5.0 QUALITY ASSURANCE

In Title 40 of the Code of Federal Regulations (CFR) Part 194, the U.S. Environmental Protection Agency (EPA) describes the quality assurance (QA) requirements needed to comply with 40 CFR Part 191, which specifies environmental radiation protection standards for disposal of transuranic (TRU) waste. The mission of the U.S. Department of Energy (DOE) Carlsbad Area Office (CAO) is to protect human health and the environment by opening and operating the Waste Isolation Pilot Plant (WIPP) for safe disposal of TRU waste, and to establish an effective system for the management of TRU waste from its generation to its disposal. To help in fulfilling this mission and to ensure that the risks and environmental impacts are identified and minimized, and that safety, reliability, and performance are optimized, it is the policy of the DOE to establish, implement, and maintain an effective QA program that supports compliance with 40 CFR Part 194, other applicable federal, state, and local regulations, and DOE Orders and requirements.

The CAO Quality Assurance Program Document (QAPD) (included in this application as Appendix QAPD; see Table 1-5 in Chapter 1.0 for a list of appendices that provide additional information supporting this chapter) establishes and describes the QA program requirements that apply to programs and projects managed by the DOE. This program-wide requirements document establishes the controls applicable to all participants within the DOE management infrastructure. From the CAO QAPD, the principal participants (Sandia National Laboratories [SNL], Westinghouse Waste Isolation Division [WID], and the TRU waste generator and storage sites) develop and implement their management systems and controls to ensure that items, processes, and services meet or exceed applicable requirements.

The adequacy and effectiveness of implementation of these management systems and controls are verified through a program of audits and surveillances conducted by the DOE and the principal participants. This program of audits and surveillances assesses the adequacy and effectiveness of implementation of the individual QA programs. A comprehensive series of assessments has determined that the DOE, SNL, and WID QA programs are adequate and effectively implemented. The adequacy of WIPP QA programs is discussed in Section 5.3. The effