methodologies described in the project-specific QAPjP's may include, but are not limited to, those listed below.

15.1.6.1 Design Review Process. Internal division reviews are included during the RI/FS phase and remedial design process along with biddability, constructibility, and operability reviews to ensure all CENPW work at the Hanford Project meets the specific requirements laid out in the work plan, QAPjP, or SAP for the task order.

15.1.6.2 Biddability, Constructibility, and Operability. Biddability, constructibility, and operability are emphasized throughout the environmental data collection and remedial design processes to ensure efficient remediation and operation. The production of a quality product requires the cooperation of design, remediation, and operations personnel each contributing their particular expertise toward a common goal. Through such a coordinated effort, errors,

conflicts, and potential operational problems can be minimized. These principals are applicable to both in-house and A-E designs or activities.

15.1.6.3 Combined Inspection and Monitoring. Where a combination of inspection and process monitoring methods are used, they will be performed in a systematic manner to assure that requirements specified in the QAPjP for control of the process and quality of the items are achieved throughout the duration of the process. Both inspection and monitoring will be provided when control is inadequate without them.

15.1.6.4 Preconstruction Conference. As soon as possible after contract award and prior to commencement of work, a preconstruction conference will be held with the contractor. The purpose of this meeting will be to address contract provisions, safety, environmental requirements, personnel requirements, and administrative matters. By the end of the meeting, the contractor and CENPW will share the same conceptions of the full scope and conditions of the contract. CENPW will keep minutes of the meeting and provide them to the contractor for his future reference.

15.1.6.5 Contractor QC Plan. Prior to starting work, the contractor will provide an acceptable interim CQCP with a complete plan furnished within 30 days after receipt of Notice to Proceed; this is a mandatory hold point for all contracts. The plan will include, as a minimum, the requirements listed in contract Special Clause 30, Construction Quality Management. See paragraph 1.2.1.1 of this CEQAPP concerning terminology. The plan will be reviewed by the Special Assistant for Quality Assessment and the Hanford Area Office. No definable feature of work will be started until the CQCP for that feature is complete and approved by the designated ACO or COR in the Hanford Area Office.

15.1.6.6 QC Coordination Meetings. Before any physical work begins onsite, a QC Coordination Meeting will be held. This meeting will be convened and conducted by the Chief of the Hanford Area Office for the purpose of reviewing the CQCP, achieving a mutual understanding with the contractor of his role in QC, and establishing a good working relationship between Hanford Area Office QAR and the CQCR. All personnel who will be directly involved in quality management on the job will be present at this meeting including a representative from the Quality Assessment Office. The meeting will specifically address the following topics:

a. Purpose of the meeting.

b. CQCP.

c. Contractor's role in Quality Management.

d. Three phases of QA/QC inspection.

e. Definable features of work, including hold points.

f. CQCP reports.

g. Correction of deficiencies.

h. CENPW options to correct noncompliance.

Minutes of the meeting will be prepared by the Hanford Area Office, signed by the contractor and CENPW to verify authenticity, and provided to the contractor for his future reference.

15.1.6.7 Three-Phase Inspections. QA/QC inspections will be conducted in a three-phase procedure as detailed below:

a. Preparatory Inspections. Will be conducted before any definable phase of work begins. The contractor will provide CENPW personnel a minimum of 24 hours notice of any preparatory inspection.

b. Initial Inspection. The contractor will also provide CENPW personnel a minimum of 24 hours notice of any initial inspection. This phase is required at the beginning of an operation to get the actual work properly underway. This phase is workmanship-oriented.

c. Followup Inspection. This is a continuous action throughout the entire time work is being performed. It involves routine checks to ensure that previously established guidelines assuring contract compliance are being followed. Where necessary, inspections will be performed on work activities to verify quality.

15.1.6.8 Resolution of Nonconformances. Final inspections shall include a records review of the results and resolutions of nonconformances identified by prior inspections. The final inspection shall be planned to reach a conclusion regarding conformance of the data or items to the required specifications.

15.1.6.9 Inspection Requirements. Completed operations and items will be inspected for completeness, markings, calibration, adjustments, protection from damage, or other specified characteristics, as required, to verify the quality and conformance of the data, actions, or items to specified requirements. Quality records will be examined for adequacy and completeness. These records will be maintained as outlined in paragraph 6.12.

15.1.6.10 Acceptance. The acceptance of environmental data, remedial actions, or equipment will be documented and approved by qualified and authorized personnel.

15.1.6.11 Modifications, Repairs, or Replacements. Modification, repair, or replacement of items and/or samples performed subsequent to final inspection will require reinspection or retests, as appropriate, to verify acceptability.

15.1.7 Records

15.1.7.1 QAR Reports. Daily QAR reports will ensure that the three-phase inspection system is functioning and that the results of all inspections and tests are available. The reports to be used are described in ER 415-1-302. It will be the responsibility of the QAR to collect and review CQCP reports on a daily basis. Any inaccuracies, inadequacies, or discrepancies found on the CQCP report will be discussed with CQCR to initiate corrective actions. If corrective action cannot be initiated immediately, the QAR will make appropriate comments on the QAR report.

15.1.7.2 Inspection Records. The QAR report will be completed in a timely manner and will record, as a minimum, the following:

a. Item inspected.

b. Date of the inspection.

c. Inspector.

d. Type of observation (method of inspection).

e. Inspection criteria, including identification of drawing and work plan element specification (and applicable revisions).

f. Equipment used during the inspection.

g. Evidence as to the acceptability of the results.

h. References to information on action taken in connection with conditions adverse to quality, nonconformance, and/or actions taken to resolve any discrepancies.

Inspection records will be maintained in accordance with paragraph 6.12.2.

15.1.7.3 Deficiency Tracking Systems. A deficiency tracking system will be used on the job site to record remediation deficiencies and to monitor them until they are corrected. In addition to enabling the QAR to keep track of deficiencies to assure that they are corrected, the deficiency tracking system will also show the areas in which the planning documents, training standards, or implementation of procedures need improvement to minimize deficiencies. The format used on a particular project is outlined in the QAPjP or QAP and the CQCP to ensure compliance with this CEQAPP.

15.1.7.4 Personnel Qualification Records. Records of QAR qualifications will be established and maintained by CENPW in accordance with chapters 2 and 6. The actual examinations used to qualify personnel will also be maintained by CENPW's Personnel Office (Training and Development Unit, Human Resources Office).

15.2 TEST CONTROL

This chapter describes CENPW's requirements for performance test control. The intent is to ensure that all items or computer programs that are used on a specific project fulfill specified requirements in addition to being appropriate and applicable to the task being performed.

15.2.1 Scope

These requirements apply to all work done for DOE-RL at the Hanford Facility by CENPW and all contractors or organizations performing Hanford Project-related activities for CENPW.

15.2.2 Requirements

In order to demonstrate satisfactory performance of items or computer programs, tests will be planned, performed, and documented. The procedures for the control of tests will be supplied in approved project-specific work plans provided by CENPW or any organization or contractors performing activities for CENPW. Test requirements and acceptance criteria will be based upon specified requirements contained in applicable design documents, codes, standards, or other pertinent technical documents.

The approval process is outlined in the executive summary. These approved project-specific work plans will contain testing protocols for all aspects applicable and relevant to the project. The responsibility for implementation of the protocols will be identified in these approved project-specific work plans. The responsibility for QA oversight will reside with the CENPW Special Assistant for Quality Assessment. The test control methods must be performed and documented in a manner allowing their use as evidentiary data.

15.2.3 Methodologies

Test control procedures will include, but are not restricted to, the following:

a. Test objectives, characteristics to be tested, test methods to be employed, and all reference documents (*i.e.*, manuals, technical literature, documents, *etc.*) used to establish such criteria and methodology. In lieu of specially prepared written test procedures, appropriate sections of related documents, such as American Society for Testing and Materials methods, supplier manuals, and equipment maintenance instructions, may be used. When used, these standards will be both specified in engineering or other authorizing documents (such as the QAPjP) and readily available to personnel performing the work. Any documents utilized must either include, or be supplemented with, adequate instructions to assure the required quality of work.

b. Safety instructions relevant to the test being performed.

c. Test requirements, including acceptance and rejection criteria and other objectives, such as required levels of precision and accuracy, as appropriate.

d. Training and personnel qualification requirements.

e. Instructions for performing the test.

f. Provisions for ensuring test prerequisites have been met. Test prerequisites will include the following, as applicable:

(1) Calibrated instrumentation.

(2) Appropriate equipment.

(3) Trained personnel.

(4) Completeness of item to be tested.

(5) Condition of test equipment and item to be tested.

(6) Suitable and controlled environmental conditions.

(7) Provisions for data collection.

g. Mandatory hold points, witness points, or verification, if required.

h. Provisions that necessary monitoring is performed.

i. Provisions that adequate test equipment and instrumentation is available and used.

j. Methods of data analysis.

k. Retest requirements.

l. Methods for documenting or recording test data results.

m. Post-test conditions, if applicable.

15.2.4 Test Results

Test results shall be documented and evaluated by a responsible, technically competent authority not directly involved in the performance of the test to assure that test requirements have been satisfied.

15.2.5 Test Records

Test records will be maintained in accordance with chapter 6 and will identify, as appropriate, the following:

a. Test requirements, plans, and procedures, including revisions.

b. Item tested.

c. Date of test.

d. Tester or data recorder.

e. Type of observation.

f. Results and acceptability for intended use.

g. Any deviations experienced during conduct of the test and the action taken in connection with such deviations.

h. Person(s) evaluating test results, including the name and signature of the technical reviewer evaluating the completed test results, with the date the evaluation was complete. All records should be complete and legible to allow use as evidentiary data.

i. Identification of M&TE. The status of such equipment must be traceable as defined in paragraph 13.3.

15.3 INSPECTION, TEST, AND OPERATING STATUS

This section describes CENPW's QA requirements for indicators that identify the inspection, test, and operating status of items.

15.3.1 Scope

These requirements apply to all work done for DOE-RL at the Hanford Facility by CENPW and all contractors or organizations performing Hanford Project-related activities for CENPW.

15.3.2 Requirements

The status of inspection and test activities will be identified either on the items or in documents traceable to the items. The purposes of the identification are to ensure that required inspections and tests will be performed, to ensure that the acceptability of the item will be known, and to ensure that items which have not successfully passed the required inspections and tests will not be inadvertently installed, used, or operated.

For example, status shall be maintained through the description of the physical location and tags, markings, shop travelers, stamps, and/or inspection records. The responsibility for implementation of the test/inspection protocols will be identified in QAPjP or QAP. The responsibility for QA oversight will reside with the Special Assistant for Quality Assessment.

The methodologies described in the project-specific work plans may include, but are not limited to, those listed below:

a. Methodology for physical identification (marking) which must include protocols for identifying subdivisions of an item (or sample).

b. Methodology for identification where physical identification is either impractical or insufficient.

c. Methodology for documentation (or chain-of-custody documentation).

d. Methodology for identifying and controlling items or materials with limited lifetimes.

APPENDIX A
ELEMENTS OF THE PROJECT PLANNING DOCUMENTS

1.0 GENERAL

This appendix describes the elements to be included for each project planning document. These project planning documents include the Work Plan, Field Sampling Plan (FSP), Quality Assurance Project Plan (QAPjP), Site Safety and Health Plan, and Community Relations Plan (CRP).

2.0 WORK PLAN

The following elements shall be included in the Work Plan:

2.1 Introduction

Include a general explanation of the reasons for the environmental data operations (EDO) and the expected results, or goals of the EDO process that are described.

2.2 Site Background and Physical Setting

The current understanding of the physical setting of the site, the site history, and the existing information on the condition of the site shall be described.

Data to be obtained during literature and information searches include, as applicable:

a. Environmental setting.

b. Climate.

c. Biotic environments.

d. Geology and physiology.

e. Hydrology.

   (1) Regional hydrology.

   (2) Hydrologic units.

f. Previous investigation and data sources.

g. Land use.

h. Description of investigation site or site groupings.

i. Potential migration pathways.

2.3 Initial Evaluation

The conceptual site model developed during scoping shall describe, to the extent possible the potential migration and exposure pathways and the preliminary assessment of human health and environmental impacts.

This initial evaluation shall include, as applicable:

a. Identify investigation site.

b. Proposed sampling methods and rationale.

(1) Groundwater/surface water.

(2) Soil.

(3) Air monitoring.

(4) Sources.

(5) Materials.

c. Description of preliminary geophysical investigations.

d. Types and volumes of waste present, including preliminary sampling (sampling plan).

e. Potential pathways of contaminants migration.

f. Preliminary public health and environmental impacts.

2.4 Work Plan Rationale

Data requirements for both the risk assessment and the alternatives evaluation identified during the formulation of the DQO's are described, and the Work Plan approach is presented to illustrate how the activities will satisfy data needs. The Work Plan rationale shall include, as applicable:

a. Specify DQO's using seven step process:

(1) State problem.

(2) Identify a decision that addresses problem.

(3) Identify inputs affecting decision.

(4) Specify domain of decision.

(5) Develop logic statement.

(6) Establish constraints on uncertainty.

(7) Optimize design for obtaining data.

b. Document data requirements for:

(1) Risk assessment.

(2) Alternative evaluation.

c. Describe Work Plan approach and rationale.

d. Describe Work Plan organization.

(1) FSP.

(2) QAPjP.

(3) Site Safety and Health Plan.

(4) CRP.

(5) Data Management Plan.

3.0 FIELD SAMPLING PLAN

The following elements shall be included in the FSP:

3.1 Site Background

If the analysis of existing data is not included in the Work Plan or QAPjP, it must be included in the FSP. This analysis includes a description of the site and surrounding areas and a discussion of known and suspected contaminant sources, probable transport pathways, and other information about the site. The analysis also includes descriptions of specific data gaps and ways in which sampling is designed to fill those gaps.

3.2 Sampling Objectives

Specific objectives or a sampling effort that describe the intended uses of data shall be stated.

3.3 Sample Location and Frequency

This section of the sampling plan identifies each sample matrix to be collected and the constituents to be analyzed. A table may be used to clearly identify the number of samples to be collected along with the appropriate number of replicates and blanks. A figure should be included to show the locations of existing or proposed sample points.

3.4 Sample Designation

A sample numbering system shall be established for each project. The sample designation includes the sample or well number, the sampling round, the sample matrix (*e.g.*, surface soil, groundwater, soil boring), and the name of the site.

3.5 Sampling Equipment and Procedures

Sampling procedures shall include step-by-step instruction for each type of sampling are necessary to enable the field team to gather data that will meet the DQO's. A list shall include the equipment to be used and the material composition of the equipment (*e.g.*, stainless steel) along with decontamination procedures.

3.6 Sample Handling and Analysis

A table shall be included that identifies sample preservation methods, types of sampling jars, shipping requirements, and holding times. Special Analytical Services requests and Contract Laboratory Program statement of work (SOW) shall be referenced for some of this information.

4.0 QUALITY ASSURANCE PROJECT PLAN

Quality Assurance Project Plans shall contain 16 elements described below. If these elements are addressed in other documents (*e.g.*, the FSP and the Work Plan) it need be referenced only in the QAPjP. Table A-1 identifies where the requirements of the 16 EPA elements are found in the respective 15 chapters of the CEQAPP or this appendix.

4.1 Title Page

The QAPjP title page shall:

a. Identify the document number, revision, and date of the QAPjP.

b. Identify the Work Plan and FSP to which the QAPjP applies, including revisions and dates.

c. Contain concurrences and approvals.

(1) Approval of internal projects (minimum).

(a) Project Officer's immediate supervisor.

(b) Quality Assurance Officer.

(2) For external projects.

(a) Organization's Project Manager.

(b) Organization's responsible QA official.

(c) Funding organization's Project Officer.

(d) Funding organization's QA Officer.

4.2 Table of Contents

The table of contents of the QAPjP shall include the Introduction, each of the 19 sections, and any appendices. If the participant's document control practices allow sections or pages to be revised individually, the table of contents shall also list the effective date of each section or page, as applicable.

Table A-1. Cross Reference of the U.S. Environmental Protection Agency 16 QAPjP Elements to the 15 chapters of the CEQAPP.

EPA Element	EPA QAMS-005 Element Description	QAPjP Section	CEQAPP Requirement
1	Title page with provision for approval signatures	Title page	App A, 4.1
2	Table of contents	Contents	App A, 4.2
3	Project description	1	App A, 4.3
4	Project organization and responsibility	2	Chapter 1; App A, 4.4
5	QA objectives for measurement data in terms of precision, accuracy, completeness, representativeness, and comparability	3	Chapter 10; App A, 4.5
6	Sampling procedures	4	App A, 3.5 & 4.6
7	Sample custody	5	Chapter 14; App A, 4.7
8	Calibration procedure and frequency	6	Chapter 13; App A, 4.8
9	Analytical procedures	7	App A, 4.9
10	Data reduction, validation, and reporting	8	Chapter 10; App A, 4.10
11	Internal quality control checks and frequency	9	Chapter 12; App A, 4.11
12	Performance and system audits and frequency	10	Chapter 9; App A, 4.12
13	Preventative maintenance procedures and schedules	11	Chapter 13; App A, 4.13
14	Specific routine procedures to be used to assess data precision, accuracy, and completeness of specific measurement parameters involved	12	Chapter 10; App A, 4.14
15	Corrective action	13	Chapter 3; App A, 4.15
16	Quality assurance reports to management	14	Chapter 2; App A, 4.16

4.3 Project Description

The QAPjP shall describe the project. This description may be brief, but shall have sufficient detail for purposes of review and approval of the QAPjP. It may be written as a supplement to the Work Plan project description. The QAPjP's for environmental monitoring programs may refer to the Effluent Monitoring Plan (EMP) or Configuration Monitoring Plan (CMP) for detail.

4.4 Project Organization and Responsibility

A table or chart showing the project organization and line authority shall be provided. Key positions and the initial incumbents shall be identified, including the QA Officer/ QA Manager and those organizations and individuals responsible for the collection of measurement data and for routine assessments of measurement systems for precision and accuracy.

4.5 Quality Assurance Objectives for Measurement Data

The QA objectives for measurement data shall be summarized in a table containing the following fields, as a minimum:

a. Measurement Parameter (Method)--Identification of substance measured and analytic method.

b. Reference--Identification of the applicable sampling/analytical/ measurement procedure.

c. Environmental Conditions--Environmental conditions under which the analysis is performed.

d. Precision--Required precision in terms of standard deviation.

e. Accuracy--Required accuracy, as a percent of true value.

f. Completeness--The minimum percentage of data points expected to be valid.

Data shall also be representative, and expressed in units comparable to those of other data sets. The QAPjP need not state these requirements.

4.6 Sampling Procedures and Equipment

Provide a description of the sampling procedures and equipment to be used. Where applicable, include the following:

a. Description of techniques or guidelines used to select sampling sites.

b. Inclusion of specific sampling procedures to be used (by reference in the case of standard procedures and by actual description of the entire procedure in the case of nonstandard procedures).

c. Charts, flow diagrams, or tables delineating sampling program operations.

d. A description of containers, procedures, reagents, *etc.* used for sample collection, preservation, transport, and storage.

e. Special conditions for the preparation of sampling equipment and containers to avoid sample contamination (*e.g.*, containers for organics should be solvent-rinsed and containers for trace metals should be acid-rinsed).

f. Sample preservation methods and holding times.

g. Time consideration for shipping samples promptly to the laboratory.

h. Sample custody or chain-of-custody procedures (to be described later in this document).

i. Forms, notebooks, and procedures to be used to record sample history, sampling conditions, and analyses to be performed.

4.7 Sample Custody or Chain of Custody

The procedures for sample custody (chain of custody for environmental monitoring) shall be identified.

4.8 Calibration Procedures and Frequency

The calibration procedures to be applied to the measuring and test equipment (M&TE) used for each measurement parameter shall be identified. The calibration frequencies and standards shall be identified unless specified in the calibration procedures. The administrative procedure for assuring that M&TE are recalibrated on schedule and identified as to their calibration status shall be identified.

4.9 Analytical Procedures and Equipment

The analytical procedures and equipment to be used for each measurement parameter shall be identified. Approved EPA procedures shall be used when available.

4.10 Data Reduction, Validation, and Reporting

The procedures for data reduction, validation, and reporting (including those listed below) shall be identified:

a. The data reduction scheme planned on collected data, including all equations used to calculate the concentration or value of the measured parameter and reporting units.

b. The principal criteria that will be used to validate data integrity during collection and reporting of data.

c. The methods used to identify and treat outliers.

d. The data flow or reporting scheme from collection of raw data through storage of validated concentrations. A flowchart will usually be needed.

e. Key individuals who will handle the data in this reporting scheme (if this has already been described under project organization and responsibilities, it need not be repeated here).

4.11 Internal Quality Control Checks

Describe and/or reference all specific internal quality control methods to be followed ("internal" refers to both laboratory and field activities). Examples of items to be considered include:

a. Replicates.

b. Spiked samples.

c. Split samples.

d. Control charts.

e. Blanks.

f. Internal standards.

g. Zero and span gases.

h. Quality control samples.

i. Surrogate samples.

j. Calibration standards and devices.

k. Reagent checks.

4.12 Performance and Systems Audits

The performance and systems audits that will be required to monitor the capability and performance of the total measurement system shall be identified. Systems audits shall be performed before or shortly after the measurement system becomes operational and on a regularly scheduled basis during the lifetime of the project or the measurement system.

4.13 Preventive Maintenance

Schedules for preventive maintenance tasks to minimize downtime of measurement systems shall be provided or referenced. Critical spare parts shall be listed. Such parts shall be available within an acceptably short time.

4.14 Specific Routine Procedures Used to Assess Data Precision, Accuracy, and Completeness

The procedures to be used for the routine assessment of precision, accuracy, and completeness shall be identified. These shall meet the requirements of chapter 10.

4.15 Corrective Action

Corrective action for measurement systems shall be described, and shall include:

a. The predetermined limits for data acceptability beyond which corrective action is required

b. Corrective action procedures

c. The positions responsible for initiating and for approving corrective actions.

Provisions shall be made for initiating corrective action as the result of such activities as performance or systems audits, laboratory, interfield comparison studies, or audits conducted by outside agencies.

4.16 Quality Assurance Reports to Management

Provisions shall be made for periodic reporting to management in accordance with CEQAPP chapter 3.

4.17 Cross-Reference Among Documents

When specific QA/QC protocols or other requirements for the QAPjP are addressed in the Work Plan, the QAPjP may then reference the page number and location in the Work Plan where the elements are described. However, the Work Plan shall include a QA Project Plan locator page immediately following the table of contents, listing each of the elements required for the QAPjP and stating the section and page in the QAPjP where it is specified.

If an element of information required for the QAPjP is not applicable to the Work Plan, "N/A" shall be inserted next to the appropriate item on the locator page, and the reason for its nonapplicability shall be briefly stated in the appropriate subsection of the QAPjP itself. The specific routine procedures used to assess data precision, accuracy, and completeness of specific measurement parameters involved, will always be included.

When procedures identified in the QAPjP are not yet approved and issued, the schedules for their development shall be indicated.

5.0 SITE SAFETY AND HEALTH PLAN

5.1 Elements of a Site Safety and Health Plan

The IA requires that the Health and Safety Plan be prepared in accordance with DOE-RL safety requirements. The following elements shall be included in Health and Safety Plans:

a. The name of a site health and safety officer, names of key personnel, and alternates responsible for site safety and health

b. A health and safety risk analysis for existing site conditions, and for each site task and operation

c. Employee training assignments

d. A description of personal protective equipment used by employees for each site task and the operations being conducted

e. Medical surveillance requirements

f. A description of the frequency and types of air monitoring, personnel monitoring, environmental sampling techniques, and instrumentation to be used

g. Site control measures

h. Decontamination procedures

i. Standing operating procedures for the site

j. A contingency plan that meets the requirement of 29 CFR 1910 120(l)(1) and (l)(2)

k. Entry procedures for confined spaces.

6.0 COMMUNITY RELATIONS PLAN

This plan will reference the DOE-RL CRP.

APPENDIX B
QUALIFICATIONS OF QUALITY ASSURANCE PROGRAM AUDIT PERSONNEL

1.0 GENERAL

This appendix will be used in conjunction with chapter 9 of this U.S. Army Corps of Engineers Quality Assurance Program Plan and establishes the requirements for the qualification of auditors and lead auditors who conduct audits related to the Environmental Restoration Remediation Action program. A lead auditor organizes and directs audits, reports audit findings, and evaluates corrective action. This appendix also provides amplified requirements for the qualifications of individuals, henceforth referred to as auditors, who participate in an audit, such as technical specialists, management representatives, and auditors-in-training.

2.0 QUALIFICATION OF AUDITORS

The responsible auditing organization will establish audit personnel qualifications and requirements for the use of technical specialists to accomplish the auditing of Quality Assurance (QA) programs. Personnel selected for QA auditing assignments will have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. Auditors will have, or be given, appropriate training or orientation to develop their competence for performing required audits. This competence will be developed by one or more of the following methods:

a. Orientation to provide a working knowledge and understanding of this document and the auditing organization's procedures for implementing audits and reporting results.

b. Training programs to provide general and specialized training in audit performance. General training will include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing. Specialized training will include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings.

c. On-the-job training, guidance, and counseling under the direct supervision of a lead auditor. Such training will include planning, performing, reporting, and followup action involved in conducting audits.

3.0 QUALIFICATION OF LEAD AUDITORS

An individual will meet the following requirements before being designated a lead auditor:

a. The lead auditor candidate must be able to communicate effectively, both in writing and orally. These skills will be attested to, in writing, by the prospective lead auditor's employer.

b. The prospective lead auditor will have sufficient training to assure his or her competence in auditing skills. Training in the following areas will be given, based upon management evaluation of the candidate's needs:

(1) A knowledge and understanding of the applicable codes, standards, regulations, and regulatory guides.

(2) The general structure of QA programs (as a whole) and their elements.

(3) Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings.

(4) Audit planning in the activities affecting quality.

(5) On-the-job training, including applicable elements of the audit program.

c. The prospective lead auditor will pass an examination that will evaluate his or her comprehension of, and ability to apply, the body of knowledge identified in appendix B, paragraph 2.b. The test may be oral, written, practical, or any combination thereof. The development and administration of the examination will be in accordance with appendix B, paragraph 2.b.

4.0 MAINTENANCE OF QUALIFICATION

4.1 Maintenance of Proficiency

Lead auditors will maintain their proficiency through one or more of the following activities:

a. Regular and active participation in the audit process.

b. Review and study of codes, standards, procedures, instructions, and other documents related to QA program and program auditing.

c. Participation in training programs. Based on annual assessments, management may extend the qualification, require retraining, or require requalification. These evaluations will be documented.

4.2 Requalification

Lead auditors who fail to maintain their proficiency for 2 years or more will require requalification. Requalification will include retraining in accordance with the requirements of appendix B, paragraph 2.b., reexamination in accordance with appendix B, paragraph 3.c., and participation as an auditor in at least one QA audit.

5.0 ADMINISTRATION

5.1 Organizational Responsibility

Training of auditors will be the responsibility of the Chief, U.S. Army Corps of Engineers, Walla Walla District, Internal Review Office (CENPW-IR). The responsible auditing organization will select and assign personnel who are independent of any direct responsibility for performance of the activities that they will audit. The lead auditor will, prior to commencing the audit, concur that assigned personnel collectively have experience and/or training commensurate with the scope, complexity, or special nature of the activities to be audited.

5.2 Qualification Examination

The development and administration of the examination for a lead auditor, required by appendix B, paragraph 3.c., is the responsibility of CENPW-IR. CENPW-IR may delegate this activity to an independent certifying agency but will retain responsibility for conformance of the examination and its administration to this document. Integrity of the examination will be maintained through appropriate confidentiality of files and, where applicable, proctoring of examinations. Copies of the objective evidence regarding the type(s) and content of the examination(s) will be retained by CENPW-IR in accordance with the requirements of appendix B, paragraph 6.

6.0 RECORDS

Records of personnel qualifications for auditors and lead auditors performing audits will be established and maintained by CENPW-IR.

6.1 Certification of Qualification

Each lead auditor will be certified by CENPW-IR as being qualified to lead audits. This certification will, as a minimum, document the following information:

a. Employer's name.

b. Lead auditor's name.

c. Date of certification or recertification.

d. Basis of qualification (*i.e.*, education, experience, communications skills, training, examination, *etc.*).

e. Signature of employer's designated representative who is responsible for such certification.

6.2 Updating of Lead Auditors' Records

Records for each lead auditor will be maintained and updated annually.

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APPENDIX C
LIST OF TYPICAL QUALITY ASSURANCE RECORDS

1.0 GENERAL

This appendix provides lists of typical Quality Assessment (QA) records. The nomenclature of these may vary for each participating organization.

2.0 RECORDS (GENERAL)

- Surveys of shafts and bore holes referenced to readily identifiable surface features.
- Geologic maps and supporting data.
- Locations and amounts of seepage.
- Instrument locations, readings, analysis, and reports for site testing.
- Technical specifications.
- Sample extraction location maps.
- Site characterization report.
- Preliminary Assessments/Site Inspections (PA's/SI's) and Remedial Investigations/ Feasibility Studies.
- Environmental assessment.
- Technical review reports and comment resolution.
- Peer review reports and comment resolution.
- Test plans, procedures, and results thereof.
- Data reduction, evaluations, analyses, and reports for Geomorphology.
- Stratigraphy.
- Tectonics.
- Seismicity.
- Geoengineering.
- Hydrology.

- Geochemistry.
- Climatology.
- Meteorology.
- Environmental impact statement.
- Environmental report.

3.0 SITING AND SITE CHARACTERIZATION QA RECORDS

- Drill hole testing procedures.
- Drill hole drilling procedures.
- Drill hole location surveys or maps.
- Drill hole logs and core samples.
- Drill hole test results (including evaluations and interpretations).
- Geophysical logs and data.
- Geophysical test results.
- Caliper logs and data.
- Radioactivity logs and data (gamma, spectral-gamma, neutron-gamma, alpha).
- Lithologic logs and data.
- Seismic and resistivity survey procedures.
- Seismic and resistivity location surveys and location maps.
- Seismic and resistivity logs and data.
- Seismic and resistivity test results (including evaluations).
- Laboratory analytical procedures.
- Laboratory calibration procedures.
- Laboratory testing procedures.

- Laboratory record books.
- Laboratory testing data and data processing.
- Geologic maps and supporting data.
- Geologic library samples.
- Geologic and soil sampling procedures.
- Geologic test results.
- Trench logs and data (including location surveys, maps, and results).
- Aerial mapping records (photographs and interpreted overlays).
- Microseismic records (paper or magnetic tape).
- Remote imagery reports and results.
- Seismicity maps and supporting data.
- Fault maps and supporting data.
- Epicenter maps and supporting data.
- Model definition and development reports.
- Model acceptance criteria reports.
- Model verification reports.
- Model exercise reports and results.
- Hydrogeologic test procedures.
- Atmospheric test procedures.
- Atmospheric test results and data.
- Site characterization plan and all reference documents.
- Test deviation records.
- Unusual occurrence reports.

- Environmental test results.
- Instrumentation installation and calibration records.
- Validated environmental data.
- QA program manual/plans.
- QA administrative procedures.
- Technical procedures (other than those identified as lifetime).
- Calibration records (until recalibrated).
- Audit and surveillance records.
- Readiness review records.
- Management assessment reports.
- Task plans.
- Waste shipment records.
- Disposal facility or remediation, radiation, and contamination survey results.
- Radiation and/or contamination exposure records for individuals entering controlled areas.

4.0 TYPICAL POST-CLOSURE QA RECORDS

- Maps that identify site boundaries.
- Drawings of site marker locations.
- Underground facility configuration drawings.
- Other records having long-term archival and historical interest.
- Groundwater and hydrologic regime maps and data (including analysis results).
- Hydrogeologic test results and data.
- Isopach maps and supporting data.
- Logs, maps, and geophysical data in support of subsurface correlation.

5.0 DESIGN RECORDS

- Applicable codes and standards used in design.
- Computer programs or corresponding mathematical model.
- Design drawings.
- Design calculations and records of checks.
- Approved design change requests.
- Design deviations.
- Design reports.
- Design verification data.
- Design specifications and amendments.
- Technical review reports and comment resolution.
- Peer review reports and comment resolution.
- Safety analysis report.
- Systems descriptions.
- Systems process and instrumentation diagrams.
- Technical analysis, evaluations, and reports.

6.0 PROCUREMENT RECORDS

- Procurement specifications.
- Purchase order including amendments.

7.0 MANUFACTURING RECORDS

- As-built drawings and records.
- Certificates of compliance.
- Eddy current examination final results.

- Electrical control verification tests results.
- Ferrite test results.
- Heat treatment records.
- Liquid penetrant examination final results.
- Location of weld filler material.
- Magnetic particle examination final results.
- Major defect repair records.
- Material properties records.
- Nonconformance reports.
- Performance test procedure and results records.
- Pipe and fitting location reports.
- Pressure tests (hydrostatic or pneumatic).
- Radiograph review records.
- Ultrasonic examination final results.
- Welding procedures.

8.0 INSTALLATION AND CONSTRUCTION RECORDS

8.1 Receiving and Storage - Nonconformance Reports

8.1.1 Civil

- Concrete cylinder test reports and charts.
- Concrete design mix reports.
- Concrete placement records.
- Inspection reports for channel pressure tests.
- Material property reports on reinforcing steel.

- Material property reports on reinforcing steel-splice-sleeve material.
- Reports of high-strength bolt torque testing.
- Soil compaction test reports.
- Location and description of structural support systems.
- Details, methods of emplacement, and location of seals used.

8.1.2 Welding

- Ferrite test results.
- Heat treatment records.
- Liquid penetrant test final results.
- Material property records.
- Magnetic particle test final results.
- Major weld repair procedures and results.
- Radiograph review records.
- Weld location diagrams.
- Weld procedures.

8.1.3 Mechanical

- Cleaning procedures and results.
- Installed lifting and handling equipment procedures, inspection, and test data.
- Lubrication procedures.
- Material properties records.
- Pipe and fitting location reports.
- Pipe hanger and restraint data.
- Pressure test results (hydrostatic or pneumatic).

8.1.4 Electrical, Instrumentation, and Control

- Cable pulling tension data.
- Cable separation data.
- Cable splicing procedures.
- Cable terminating procedures.
- Certified cable test reports.
- Relay test procedures.

8.1.5 General

- As-built drawings and records.
- Final inspection reports and releases.
- Nonconformance reports.
- Specifications and drawings.

8.1.6 Pre-Operational and Startup Test Records

- Final system adjustment data.
- Pressure test results (hydrostatic or pneumatic).
- Instrument alternating current systems and inverters test procedures and reports.
- Offsite power source energizing procedures and test reports.
- Onsite emergency power source energizing procedure and test reports.
- Pre-operational test procedures and results.

APPENDIX D
REQUIREMENTS FOR THE QUALIFICATION OF NONDESTRUCTIVE EXAMINATION PERSONNEL

1.0 GENERAL

This appendix will be used as a supplement to chapter 2. It establishes the requirements for the qualification of personnel who perform radiographic, magnetic particle, ultrasonic, liquid penetrant, eddy current, neutron radiographic, and leak testing, which will be referred to as nondestructive examination (NDE), to verify conformance to specified requirements related to the Environmental Restoration Remedial Action Program.

2.0 APPLICABLE DOCUMENTS

The American Society of Nondestructive Testing-recommended Practice No. SNT-TC-1A, June 1980 edition, and its applicable supplements will apply as requirements for NDE personnel covered by this appendix.

3.0 PROGRAM

U.S. Army Corps of Engineers, Walla Walla District, will establish and administer written procedures for the control and administration of NDE personnel training, examination, and certification.

4.0 CERTIFICATE OF QUALIFICATION

The qualification of personnel will be certified in writing and will include the following information:

a. Employer's name.

b. Identification of person being certified.

c. Activities certified to perform.

d. Basis used for certification that includes such factors as:

   (1) Education, experience, and training (when necessary).

   (2) Test results (where applicable).

   (3) Results of capability demonstration.

e. Results of periodic evaluation.

f. Results of physical examination (when required).

g. Signature of employer's designated representative who is responsible for such certification.

h. Dates of certification and certification expiration.

5.0 RECORDS

Personnel qualification records described in paragraph 2.1.4 and other related documents derived from SNT-TC-1A will be maintained in accordance with chapter 6.

APPENDIX E
GENERATION OF ENVIRONMENTAL DATA

1.0 GENERAL

This chapter defines minimal criteria that shall be followed to assure the quality of the field and analytical aspects of environmental data generation activities. Environmental data includes, but is not limited to, the results from the analyses of samples of air, soil, water, biota, waste, or any combinations thereof. U.S. Army Corps of Engineers, Walla Walla District (CENPW) policy is to follow U.S. Environmental Protection Agency (EPA) procedures whenever they are applicable, relevant, or appropriate. Request for variances from the EPA procedures will be directed to the EPA through Department of Energy, Richland Operations Office (DOE-RL).

Environmental data generation efforts are comprised of four parts:

- Establishment of Data Quality Objectives (DQO's).
- Design of field measurement and sampling strategies and specification of laboratory analyses and data acceptance criteria.
- Implementation of the sampling and analysis strategies.
- Data quality assessment.

These separate parts are discussed in other chapters of this U.S. Army Corps of Engineers Quality Assurance Program Plan (CEQAPP).

DQO's shall be adopted prior to application of this protocol. Data generated under this protocol are subject to a final assessment to determine if the DQO's were met.

2.0 SCOPE

These minimum requirements apply to all work done for DOE-RL at the Hanford Facility by CENPW and all contractors or organizations involved in the generation of Hanford Project-related environmental data for CENPW. More detailed and specific guidance setting forth protocols and criteria for hazardous waste remedial activities has been developed by U.S. Army Corps of Engineers (USACE) in Engineering Regulation 1110-1-263 and shall be followed by all USACE Field Operating Activities and USACE contractors.

3.0 DEFINITION OF TERMS

The specific terminology used in this chapter has been included in the glossary.

4.0 SIGNIFICANCE AND USE

Environmental data are often required for making regulatory and programmatic decisions. These data must be of known quality and commensurate with their intended use.

Data generation efforts involve establishment of DQO's, design of the project plan to meet the DQO's, implementation of the project plan, and assessment of the data to determine if the DQO's were met.

There are certain minimal criteria that must be met by field and laboratory organizations generating environmental data. Additional activities may be required based on the DQO's of the data collection effort.

This protocol defines the minimal criteria for field and laboratory organizations generating environmental data and identifies some other activities that may be required based on the DQO's. This protocol also emphasizes the importance of communication among those involved in establishing DQO's, planning and implementing the sampling and analysis aspects of environmental data generation activities, and assessing data quality.

5.0 PROJECT SPECIFICATION

Project activities should be defined prior to the start of any field or laboratory activities. At a minimum, project specifications shall address the following topics:

5.1 DQO's

DQO's for the data generation activity should be defined prior to the initiation of the field and laboratory work. It is desirable that the field and laboratory organizations be aware of the DQO's to enable personnel conducting the work to make informed decisions during the course of the project.

5.2 Project Management

The project should be designed to meet the DQO's. The Program Management Plan shall define the following:

5.2.1 Project Objectives. Project objectives provide background information, state the reasons for the data collection effort, identify any regulatory programs governing the data collection, define specific objectives for each sampling location, and describe the intended uses of the data.

5.2.2 Project Management. A person(s) shall be designated to have the responsibility and authority for:

- Developing project documents that implement the DQO's.

- Selecting field and laboratory organizations to conduct the work.
- Coordinating communication among field and laboratory organizations and government agencies as required.
- Reviewing and assessing the final data.

This person will be the Technical Manager appointed by the Chief, Environmental Engineering Branch, in association with the Project Manager in the Hanford Area Office.

5.2.3 Sampling Requirements. Sampling locations, equipment, procedures, and sample preservation and handling requirements shall be specified.

5.2.4 Analytical Requirements. Analytical procedures, analyte list, required detection limits, and required precision and bias shall be specified. Regulatory requirements and DQO's shall be considered when developing the specifications.

5.2.5 Quality Assurance/Quality Control (QA/QC) Requirements. The QA/QC requirements shall address both field and laboratory activities. The means for controlling false positive and false negatives shall be specified. Standard practices for field and laboratory operations, as described in appendix E, paragraphs 6 and 7 of this document, shall be required.

5.2.6 Field QC. The types and frequency of field QC samples to be collected, including field blanks, trip blanks, equipment rinsates, field duplicates, background samples, reference materials, material blanks, and split samples shall be specified in the Quality Assurance Project Plan (QAPjP). Control parameters for field activities shall also be described (see appendix E, paragraph 6.6.4).

5.2.7 Laboratory QC. The types and frequency of use of laboratory QC samples such as laboratory control samples, laboratory blanks, matrix spikes, matrix duplicates, and matrix spike duplicates shall be specified. Any specific performance criteria shall be specified. Data validation criteria shall be defined. The development and use of control charts shall be described.

5.2.8 Project Documentation. All documents required in planning, implementing, and evaluating the data collection effort shall be specified in the QAPjP. These may include, but are not limited to, a statement of work, technical and cost proposals, a work plan, a Sampling and Analysis Plan (SAP), a Health and Safety Plan, a Community Relations Plan, documents required by regulatory agencies, requirements for raw field and analytical records, technical reports assessing the environmental data, and a records retention policy (as outlined in chapter 6). Planning documents shall specify the required level of document control and identify personnel having access. Document formats that may be required to ensure that all data needs are satisfied shall be specified. In addition, a project schedule that identifies critical milestones and completion dates should be available.

6.0 STANDARD PROTOCOL FOR ENVIRONMENTAL FIELD OPERATIONS

6.1 Purpose

The field organization must conduct its operations in such a way as to provide reliable information that meets the DQO's. To achieve this, certain minimal policies and procedures must be implemented.

6.2 Organization

The field organization shall be structured so that each member of the organization has a clear understanding of his or her duties and responsibilities and the relationship of those responsibilities to the total effort. The organizational structure, functional responsibilities, levels of authority, job descriptions, and lines of communication for activities shall be established and documented in a separate project-specific QAPjP.

6.2.1 Management. The management of the field organization is responsible for establishing organizational, operational, health and safety, training, and QA policies. The management shall ensure that:

- The appropriate methodologies are followed as documented in the Standing Operating Procedures (SOP's).
- Personnel clearly understand their duties and responsibilities.
- Each staff member has access to appropriate project documents.
- Any deviations from the project plan are communicated to project management and documented.
- Communication occurs between the field, laboratory, and project management, as specified in the project plan.

Management shall foster an attitude within the organization that emphasizes the importance of quality and supports the implementation of this CEQAPP.

6.2.2 QA Function. The Special Assistant for Quality Assessment will have a person or persons responsible for monitoring field operations to ensure that the site facilities, equipment, personnel, procedures, practices, and documentation are in conformance with this CEQAPP and any applicable QAPjP or Quality Assurance Plan (QAP).

6.2.3 Personnel. Personnel qualifications and training requirements for all positions are outlined in chapter 3. Each member of the organization shall have the education, training, technical knowledge, and experience, or a combination thereof, to enable that individual to perform assigned functions. Personnel qualifications shall be documented in terms of

education, experience, and training. Training shall be provided for each staff member as necessary to properly perform their functions.

6.3 Field Logistics

6.3.1 General. Sampling site facilities shall be examined prior to the start of work to ensure that all required items are available. The actual area of sampling shall be examined to ensure that vehicles, equipment, and personnel have access to the site. Security, health and safety, and protection of the environment shall be controlled at the site support areas and the sampling site.

6.3.2 Field Measurements. The project planning documents shall address the type of field measurements to be performed and establish an appropriate area to perform the work. The planning documents shall address ventilation, protection from extreme weather and temperatures, access to stable power, and provision for water and gases of required purity. Plans shall be made to identify and supply applicable safety equipment. As specified in the Project Health and Safety Plan, safety equipment may include, but is not limited to, fire extinguishers, eyewash, respirators, spill control materials, and other personal protective equipment.

6.3.3 Sample Handling, Shipping, and Storage Area. The determination as to whether sample shipping is necessary shall be made during planning for the project. This need is established by evaluating the analyses required, holding times, and location of the site and the laboratory. Shipping or transporting of samples to a laboratory shall be done in a timely manner, ensuring that the laboratory is allowed sufficient time to perform analysis within any required holding times.

Samples shall be packaged, labeled, and documented in an area that minimizes sample contamination and provides for safe storage. The level of custody and sample storage requirements shall be outlined in the planning documents.

6.3.4 Chemical Storage. Safe storage areas for solvents, reagents, standards, and reference materials shall be adequate to preserve their identity, concentration, purity, and stability prior to use.

6.3.5 Decontamination. Decontamination of sampling equipment may be done at the location where sampling occurs, prior to going to the sampling site, or in designated areas near the sampling site. Project documentation shall specify where this work will be performed and how it will be accomplished. If decontamination is to be done at the site, water of appropriate purity shall be available. The method of accomplishing decontamination, the materials, and water purity shall be specified in planning documents or SOP's. Solvents and/or phosphate detergents should not be used in the decontamination of sampling and drilling equipment at the site as their use creates waste disposal and environmental problems. If at all possible, steam cleaning, pressure water cleaning, stiff brushes, *etc.*, are preferred to the use of solvents and/or detergents in the cleaning of sampling and drilling equipment. If solvents and/or detergents must be used in the

decontamination of sampling and drilling equipment, the procedures and equipment used to prevent contamination of the environment and their method of containment and disposal shall be addressed in planning documents, SOP's, the QAPjP, *etc.*

6.3.6 Waste Storage Area. During the sampling process and during onsite or in situ analysis, waste materials are generated. Planning documents and SOP's shall outline the method for storage and disposal of these waste materials. Adequate facilities shall be provided for the collection and storage of all wastes. These facilities shall be operated to minimize environmental contamination. Waste storage and disposal facilities shall comply with DOE-RL requirements.

6.3.7 Data Storage Area. The planning documents shall specify the location of long-term and short-term storage for field records as outlined in chapter 6.

6.4 Equipment and Instrumentation

6.4.1 Equipment and Instrumentation. The equipment, instrumentation, and supplies required at the sampling site shall be appropriate to accomplish the activities planned. The equipment and instrumentation shall meet the requirements of pertinent specifications, methods, and SOP's. Before the field staff arrive at the site, a list of required items shall be prepared and checked to ensure availability at the site.

6.4.2 Maintenance and Calibration of Equipment and Instrumentation. An SOP or operation and maintenance manual shall set forth methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, and calibration of equipment and instrumentation used in performing geophysical measurements, analytical measurements, or in situ measurements. For common malfunctions, procedures or manuals may outline typical problems, methods of troubleshooting, and possible corrective actions to be taken. Procedures shall designate a person(s) responsible for maintenance and calibration. Records shall be maintained of all inspections, maintenance, repairs, testing, and calibration. These records shall be accessible to regulators during inspections and audits.

6.5 SOP's

CENPW will have SOP's for all procedures routinely performed that affect data quality. The SOP's will be reviewed and approved by DOE-RL. The SOP's shall be available for the following areas and shall contain, at a minimum, the information described. The SOP's shall be readily available in the field to sampling personnel and shall contain a signature page with the dated signature of each individual whose effort is covered by that particular SOP, affixed thereon, thus signifying that the signatory has read and understands the SOP. If a procedure is performed exactly as described in a published method, that method shall be available as required of other SOP's.

6.5.1 Sample Management. These SOP's describe the numbering and labeling system, chain-of-custody procedures, and tracking of samples from collection to shipment or relinquishment to the laboratory. Sample management also includes the specification of

holding times, volume of samples required by the laboratory, preservatives, and shipping requirements.

6.5.2 Reagent/Standard Preparation. These SOP's describe the procedures used to prepare reagents and standards. Information concerning specific grades of materials used in reagent and standard preparation, appropriate glassware and containers for preparation and storage, labeling and record keeping for stocks and dilutions, shelf life and solution validations, and safety precautions to be taken should be included.

6.5.3 Decontamination. These SOP's describe the procedures used to clean field equipment before and during the sample collection process. The SOP's should include cleaning materials used, the order of washing and rinsing with the cleaning materials, requirements for protecting or covering cleaned equipment, procedures for disposing of cleaning materials, and safety considerations.

6.5.4 Sample Collection Procedures. SOP's for sample collection procedures shall describe how the procedures are actually performed in the field and not be a simple reference to standard methods, unless a procedure is performed exactly as described in the published method. Industry-recognized methods from source documents published by the EPA, American Society for Testing Materials, U.S. Department of the Interior, National Water Well Association, American Petroleum Institute, or other recognized organizations should be used if possible. The SOP for sample collection procedures should include the following:

- Applicability of the procedure.
- Equipment required.
- Detailed description of procedures to be followed in collecting the samples, including sample preservation and shipping.
- Common problems encountered.
- Precautions to be taken.
- Health and safety considerations.

6.5.5 Equipment Calibration and Maintenance. These SOP's describe procedures used to ensure that field equipment and instrumentation are in working order. The SOP's describe calibration procedures and schedules, maintenance procedures and schedules, maintenance logs, service contracts or service arrangements for equipment, and spare parts available in-house. Calibration and maintenance of field equipment and instrumentation shall be in accordance with manufacturers' specifications and shall be documented.

6.5.6 Field Measurements. These SOP's describe all methods used in the field to determine a chemical or physical parameter. The SOP's shall address criteria from appendix E, paragraph 7 as appropriate.

6.5.7 Corrective Action. These SOP's describe procedures used to identify and correct deficiencies in the sample collection process. These should include specific steps to correct deficiencies, such as performing additional decontamination of equipment, resampling, or additional training of field personnel in methods/procedures. The SOP's shall specify that each corrective action must be documented with a description of the deficiency, the corrective action taken, and the person(s) responsible for implementing the corrective action.

6.5.8 Data Reduction and Validation. These SOP's describe procedures used to compute results from field measurements and to review and validate these data. They should include all formulas used to calculate results and procedures used to verify independently that field measurement results are correct.

6.5.9 Reporting. These SOP's describe the process for reporting the results of field activities.

6.5.10 Records Management. These SOP's describe the procedures for generating, controlling, and archiving field records. The SOP's should describe the responsibilities for record generation and control and the policies for record retention, including type, time, security, and retrieval and disposal authorities. Records should include project-specific and field operations records as described in chapter 6 and appendix C.

6.5.11 Waste Disposal. These SOP's describe the policies and procedures for disposal of waste materials resulting from field operations. Disposal of all wastes must conform to procedures referred to in the Interagency Agreement (IA) with DOE-RL.

6.5.12 Health and Safety. These SOP's describe policies and procedures designed to provide a safe and healthy working environment for field personnel and to conform to DOE-RL health and safety requirements.

6.6 Field QA/QC Requirements

6.6.1 Quality Assurance Project Plan (QAPP). CENPW has written this CEQAPP, which describes the organization's QA policy. The plan shall specify the responsibilities of the field management, field staff, and the QA function in the areas of QA and QC. The plan will also describe the field and other QC procedures followed by the organization.

6.6.2 QAPjP. All projects, particularly those that are large and/or complex, will likely require a QAPjP. The QAPjP details the QA/QC goals and protocols for a specific data collection activity to ensure that the data generated by sampling and analysis activities are of a quality commensurate with their intended use. The QAPjP is described in paragraph 1.4, and appendix A, paragraph 4.

6.6.3 Control Samples. Control samples are QC samples that are introduced into a process to monitor the performance of the system. Control samples, which may include blanks, duplicates, spikes, analytical standards, and reference materials, can be used in different phases of the overall process beginning with sampling and continuing through transportation,

storage, and analysis. The types of control samples used and the frequency of usage are dependent on the DQO's of the data collection effort and must be specified for each project. For most analytical procedures, blanks and standard matrix spikes shall be included with the daily analysis of samples. For methods where this requirement is not appropriate (*e.g.*, asbestos, oil, grease, *etc.*), an explanation will be provided in the QAPjP and/or the applicable method as to the control measure being used to assess the quality of the data.

6.6.4 Procedures for Establishing Acceptance Criteria. Procedures shall be in place for establishing acceptance criteria for field activities as required in the project planning documents. Acceptance criteria may be qualitative or quantitative. Field events or data that fall outside of established acceptance criteria may indicate a problem with the sampling process that must be investigated. In general, the maximum limit for quantitative acceptance criteria should be +/- 25 percent of the mean, unless justification can be provided for allowing wider acceptance criteria. Ordinarily, the standard acceptance criteria is based on the repeated analysis of a standard or a known sample from which the mean is calculated.

6.6.5 Deviations. Any activity not performed in accordance with SOP's or project planning documents is considered a deviation from plan. Deviations from plan may or may not affect data quality. All deviations from the plan shall be documented as to the extent of and reason for the deviation.

6.6.6 Corrective Action. Errors, deficiencies, deviations, or field events or data that fall outside established acceptance criteria require investigation. In some instances, corrective action may be needed to resolve the problem and restore proper functioning to the system. The investigation of the problem and any subsequent corrective action taken shall be documented as outlined in appendix E, paragraph 3.2.

6.6.7 Data Handling Procedures. These procedures are covered in chapter 10.

6.7 QA Review

6.7.1 General. The QA Reviews are outlined in appendix E, paragraph 3.6. Assessments are made to ensure that QA/QC procedures are in use and to ensure that field staff conform to these procedures. The program participant responsible for environmental data operations will define criteria for selecting the types of review to be performed, including the use of readiness reviews and/or technical or peer reviews. The selection process for the review groups and the process by which reviews are performed will be documented and implemented in accordance with written procedures. Planning documents shall specify the requirements for internal, external, and onsite assessment. These documents shall specify the frequency and documentation of these assessments.

6.7.2 Evaluation of Field Records. The review of field records shall be conducted by one or more persons knowledgeable in field activities, evaluating at a minimum the following subjects. At the conclusion of the review, the reviewer shall sign and date the documentation signifying that the review did occur.

a. Completeness of Field Reports--This review ensures that all requirements for field activities in the planning documents have been fulfilled, that complete records exist for each field activity, and that the procedures specified in the planning documents have been implemented. Emphasis on field documentation will help assure sample integrity and sufficient technical information to recreate each field event. The results of this completeness check shall be documented, and environmental data affected by incomplete records shall be identified.

b. Identification of Valid Samples--This review involves interpretation and evaluation of the field records to detect problems affecting the representation of environmental samples. Examples of items that would indicate invalid samples include improper well development, improperly screened wells, instability of pH or conductivity, and collection of volatiles near combustion engines. The field records shall be evaluated against planning documents and SOP's. The reviewer shall document the sample validity and identify the environmental data associated with poor or incorrect field work.

c. Correlation of Field Test Data--The results of field measurements obtained by more than one method shall be compared. For example, surface geophysics may be surveyed using both ground-penetrating radar and a resistivity survey.

d. Identification of Anomalous Field Test Data--Anomalous field test data should be identified. For example, a water temperature for one well that is five degrees higher than any other well temperature in the same aquifer should be noted. The impact of anomalous field measurement results on the associated environmental data shall be evaluated.

e. Validation of Field Analysis--All data from field analysis that are generated in situ or from a mobile laboratory shall be validated per appendix E, paragraph 7.7.2. The results of the validation shall be reported. The report shall discuss whether the QC checks meet the acceptance criteria and whether corrective actions were taken for any analysis performed when acceptance criteria were exceeded.

f. Precision and Accuracy of Data--The precision and accuracy will be routinely assessed for all environmental data operations. Specific procedures will be prepared to assess precision and accuracy on a routine scheduled basis related to a data collection or test activity.

g. Completeness of Data--For each major measurement or test parameter (including all pollutant measurement systems) routine procedures used to assess the precision, accuracy, and completeness of the measurement or test data will be prepared and controlled. These procedures will include the equations to calculate precision, accuracy, and completeness in addition to the methods used to gather data or conduct tests for precision and accuracy. Examples of these procedures include, but are not limited to:

- Central tendency and dispersion, arithmetic mean, range, standard deviation, relative standard deviation, pooled standard deviation, and geometric mean.

- Assessing data quality, accuracy/bias, precision within laboratories and between laboratories, representation, comparability, and completeness.
- Significance tests, u-tests, f-tests, chi-square tests.
- Confidence limits.
- Testing for outliers.

6.7.3 QA Reports to Management. The QA program shall provide for the periodic reporting of pertinent QA/QC information to management to allow assessment of the overall effectiveness of the QA program.

6.8 Field Records

Records provide the direct evidence and support for the necessary technical interpretations, judgments, and discussions concerning project activities. These records, particularly those that are anticipated to be used as evidentiary data, must directly support current or ongoing technical studies and activities and must provide the historical evidence needed for later reviews and analyses. Records shall be legible, identifiable, retrievable, and protected against damage, deterioration, or loss.

Field records generally consist of bound field notebooks with pre-numbered pages, sample collection forms, personnel qualification and training forms, sample location maps, equipment maintenance and calibration forms, chain-of-custody forms, sample analysis request forms, and field change request forms. All records shall be completed with black, waterproof ink.

Procedures for reviewing, approving, and revising field records must be clearly defined, with the lines of authority included. As a minimum, all documentation errors shall be corrected by drawing a single line through the error and initialing by the responsible individual, along with the date of change. The correction is written adjacent to the error.

Any deviations from the planning documents shall be recorded.

6.8.1 Personnel Training and Qualification Records. It is the responsibility of the organization to establish personnel qualifications and training requirements. Each staff member shall have the education, training, technical knowledge, experience, or a combination thereof, to enable that individual to perform assigned functions. Personnel qualifications shall be documented in terms of education, experience, and training. Training shall be provided for all staff members so that they can properly perform their functions.

6.8.2 SOP's. SOP's shall be available to those performing the task outlined. Any revisions to field SOP's shall be written and distributed to all affected individuals to ensure implementation of changes. Areas covered by SOP's are given in appendix E, paragraph 6.5. The SOP's shall contain a signature sheet containing signatures and dates signifying that

all onsite personnel who will use the SOP's have read and understand the contents of the SOP's.

6.8.3 QAP's. The CEQAPP and all applicable QAPjP's shall be on file and available to those performing the onsite tasks.

6.8.4 Equipment Maintenance. Maintenance procedures shall be clearly defined and written for each measurement system and required support equipment. When maintenance is necessary, it shall be documented either on standard forms or in logbooks. A history of the maintenance record of each system serves as an indication of the adequacy of maintenance schedules and parts inventory.

6.8.5 Calibration and Traceability of Standards/Reagents. Calibration is a reproducible reference point to which all sample measurements can be correlated. A sound calibration program shall include provisions for documentation of frequency, conditions, standards, and records reflecting the calibration history of a measurement system. The accuracy of the calibration standards is an important point to consider because all data will be in reference to the standards used. A program for verifying and documenting the accuracy of all working standards against primary grade standards shall be routinely followed. The primary grade standards for analyses shall be either Standard Analytical Reference Materials as supplied by the U.S. Army Toxic and Hazardous Materials Agency (USATHAMA), EPA standards, National Institute of Standards and Technology (NIST) Standard Reference Materials (SRM's), or a standard characterized as to identity and purity and referenced to NIST SRM's.

6.8.6 Sample Collection and Tracking Records. To ensure maximum utility of the sampling effort and resulting data, documentation of the sampling protocol, as performed in the field, is essential. Sample collection records shall contain, as a minimum, persons conducting the activity, sample number, sample location, equipment used, climatic conditions, documentation of adherence to protocol, and unusual observations. The actual sample collection record is usually one of the following: a bound field notebook with pre-numbered pages, a pre-printed form, or digitized information on a computer tape or disc.

Sample tracking records involving the possession of samples from the time they are obtained until they are disposed of shall be documented with the following minimum information:

- Project name.
- Signatures of samplers.
- Sample number, date and time of collection, and grab or composite sample designation.

- Signatures of individuals involved in sample transfer.

- If applicable, the air bill or other shipping number.

6.8.7 Maps and Drawings. Project planning documents and reports often contain maps. The maps are used to document the location of sample collection points and monitoring wells and as a means of presenting environmental data. Information used to prepare maps and drawings is normally obtained through field surveys, property surveys, surveys of monitoring wells, aerial photography, or photogrammetric mapping. The final, approved maps shall have a revision number and date and shall be subject to the same controls as other project records.

6.8.8 Results from Control Samples. Documentation requirements for collection of QC samples (such as field, trip, and equipment rinsate blanks, duplicate samples, spikes, and reference materials) shall be maintained.

6.8.9 Correspondence. Project correspondence can provide evidence supporting technical interpretations. Correspondence pertinent to the project shall be kept and placed in the project files.

6.8.10 Deviations. Field changes and deviations from planning documents shall be reviewed and approved by the authorized personnel who performed the original technical review or by their designee. All deviations from procedural and planning documents shall be recorded in the site log, signed, and dated.

6.8.11 Final Report. The final report shall summarize the field activities, the data, results of deviations from planning documents, and the interpretation of the data. The planning documents shall outline the items to be included in the report, which may include any special formats required, QC reporting requirements, conclusions, and recommendations.

6.9 Document Storage

Procedures have been established to ensure that documents required to recreate the sampling, analysis, and reporting of information are stored. Chapter 6 of this CEQAPP covers these procedures.

7.0 STANDARD PROTOCOL FOR ENVIRONMENTAL LABORATORY OPERATIONS

7.1 Purpose

Each laboratory must conduct its operations in such a way as to provide reliable information. To achieve this, certain minimal policies and procedures must be implemented.

7.2 Organization

The laboratory shall be structured so that each member of the organization has a clear understanding of his or her duties and responsibilities and the relationship of those responsibilities to the total effort. The organizational structure, functional responsibilities, levels of authority, job descriptions, and lines of communication for activities shall be established and documented in the laboratory QAPjP in accordance with the CEQAPP and the CENPW QAPjP. The laboratory shall also maintain a current list of accreditation from government agencies or private associations.

7.2.1 Management. The management of the laboratory is responsible for establishing organizational, operational, health and safety, and QA policies. These responsibilities include oversight of personnel selection, development, and training; review, selection, and approval of methods of analysis; and development, implementation, and maintenance of a QA program. The management shall foster an attitude within the organization that emphasizes the importance of quality and supports the implementation of this CEQAPP and CENPW QAPjP.

7.2.2 Assistance from External Environmental Monitoring Systems/Support Laboratories. If required, CENPW may request support from environmental monitoring systems/support laboratories in providing necessary inspection materials, devices, and technical assistance. CENPW will arrange support from these laboratories through the Environmental Restoration Program Office. The Environmental Restoration Program Office can make arrangements for assistance from the following laboratories:

a. Environmental Monitoring Systems Laboratory
ATTN: Director
Research Triangle Park, NC 27711

b. Environmental Monitoring and Support Laboratory
ATTN: Director
26 West St. Clair Street
Cincinnati, OH 45268

c. Environmental Monitoring and Support Laboratory
ATTN: Director
P.O. Box 15027
Las Vegas, NV 89115

d. Department of Energy Environmental Measurements Laboratory
ATTN: Director
376 Hudson Street
New York, NY 10014

7.2.3 QA Function. The laboratory shall have a person or persons responsible for monitoring laboratory operations to ensure that the facilities, equipment, personnel, methods,

practices, and documentation are in conformance with the laboratory QAPP and any applicable QAPjP's. The QA monitoring function shall be entirely separate from and independent of personnel engaged in the direction and conduct of the work being monitored. The QA function shall inspect records to ensure that analyses were performed correctly and within the proper timeframe; maintain copies of the QAPP and QAPjP's pertaining to all analyses; perform assessments of the laboratory to ensure adherence to the QAPP; periodically submit written status reports to management, noting any problems and the corrective actions taken; ensure that any deviations from the approved QAPP, QAPjP, or SOP's were properly authorized and documented; and ensure that the reported results accurately reflect the raw data. The responsibilities of the QA function and the procedures used in carrying out those responsibilities shall be in writing and shall be maintained.

7.2.4 Personnel. It is the responsibility of the organization to establish personnel qualifications and training requirements for all positions. Each member of the organization shall have the education, training, technical knowledge, and experience, or a combination thereof, to enable that individual to perform assigned functions. Personnel qualifications shall be documented in terms of education, experience, and training. Training shall be provided for each staff member as necessary to properly perform their functions. The suggested minimum qualifications are as follows:

a. Laboratory Director--Should have earned a Baccalaureate Degree in Science or Engineering from an accredited college or university, or the equivalent, and have at least 5 years experience in laboratory work.

b. Senior Staff--Should have earned a Baccalaureate Degree in Science or Engineering, or the equivalent, from an accredited college or university and have at least 2 years experience at the bench level.

c. Technical Staff--Should have formal training in the sampling and analytical methodology and QC as applied to the specific sample types and concentration levels of analytes that are of interest to the project.

d. Subcontractors--The use of subcontractors shall not jeopardize the quality of the data. Therefore, subcontractors shall comply with the requirements of appendix E, paragraphs 6 and 7, as appropriate to the specific task(s) they are performing.

7.3 Facilities

7.3.1 General. Each laboratory shall be of suitable size and construction to facilitate the proper conduct of the analyses. Adequate bench space or working area per analyst shall be provided. The space requirement per analyst depends on the equipment or apparatus that is being utilized, the number of samples that the analyst is expected to handle at any one time, and the number of operations that are to be performed concurrently by a single analyst. The laboratory shall be well ventilated, adequately lit, free of dust and drafts, protected from extreme temperatures, and have access to a stable source of power. In addition, the laboratory shall have safety equipment including fire extinguisher, eye wash and safety

shower facilities, and spill control materials consistent with the particular laboratory operation. Laboratories shall be designed so that there is adequate separation of functions to ensure that no laboratory activity has an adverse effect on the analyses. The laboratory may require specialized facilities such as a perchloric acid hood or glove-box.

7.3.2 Sample Handling, Receiving, and Storage Area. As necessary to ensure safe and secure storage and prevent contamination or misidentification, there shall be adequate facilities for receipt and storage of samples. The level of custody required and any special requirements for storage, such as refrigeration and lighting, shall be described in planning documents.

7.3.3 Chemical Storage. Safe and secure storage areas for reagents, solvents, standards, and reference materials shall be adequate to preserve their identity, concentration, purity, stability, and comply with best management practices.

7.3.4 Laboratory Operations Area. Separate space for laboratory operations and appropriate ancillary support shall be provided, as needed, for the performance of routine and specialized procedures.

7.3.5 Waste Storage Area. Adequate facilities shall be provided for the collection and storage of all wastes, and these facilities shall be operated so as to minimize environmental contamination. Waste storage and disposal facilities shall comply with applicable Federal, State, and local regulations. If the laboratory is onsite, procedures noted in the IA with DOE-RL shall apply.

7.3.6 Data Storage Area. Space shall be provided for the storage and retrieval of all documents as specified in appendix E, paragraph 7.8. The storage environment shall be maintained to assure the integrity of the materials stored. Access shall be limited to authorized personnel only.

7.3.7 Data Management Area. Space shall be provided for the computerized management and entry of data into a data management system.

7.4 Equipment and Instrumentation

7.4.1 Equipment and Instrumentation. Equipment and instrumentation shall meet the requirements and specifications of the specific test methods and other SOP's. The laboratory shall maintain an equipment and instrument description list that includes the manufacturer, model number, year of purchase, accessories, and any modifications, updates, or upgrades that have been made.

7.4.2 Maintenance and Calibration of Equipment and Instrumentation. Equipment and instrumentation shall be adequately inspected, cleaned, maintained, tested, and calibrated as required in the SOP or operations manual. SOP's or manuals shall specify identification and repair of common maintenance problems. Procedures shall designate a person(s) responsible

for maintenance. Records of all inspections, maintenance, repairs, testing, and calibration shall be maintained.

7.4.3 Commercial Devices. Calibration controls are not required for rulers, tape measures, and like devices if normal commercial equipment provides adequate accuracy.

7.5 SOP's

The laboratory shall have written SOP's for all laboratory functions that affect data quality. Procedures and methods shall be performed in the laboratory as described in the SOP's. Any modification of an SOP made during a data collection activity must be documented. SOP's shall be available for the following areas and shall contain, at a minimum, the information described.

7.5.1 Sample Management. These SOP's describe the receipt, handling, and storage of samples.

a. Sample Receipt and Handling--These SOP's describe the precautions to be used in opening sample shipment containers as well as procedures used to:

- Verify that chain-of-custody has been maintained.
- Examine samples for damage.
- Check for proper preservatives and temperature.
- Assign the testing program.
- Log samples into the laboratory sample streams.

b. Sample Scheduling--These SOP's describe the procedures and criteria used for scheduling work in the laboratory, including procedures used to ensure that holding time requirements are met.

c. Sample Storage--These SOP's describe the storage conditions for all samples, procedures used to verify and document daily storage temperature, and procedures used to ensure that custody of the samples is maintained while in the laboratory.

7.5.2 Reagent/Standard Preparation. These SOP's detail procedures used to prepare standards and reagent mixtures. In addition, these SOP's shall specify the requirements concerning the purity of materials used, including water; appropriate glassware and containers; record keeping and labeling, including dating; procedures used to verify concentration, purity, and stability; and safety precautions necessary to meet the requirements of the DQO's or test methods.

7.5.3 General Laboratory Techniques. These SOP's detail all essentials of laboratory operations not addressed in other SOP's. These techniques include, but are not limited to, glassware cleaning procedures, operation of analytical balances, pipetting techniques, and use of volumetric glassware.

7.5.4 Analytical Methods. SOP's pertaining to analytical methods for sample analysis will contain a complete description of how the analysis is actually performed in the laboratory and not a simple reference to standard methods. Industry-recognized methods from source documents published by the EPA, American Public Health Association, American Society for Testing Materials, the National Institute for Occupational Safety and Health, USATHAMA, or other recognized organizations should be used if possible. The SOP for analytical methods should include the following:

a. A summary of the method listing the analytes, the applicable matrix, and a brief description of the analytical procedure.

b. A section in the application of the method including the tested concentration range, sensitivity of instrument response, detection limit, interferences, analysis rate, and safety information.

c. A section compiling all the apparatus and chemicals used in the performance of the method. Specifics must be supplied pertaining to the make and model of the instrument(s) used.

d. A section detailing the initial and daily calibrations required for the performance of the method. Specific procedures must be provided for the preparation and validation of standards, the actual instrument calibration and tuning, the analysis performed on the calibration data, and a description on the criteria for, and use of, calibration check standards.

e. The sample handling and storage procedures need to be described. Included in this section are the preservation procedures, containers and storage conditions, holding time limitations, and the measure used to verify the integrity of working calibration and control spike solutions.

f. A step-by-step detailed description of the actual procedure to be used in the analysis of samples must be provided. Included shall be a summary of the separations, chemical reactions, and the instrumental analysis.

g. A detailed procedure for the calculation of sample concentrations from the instrument responses, including calibration curves and formulas, must be provided.

h. The detailed step-by-step procedures for the preparation of standard matrix spiked QC samples shall be provided. A description of the QC charts to be used and how they will be maintained shall be included along with a listing of the initial warning and control limits.

i. Published references for the described procedures shall be provided. Major deviations from the referenced method shall be summarized.

j. A demonstration of the applicability and limitation of the method including, but not limited to, statistical evaluation of the data, calibration curves, chromatograms, and actual data from standard matrix samples shall be provided.

7.5.5 Equipment Calibration and Maintenance. These SOP's describe procedures used to ensure that laboratory equipment and instrumentation are in working order. The SOP's describe calibration procedures and schedules, maintenance procedures and schedules, maintenance logs, service contracts or service arrangements for all equipment, and spare parts available in-house. Calibration and maintenance of laboratory equipment and instrumentation shall be in accordance with manufacturers' specifications and shall be documented.

7.5.6 QC Data. These SOP's detail the type, purpose, and frequency of QC samples analyzed in the laboratory and establish acceptance criteria. They should include information on the applicability of the QC sample to the analytical process, the statistical treatment of the data, and the responsibility of laboratory staff and management in generating and using the data. The use of a referee laboratory, if applicable, and the criteria for the acceptance of data when results from primary laboratory and referee laboratory differ shall be detailed. The criteria for the selection of a laboratory as a referee laboratory and the continuing review of the referee laboratories capability, including external auditing and the type and level of QC of the referee laboratory, shall be described.

7.5.7 Corrective Action. These SOP's describe procedures used to identify and correct deficiencies in the analytical process. These include specific steps to take in correcting deficiencies such as preparation of new standards and reagents, recalibration and restandardization of equipment, reanalysis of samples, or additional training of laboratory personnel in methods and procedures. The SOP shall specify that each corrective action must be documented with a description of the deficiency, the corrective action taken, and the person(s) responsible for implementing the corrective action.

7.5.8 Data Reduction and Validation. These SOP's describe the procedures used to review and validate the data. They should include procedures for computing and interpreting the results from QC samples and procedures used to independently verify that the analytical results are correct. In addition, routine procedures used to monitor precision and bias, including evaluations of reagent, field, and trip blanks, calibration standards, control samples, duplicate and matrix spike samples, and surrogate recovery should be detailed in an SOP.

7.5.9 Reporting. These SOP's describe the process for reporting the analytical results. The procedure used for the rounding of numbers in conjunction with a description of the allowable significant figures shall be included. In addition, the details on the computerized data management system, including equipment requirements, data checking routines, format of the data, and transfer files shall be provided.

7.5.10 Records Management. These SOP's describe the procedures for generating, controlling, and archiving laboratory records. The SOP's should detail the responsibilities for record generation and control and the policies for record retention, including type, time, security, and retrieval and disposal authorities. Records shall include project-specific and laboratory operations records.

a. Project-specific records related to analyses performed for a group of samples shall be maintained. These records may include an index of documents, correspondence, chain-of-custody records, request for analysis, calibration records, raw and finished analytical and QC data, data reports, and project planning documents.

b. Laboratory operations records, which document the overall laboratory operation, shall be maintained. These records may include laboratory notebooks, instrument performance logs, and maintenance logs in bound notebooks with pre-numbered pages; laboratory bench-sheets; software documentation; control charts; reference material certification; personnel files; laboratory SOP's; and corrective action reports.

7.5.11 Waste Disposal. These SOP's describe the policies and procedures for disposal of chemicals including standard and reagent solutions, process waste, and samples. Disposal of these materials shall conform to the IA with DOE-RL.

7.5.12 Health and Safety. These SOP's describe policies and procedures designed to provide a safe and healthy working environment for laboratory staff and to conform to DOE-RL health and safety requirements.

7.6 Laboratory QA/QC Procedures

7.6.1 QAPP. The laboratory shall have a written QAPP that describes the organization's QA policy and shall be in accordance with the CEQAPP and CENPW QAPjP. The QAPP shall specify the responsibilities of the laboratory staff, laboratory management, and the QA function in the areas of QA and QC and describe the QC procedures followed by the laboratory, including:

- The use of control samples.
- The statistical and mathematical basis for assigning warning and rejection limits.
- The detection of shifts, trends, or biases.
- How an out-of-control condition is detected.
- How control is re-established.
- How out-of-control events and corrective actions are documented.

- How reporting limits are established, including their dependence on serial dilutions and sample size.

- How instrument calibration and maintenance logs, corrective action reports, and routine QC data summaries are maintained.

- QA assessment procedures used.

[See EPA QAMS-004/80 for an example.]

7.6.2 QAPjP. All projects, particularly those that are large and/or complex, will likely require a QAPjP and should be in accordance with the CEQAPP and CENPW QAPjP. The QAPjP details the QA/QC goals and protocols for a specific data collection activity to ensure that the data generated by sampling and analysis activities are of a quality commensurate with their intended use. QAPjP elements are described in paragraph 1.4 and appendix A, paragraph 4 of the CEQAPP.

7.6.3 Method Proficiency. The laboratory shall have procedures for demonstrating proficiency with each analytical method used in the laboratory. These shall include procedures for demonstrating the precision and bias of the method as performed by the laboratory and procedures for determining the minimum quantity that can be determined while meeting the requirements of the data quality objectives. Consideration shall be given to both within-day and between-day variations. All terminology, procedures, and frequency of determinations associated with the laboratory's establishment of the minimum detectable quantity shall be well-defined and well-documented. Documented precision, bias, and minimum detectable quantity information shall be maintained for all methods performed in the laboratory. In general, the maximum limit for quantitative acceptance criteria should be +/- 25 percent of the mean, unless justification can be provided for allowing acceptance criteria outside of these limits. Ordinarily, the standard acceptance criteria is based on the repeated analysis of a standard or known sample from which the mean is calculated.

7.6.4 Laboratory Control Procedures. The laboratory shall have procedures for demonstrating that the laboratory is in control during each data collection activity.

a. Control Samples--The laboratory shall analyze control samples for each analytical method. A control sample consists of a standard matrix spiked with analytes representative of the target analytes. Control sample(s) shall be analyzed with each batch of samples processed to verify the precision and bias of the analytical process. The results of the control sample(s) are prepared to control limits established for both precision and bias to determine usability of the data (see appendix E, paragraph 7). The results of the control samples shall be plotted and maintained on control charts. The control charts shall be reviewed daily by the laboratory and periodically by the Contracting Officer or his representative and should be part of the data package maintained for that batch (lot) of samples. Analytical data generated with control samples that fall within prescribed limits are judged to be generated while the laboratory was in control. Data generated with control samples that fall outside of the established control limits may be judged to be generated

during an "out-of-control" situation. These data are considered suspect and must be repeated or reported with qualifiers.

b. Method Blank--A method blank shall be analyzed with each batch of samples processed to assess contamination levels in the laboratory. The laboratory shall have guidelines in place for accepting or rejecting data based on the level of blank contamination.

7.6.5 Determination of Matrix Effects. The laboratory shall have procedures for documenting the effect of the matrix on method performance. The type of matrix-specific information required for a specific data collection activity is dependent on the DQO's of the activity.

a. Matrix Spikes--Procedures shall be in place for determining the bias of the method in the matrix. These procedures should include analysis of matrix spikes, use of surrogates for organic methods, and the method of standard additions for metal and inorganic methods. The frequency of use of these techniques shall be based on the DQO's of the data collection activity. Standard matrix spikes, as described in appendix E, paragraph 7.6.4.a, are included with each batch of samples and are carried through the entire analytical procedure. For most analytical procedures, standard matrix spikes shall be included with the daily analysis of samples. For methods where this requirement is not appropriate *(e.g.*, asbestos, oil, grease, *etc.)*, an explanation will be provided in the QAPjP and/or the applicable method as to the control measures being used to assess the quality of the data.

b. Matrix Duplicates/Matrix Spike Duplicates--Procedures shall be in place for determining the precision of the method in the matrix, if required. These procedures may include analysis of matrix duplicates and/or matrix spike duplicates. The use of surrogates for organic analyses and the method of standard additions for inorganic analyses are strongly recommended as an adjunct to matrix spike/matrix spike duplicates as the surrogate recoveries can provide additional information on the possible matrix effects of individual samples. The frequency of use of these techniques shall be based on the DQO's of the data collection activity.

c. Sample-Specific Detection Limit--Procedures shall be in place for determining the method detection limit in a specific sample or group of samples. The frequency of use of these procedures shall be based on the DQO's of the data collection activity.

7.6.6 Procedures for Establishing Control Limits

a. Procedures shall be in place for establishing and updating control limits for analysis control. Control limits shall be established in order to evaluate laboratory precision and bias based on the analysis of control samples (see appendix E, paragraph 7.6.4.a). Typically, control limits for bias are based on the historical mean recovery plus or minus three standard deviation units and control limits for precision range from zero (no difference between duplicate control samples) to the historical mean Relative Percent Difference plus three standard deviation units. The maximum acceptance criteria shall be as stated in appendix E, paragraph 7.6.3.

b. Procedures shall be in place for monitoring historical performance and should include graphical (control charts) and tabular presentations of the data.

7.6.7 Deviations. Any activity not performed in accordance with laboratory SOP's or project planning documents is considered a deviation from plan. Deviations from plan may or may not affect data quality. All deviations from plan shall be documented as to the extent of and reason for the deviation.

7.6.8 Corrective Action. Errors, deficiencies, deviations, or laboratory events or data that fall outside of established acceptance criteria require investigation. In some instances, corrective action may be needed to resolve the problem and restore proper functioning to the analytical system. The investigation of the problem and any subsequent corrective action taken shall be documented as outlined in paragraph 3.2 of this CEQAPP.

7.6.9 Data Handling Procedures. Data handling procedures can be found in chapter 10 of this CEQAPP.

7.7 QA Review

7.7.1 General. The QA program shall provide for routine evaluations of the effectiveness of laboratory QA/QC procedures and conformance of the laboratory to these procedures. These evaluations can be performed by persons internal or external to the organization and can involve onsite evaluations and/or performance evaluation studies.

a. Internal Assessment--The analyst is responsible for continually monitoring individual compliance with the QA/QC program. In addition, on some frequent basis, the QA officer, or an appropriate management designee, must review laboratory data and operations for compliance with the QA/QC program. The results of the internal assessment should be reported to management with requirements for a plan to correct observed deficiencies.

b. External Assessment--The laboratory should periodically be subjected to evaluation by an assessor who is independent of the laboratory. This may be a representative of a government agency or other independent organization. The results of the external assessment should be submitted to management with requirements for a plan to be developed by management to correct observed deficiencies.

c. Onsite Evaluation--Onsite evaluations should be conducted as part of both internal and external assessments. An onsite evaluation includes a complete evaluation of facilities, staff, instrumentation, SOP's, analytical methods, sample management procedures, and QA/QC policies and procedures as they relate to the generation of data for specific analytical and regulatory applications. Records of each evaluation shall be maintained by the laboratory. These records should include the date of the evaluation, the area(s) or analyses inspected, the person performing the evaluation, findings and problems, actions recommended and taken to resolve existing problems, and scheduled date for reinspection.

Any problems identified during the course of an onsite evaluation that are likely to affect data integrity shall be immediately brought to the attention of management.

d. Performance Evaluation Studies--Performance evaluation studies are used to measure the performance of the laboratory on unknown samples. Performance evaluation samples are typically submitted to the laboratory as blind samples by an independent outside source. The results are compared to predetermined acceptance limits set by the submitting agency. The organization providing the performance evaluation samples shall have documentation on how the samples were characterized and validated, how limits of acceptability are established, how the resultant data are validated, and what criteria are used to determine the acceptability of that data. This documentation shall be provided to the contracting officer or the contracting officer's technical representative and the customer. Records of all performance evaluation studies shall be maintained by the laboratory. Problems identified as a result of participation in performance evaluation studies shall be immediately investigated and corrected.

7.7.2 Evaluation of Laboratory Data. The evaluation of laboratory data shall be conducted by one or more persons knowledgeable in laboratory activities. All data shall be evaluated by the QA section of the laboratory. In addition, at least 10 percent of the data shall be evaluated by an external auditor. The final step in any evaluation shall be the attesting, in writing, of the laboratory QA officer as to the validity and usability of the data. Data evaluation should include the following subjects, at a minimum:

a. Completeness of Laboratory Data--This ensures that: (1) all samples and analyses required by the project planning documents have been processed, (2) complete records exist for each analysis and the associated QC samples, and (3) the procedures specified in project planning documents and SOP's have been implemented. The results of the completeness check should be documented.

b. Evaluation of Data with Respect to Detection Limits--Analytical results should be compared to required detection limits. Any detection limits that exceed regulatory limits or action levels as specified in the project planning documents should be identified.

c. Evaluation of Data with Respect to Control Limits--The results of QC and calibration check samples should be compared to control criteria. Data not within control limits require comment, corrective action, documentation, and reviewers should check that corrective action reports and the results of reanalysis are available. Samples associated with out-of-control QC data should be identified in a written record of the data review, and an assessment of the utility of such analytical results should be recorded.

d. Review of Holding Time Data--Sample holding times should be compared to those required by the project planning documents, and all deviations should be noted.

e. Evaluation of Performance Evaluation (PE) Results--PE study results can be helpful in evaluating the impact of out-of-control conditions. Recurring trends or problems

evident in PE studies should be documented in the review, and their effect on environmental data should be evaluated.

f. Correlation of Laboratory Data--The results of data obtained from related laboratory tests, such as Purgeable Organic Halide and Volatile Organic, shall be documented and the significance of differences discussed in the review reports.

7.7.3 QA Reports to Management. The QA program shall provide for the periodic reporting of pertinent QA/QC information to management to allow management to assess the overall effectiveness of the QA program.

7.8 Laboratory Records

All information relating to laboratory facilities, equipment, personnel, methods, and practices shall be documented. A floor plan of the facilities shall be kept current. Copies of the SOP's and the equipment manuals provided by the manufacturer shall be accessible to the work place.

Handwritten test data shall be recorded legibly in ink in laboratory notebooks or on designated bench sheets. Each page shall be signed by the person who performed the analysis and entered the data. Corrections shall be made in ink by drawing a single line through the information to be changed and initialling and dating the change. The reason for the change shall be indicated.

Strip-chart recorder printouts shall be signed by the person who performed the instrumental analysis. If corrections need to be made in computerized data, a system parallel to the corrections for handwritten data shall be in place. If manual calculations are performed, the reason for such action and the instrument output will be provided.

Records of sample management shall be available to permit the re-creation of an analytical event for review in the case of an audit or investigation of a dubious result. The actual data shall be maintained in a data package. A data package contains all the data necessary to support the results of one analytical method for one lot of samples. Data packages must be "free standing;" that is, all data should be available with minimum reference to other documents or files. The data package shall be forwarded to CENPW and ultimately DOE-RL at the completion of the project unless otherwise specified. Records to be contained in the data package shall include, but are not limited to, the following:

- Original chromatograms, strip charts, or other instrument output.
- Original chain-of-custody form or copy with location of original noted.
- All hard copy gas chromatograph/mass spectrograph (GC/MS) output.
- Copies of all relevant notebook pages.

- Copies of raw data and computer transfer files.
- Contents checklist.
- Review checklist.
- Approval checklist.

7.8.1 Personnel Training and Qualification Records. It is the responsibility of the organization to establish personnel qualifications and training requirements. Each staff member shall have the education, training, technical knowledge, and experience, or a combination thereof, to enable that individual to perform assigned functions. Personnel qualifications shall be documented in terms of education, experience, and training. Training shall be provided for all staff members so they can properly perform their functions.

7.8.2 SOP's. SOP's shall be written and available for all methods and practices.

7.8.3 QAP's. The QAPP and all applicable QAPjP's shall be on file.

7.8.4 Equipment Maintenance. Maintenance and performance logs shall be kept on all equipment and instrumentation and must include:

- The name of the equipment and the manufacturer.
- The model and serial number of the equipment.
- The date the equipment was placed in service.
- Instructions for proper maintenance procedures.
- The dates of the maintenance/performance checks and names of personnel performing them.
- If nonroutine repairs were performed as a result of a malfunction, the nature and cause of the malfunction, and the name of the person performing the repair.

7.8.5 Proficiency. Proficiency information on all compounds reported shall be maintained and shall include:

- Precision.
- Bias.
- Method detection limits.
- Spike recovery, where applicable.

- Surrogate recovery, where applicable.
- Checks on reagent purity, where applicable.
- Checks on glassware cleanliness, where applicable.

7.8.6 Traceability. Traceability of standards, reagents, and weights shall be documented. Traceability to national or international sources shall be indicated.

7.8.7 Calibration. Calibration and standardization data records for each instrument and method shall include:

- The data of the last calibration.
- The calibration history.
- The frequency of calibration.
- Outside sources of calibration, if used (*e.g.*, the manufacturer).
- Date of preparation, expiration date, and name of person performing the preparation of standards.
- Written procedures for instrument calibration.

7.8.8 Sample Management. All required records pertaining to sample management shall be maintained and updated regularly. These include chain-of-custody forms, sample receipt forms, and sample disposition records.

7.8.9 Original Data. The raw data and calculated results for all samples shall be maintained in laboratory notebooks and logs, bench sheets, files, and other sample tracking or data entry forms. Instrumental output shall be stored in a computer file or a hard copy report.

7.8.10 QC Data. The raw data and calculated results for all QC and field samples and standards shall be maintained in the manner described in appendix E, paragraph 7.8.9. QC samples include, but are not limited to, control samples, method blanks, matrix spikes, and matrix spike duplicates.

7.8.11 Correspondence. Project correspondence can provide evidence supporting technical interpretations. Correspondence pertinent to the project shall be kept and placed in the project files.

7.8.12 Final Report. A copy of the final report submitted to the sponsor of the work or other designated individual shall be retained.

7.9 Document Storage

A written policy concerning the length of time that documentation is to be retained shall be in place and understood by the appropriate personnel, including the sponsor of the work. Deviations from this policy shall be documented and readily available to those individuals responsible for the deletion/destruction of expired documentation. Chapter 6 of this CEQAPP covers CENPW document storage requirements.

GLOSSARY

Section I
Acronyms

ACO	Administrative Contracting Officer
A-E	Architect-Engineer
AFARS	Army Federal Acquisition Regulation Supplement
AR	Army Regulation
ARAR	Applicable or Relevant and Appropriate Requirements
CENPD	U.S. Army Corps of Engineers, North Pacific Division
CENPW	U.S. Army Corps of Engineers, Walla Walla District
CENPW-IR	U.S. Army Corps of Engineers, Walla Walla District, Internal Review Office
CEQAPP	U.S. Army Corps of Engineers Quality Assurance Program Plan
CFR	Code of Federal Regulation
COR	Contracting Officer's Representative
CQCP	Contractor Quality Control Plan
CQCR	Contractor Quality Control Representative
CRP	Community Relations Plan
DFARS	Defense Federal Acquisition Regulation Supplement
DOE	U.S. Department of Energy
DOE-RL	U.S. Department of Energy Field Office, Richland
DQO	Data Quality Objective
EC	Engineering Circular
EDO	Environmental Data Operations
EFARS	Engineer Federal Acquisition Regulation Supplement
EPA	U.S. Environmental Protection Agency
ER	Engineering Regulation
ERRA	Environmental Restoration Remediation Action
FAR	Federal Acquisition Regulation
GS/MS	Gas Chromatograph/Mass Spectrograph
HSP	Health and Safety Plan
IA	Interagency Agreement
LAN	Local Area Network
MARKS	Modern Army Record Keeping System (AR 25-400-2)
MCL	maximum concentration limit
M&TE	measuring and test equipment
NDE	nondestructive examination
NIST	National Institute of Standards and Testing
NPW-H-OM	Walla Walla District, Hanford, Office Memorandum
NPWOM	Walla Walla District Office Memorandum
NQA	Nuclear Quality Assurance
PA's/SI's	Preliminary Assessments/Site Inspections
PE	Performance Evaluation
PMP	Program Management Plan

Acronyms (Continued)

PPMD	Programs and Project Management Division
PRB	Project Review Board
QA	Quality Assurance
QAP	Quality Assurance Plan
QAPjP	Quality Assurance Project Plan
QAPP	Quality Assurance Program Plan
QA/QC	Quality Assurance/Quality Control
QAR	Quality Assurance Representative
QARD	Quality Assurance Requirements Document
QARLT	Quality Assurance Representative Laboratory Technician
QC	Quality Control
RI/FS	Remedial Investigation/Feasibility Study
SAP	Sampling and Analysis Plan
SOP	Standing Operating Procedure
SRM	Standard Reference Materials
TPA	Tri-Party Agreement
USACE	U.S. Army Corps of Engineers
USATHAMA	U.S. Army Toxic and Hazardous Materials Agency
WHC	Westinghouse Hanford Company

Section II
Terms

Acceptance Criteria--Specified limits placed on characteristics of an item, process, or service defined in codes, standards, or other requirements.

Activities that Effect Quality--Activities that, if not performed properly, could compromise the validity of the information or data reported, could result in unacceptable risk to the environmental health or safety of the public or the workers involved, or could have a detrimental effect on the achievement of the prime objectives of the mission.

Applicable or Relevant and Appropriate Requirements--Those cleanup standards, standards of control, and other substantive environmental protection requirements, criteria, or limitations promulgated under section 121(d) (2) of Comprehensive Environmental Recovery, Compensation, and Liability Act.

Audit--A planned and documented activity performed in accordance with procedures to be determined by investigation, examination, or evaluation of objective evidence. The audit determines the extent to which applicable elements of the quality assurance program have been developed and documented in accordance with specified requirements, the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. A systematic check to determine the quality of the operation of some function or activity. Audits can be internal examinations of programs or activities under an organization's control and within its organizational structure or external examinations of programs or activities of another organization. An Environmental Protection Agency system audit is a qualitative nature that consists of an onsite review of a laboratory's quality assurance system and physical facilities for sampling, calibration, and measurement. An audit should not be confused with surveillance (such as Environmental Protection Agency performance audits) or inspection activities performed for the sole purpose of process control or product acceptance.

Authorized Representative--Any person, including a contractor, who is specifically designated by a Party to have a defined capacity, including an advisory capacity for example Contracting Officer's Representative.

Background Sample--A sample taken from a location on or proximate to the site of interest. This is taken to document baseline or historical information.

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

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

Co-located Samples--Independent samples collected as close as possible to the same point in space and time and intended to be identical.

Terms (Continued)

Comprehensive Environmental Response, Compensation, and Liability Act [(CERCLA) also known as Superfund]--The Federal statute enacted in 1980 and reauthorized in 1986, which provide the statutory authority for cleanup of hazardous substances that could endanger public health or welfare of the environment.

Computer Program--A sequence of instructions suitable for processing by a computer. Processing may include the use of an assembler, a compiler, an interpreter, or a translator to prepare the program for execution as well as to execute it.

Conditions Adverse to Quality--An all-inclusive term used in reference to any of the following: failure to meet performance objectives, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one which, if left uncorrected, could have a serious effect on safety or operation.

Configuration--The physical, functional, and operational characteristics at any point in time. An approved configuration is one which has been verified to conform to the configuration bases and approved by design authority.

Contamination (Contaminated)--Any unwanted undesirable foreign material on the surface of an item, in the atmosphere, or in process liquids or gases. A parameter in a specified environmental medium having a maximum source concentration above an action level or regulatory threshold.

Controlled Process--A process, other than a special process, that affects the quality of data, design, procurement, fabrication, construction, testing, operation, or maintenance, and which therefore requires the application of controls to assure successful performance.

Corrective Action--Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

Data--All administrative, managerial, financial, scientific, test, engineering, and analytical information and documentation required for delivery by contract, or developed within a program.

Data Accuracy--A measure of the degree of agreement of a measurement (or an average of measurements of the same thing or a mean of a set of results), X, with an accepted reference or true value T. Accuracy is a measurement of the bias in a system. Accuracy is assessed by means of reference samples and percent recoveries.

Data Comparability--A measure of the confidence with which one data set can be compared to another.

Section II
Terms (Continued)

Data Completeness--A measure of the amount of valid data obtained from a measurement system compared to the amount that was planned or that was expected to be obtained under correct normal corrections.

Data Precision--The measurement of agreement of a set of replicate results among themselves without assumption of any prior information as to the true result. Precision is assessed by means of duplicate/replicate sample analysis. The measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions. Precision is most desirably expressed in terms of the standard deviation. Various measures of precision exist depending on the "prescribed similar conditions."

Data Quality--The totality of features and characteristics of data that bear on its ability to satisfy a given purpose. The characteristics of major importance are legibility, data accuracy, data precision, data completeness, data representation, and data comparability.

Data Quality Objectives--Statements of the level of uncertainty that a decision maker is willing to accept in results derived from environmental data. (See Environmental Protection Agency/Quality Assurance Management Staff, July 16, 1986.)

Data Reduction--Any and all processes which change either the form of expression or quantity of data values or number of data items.

Data Representation--The measure of the degree to which data accurately and precisely represent a characteristic of a population, parameter variation at a sampling point, or an environmental condition.

Data Validation--A systematic effort to: (1) review data to assure acceptable data quality, (2) review a body of data against a set of criteria to provide assurance that the data are adequate for their intended use, and (3) review process conducted to confirm the degree of truth in an analytical measurement. The process includes the review of all pertinent sample analysis and quality assurance/quality control data compared to recognized standards or criteria. Data validation consists of data editing, screening, checking, auditing, verification, certification, and review. The "screening" process may be done by manual and/or computer methods, and it may utilize any consistent techniques such as sample limits to screen out impossible values or complicated acceptable relationships of the data with other data.

Defensible--The ability to withstand any reasonable challenge related to veracity or truthfulness.

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

Terms (Continued)

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

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

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

Deviation--A departure from specified requirements.

Electronic Records--Records created, stored, or transmitted using personnel computers, word processors, and associated electronic office equipment.

Environmental data generation activity--Tasks associated with the production of environmental data, including planning, sampling, and analysis.

Equipment Rinsate (Equipment Blank)--A sample of analyte-free media which has been used to rinse the sampling equipment. It is collected after completion of decontamination and prior to sampling. This blank is useful in documenting adequate decontamination of sampling equipment.

Error--A discrepancy between a computed, observed, or measured value and the true, specified, or theoretically correct value or condition.

Examination--An element of inspection consisting of investigation of materials, components, supplies, and services to determine conformance to those specified requirements which can be determined by such investigation. Examination is usually nondestructive and includes some physical manipulation, gauging, and measurement.

External Audit--An audit of those portions of another organization's quality assurance program not under the direct control or within the organizational structure of the auditing organization.

Field Blank--A sample of analyte-free media similar to the sample matrix that is transferred from one vessel to another or exposed to the sampling environment at the sampling site. This blank is preserved and processed in the same manner as the associated samples. A field blank is used to document contamination in the sampling and analysis process.

Field Duplicates--Co-located samples which are analyzed independently. These duplicates are useful in documenting the precision of the sampling and analytical processes. Field duplicates should be taken from areas of known contamination.

Final Design--Approved design output documents and approved changed thereto.

Terms (Continued)

Hazardous Material--Any material that poses a threat to human health and or the environment, especially when improperly used, stored, or disposed of.

Hazardous Waste--Those Waste included in the definitions of Resource Conservation and Recovery Act 1004 (%) and Revised Code of Washington 70.105.010(15).

Indoctrination--Instruction(s) that familiarize a person with a particular subject but does not enable him to perform work.

Inspection--Examination or measurement to verify whether an item or activity conforms to specified requirements.

Inspector (Quality Assurance Representative)--A person who performs inspection activities to verify conformance to specified requirements.

Internal Audit--An audit of those portions of an organization's quality assurance program retained under its direct control and within its organizational structure.

Laboratory Control Sample (Standard Matrix Spike)--A rigorously characterized (known) matrix spiked with compound(s) representative of the target analytes. This is used to document laboratory performance.

Material Blank--A sample of construction materials such as those used in well installation, well development, pump and flow testing, and slurry wall construction. Examples of these materials are bentonite, sand, drilling fluids, and source and purge water. This blank documents contamination resulting from use of the construction materials.

Matrix Duplicate--An intralaboratory split sample which is used to document the precision of a method in a given sample matrix.

Matrix Spike (Natural Matrix Spike)--An aliquot of sample spiked with a known concentration of target analyte(s). The spiking occurs prior to sample preparation and analysis. A matrix spike is used to document the bias of a method in a given sample matrix.

Matrix Spike Duplicates--Intralaboratory split samples spiked with identical concentrations of target analyte(s). The spiking occurs prior to sample preparation and analysis. They are used to document the precision and bias of a method in a given sample matrix.

Measuring and Test Equipment--Devices or systems used to calibrate, measure, gage, test, or inspect (1) to control or acquire data to verify compliance to specified requirements, (2) to establish characteristics or values, or (3) for purposes of decision making, or design of facilities or processes.

Terms (Continued)

Method Blank--An analyte-free media to which all reagents are added in the same volumes or proportions as used in sample processing. The method blank must be carried through the complete sample preparation and analytical procedure. The method blank is used to document contamination resulting from the analytical process.

Nonconformance--A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

Participant--The Department of Energy, Richland Operations Office, other government agencies, or any of the prime contractors to the Department of Energy, Richland Operations Office, or their subcontractors who have an involvement in the Hanford Program.

Peer Review--A documented critical review of work that goes beyond the state-of-the-art or where potential uncertainty exists. A peer review is an in-depth critique of assumptions, documents, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, conclusions, and material or data that requires interpretation, or judgement to verify or validate them.

Performance Evaluation Samples--Samples of like matrix to actual samples spiked with compound(s) representative of the target analytes. Neither the identity nor the quantity of analytes is known to the laboratory. They are used as a measure of performance of the laboratory.

Procedures--A document that specifies or describes how an activity is to be performed.

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

Program--An organized set of activities within a resource area having common objectives based on strategy set forth to meet assigned goals. It may include one or more projects and research and development activities in support of new, improved, or more efficient supply, or conservation systems or procedures.

Project--Single or multiple data collection activities that are related through the same planning sequence.

Project planning documents--All documents related to the definition of the environmental data collection activities associated with a project.

Protocol--Series of detailed instructions.

Terms (Continued)

Quality Assurance--All those planned and systemic action necessary to prove that a structure, system, or component will perform satisfactorily in service. When the product is a report of a significant study or investigation, quality assurance also comprises those planned and systemic actions necessary to provide adequate confidence in the validity and integrity of the reported data, methods and procedures and in the protection, retrievability, and replicability of the data. Quality assurance includes a multidisciplinary system of management controls backed by quality verification and overview activities that demonstrate completeness and appropriateness of achieved quality.

Quality Assurance Program--The generic plans and procedures, and the implementation thereof, established to meet the requirements of the Quality Assurance Requirements Document. The total integrated program for assuring the reliability of monitoring and measurement data. A system for integrating the quality planning, quality assessment, and quality improvement efforts to meet user requirements. For the purpose of this Corps of Engineers Quality Assurance Program Plan, the Quality Assurance Program Plans, Quality Assurance Project Plans, Quality Assurance Plans, work plans, Sampling and Analysis Plans, and their implementing procedures comprise the quality assurance program.

Quality Assurance Project Plan--An orderly assemblage of detailed procedures designed to produce data of sufficient quality to meet the Data Quality Objectives for a specific data collection activity.

Quality Assurance Program Plan--An orderly assemblage of management policies, objectives, principles, and general procedures by which an organization involved in environmental data generation activities outlines how it intends to produce data of known quality.

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

Quality Control--The quality assurance action that control the attributes of a material, sample, process, component, system, or facility in accordance with predetermined quality requirements. The routine application of procedures for obtaining prescribed standards of performance in the monitoring and measurement process. These actions necessary to control and verify the features and characteristics of a material, process, product, or service to specified requirements.

Readiness Review--A systematic, documented review of the readiness for start-up or continued extended use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to institution of a major phase of work.

Referee Laboratory--A laboratory selected by the contracting organization to provide analysis of split samples as a check on the performing laboratory.

Terms (Continued)

Record of Decision--The Comprehensive Environmental Response, Compensation, and Liability Act document used to select the method of remedial action to be implemented at a site after the Feasibility Study/Proposed Plan process has been completed.

Reference Material--A material containing known quantities of target analytes in solution or in a homogeneous matrix. It is used to document the bias of the analytical process.

Remedial Action--The Comprehensive Environmental Response, Compensation, and Liability Act process of restorative action executed after investigative steps have been completed and after issuance of the Record of Decision and after Remedial Design has been completed.

Remedial Design--The Comprehensive Environmental Response, Compensation, and Liability Act process of design for remedial action alternative that was selected in the Record of Decision.

Remedial Investigation--The Comprehensive Environmental Response, Compensation, and Liability Act process of determining the extent of hazardous substance contamination and, as appropriate, conducting treatability investigations. The Remedial Investigation is done in conjunction with the Feasibility Study.

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

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

Right of Access--The right of Corps of Engineers, Walla Walla District or designated representative to enter the premises of the contractor for the purpose of inspection, surveillance, or quality assurance audit.

Sample--An environmental sample or field sample is a representative sample of any material (aqueous, nonaqueous, or multimedia) collected from any source for which the determination of composition or contamination is requested or required.

Sample Lot--The number of samples, including quality control samples, that can be processed through a step of the analytical method during a single time period (not to exceed 1 day) as determined by time or by the equipment limiting step of the method.

Significant Condition Adverse to Quality--A condition which, if left uncorrected, could have a serious effect on safety or operability. This term includes environmental and program compliance.

Terms (Continued)

Site--An aggregate area, operable unit, or waste management unit, as appropriate to the context of the project, as opposed to the term "Hanford Site," which applies to the entire Department of Energy reservation.

Software--Computer programs, procedures, rules, and associated documentation and data pertaining to the operation of a computer system.

Special Process--A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspecting or testing the product.

Spike--The addition of a known quantity of an analyte to a blank, reference, or unknown sample. Used to assess accuracy and precision by evaluating percent recovery. Spikes are also used for analysis by the method of known addition.

Split Samples--Aliquots of sample taken from the same container and analyzed independently. These are usually taken after mixing or compositing and are used to document intra- or interlaboratory precision.

Standard Addition--The practice of adding a known amount of an analyte to a sample immediately prior to analysis. It is typically used to evaluate matrix effects.

Standing Operating Procedures--The established written procedures of a given organization. Special project plans may require different procedures than the established Standing Operating Procedures. (as per Army Regulation 310-50)

Storage Facilities--Warehouse, yard, or other areas designated and prepared for holding items.

Surveillance--The act of monitoring or observing to verify whether an item or activity conforms to specified requirements. Observations or monitoring to determine the acceptability of items or activities are inspections rather than quality assurance surveillance.

Surrogate--An organic compound which is similar to the target analyte(s) in chemical composition and behavior in the analytical process, but which is not normally found in environmental samples.

Technical Information--A generic term applied to data or other information that is used (1) directly or indirectly to investigate or characterize a site, (2) to design the remediation facility or process, or (3) to maintain surveillance.

Terms (Continued)

Technical Review--A documented critical review of work that is within the state-of-the-art. A technical review is an in-depth analysis and evaluation of documents, activities, material, or data for applicability, correctness, technical adequacy, completeness, appropriateness of interpretation, and assurance that established requirements are satisfied.

Trend Analysis--A statistical methodology used to detect net changes or trends, for example, in contaminant levels over time.

Trip Blank--A sample of analyte-free media taken from the laboratory to the sampling site and returned to the laboratory unopened. A trip blank is used to document contamination attributable to shipping and field handling procedures. This type of blank is useful in documenting contamination of volatile organic samples.

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

Validated Data--Data are valid when the methods, practices, techniques, and equipment used to obtain and treat them are technically sound, based on objectivity, and selected properly.

Validation--The documented confirmation of the adequacy (*i.e.*, the suitability for its intended purpose) of the work under review.

Verification--The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.

Verify--To determine or test the truth or accuracy by comparison or reference.

Waiver--Documented authorization to depart from specified requirements.

Work Plan--Work plans define the scope of services, level-of-effort, costs, and schedules for performing Environmental Restoration Remediation Action activities. In general, the work plan describes what will be done.

REFERENCES

U.S. Department of Energy Documents

DOE Order 1324.2A, Records Disposition.

DOE Order 5000.3A, Occurrence Reporting and Processing of Operations Information.

DOE Order 5400.6C, Quality Assurance.

DOE Order 5484.1, Environmental Protection, Safety, and Health Protection Information Reporting Requirements.

DOE-RL Order 5000.3A, Occurrence Reporting and Processing of Operations Information.

DOE-RL Order 5480.4, Environmental Protection, Safety, and Health Protection Standards for Richland Operation Office.

U.S. Army Documents

AR 18 Series, Information Management.

AR 25-400-2, The Modern Army Record Keeping System (MARKS).

AR 310-50, Authorized Abbreviations, Brevity Codes, and Acronyms.

OPM Handbook X-118, Qualification Standards for Positions under the General Schedule.

U.S. Army Corps of Engineers Documents

ER 5-7-1, Project Management.

ER 10-1-3, Divisions and Districts.

ER 350-7-1, Professional Development of Construction Personnel.

ER 415-1-11, Biddability, Constructibility, and Operability.

ER 415-1-260, Resident Engineer's Management Guide.

ER 415-1-302, Construction Inspection and Work Records.

ER 1110-1-71, Quality Management.

REFERENCES (Continued)

U.S. Army Corps of Engineers Documents (Continued)

ER 1110-1-263, Chemical Data Quality Management for Hazardous Waste Remedial Activities.

ER 1110-2-1200, Plans and Specifications.

ER 1110-345-100, Design Policy for Military Construction.

ER 1180-1-6, Construction Quality Management.

CENPD Document

NPDR 690-1-335, North Pacific Division Merit Promotion and Placement Plan.

CENPW Documents

NPW-H-OM 25-1-1, Publications, Correspondence, and Records Management.

NPW-H-OM 200-1-1, Document Clearance.

NPWOM 10-1-3, Directory and Position Charts and Functional Statements.

NPWOM 385-1-1, Accident Prevention on Contract Work.

NPWOM 715-1-8, District Acquisition Manual.

Other Document

ASME NQA 1-1989, Quality Assurance Program Requirements for Nuclear Facilities.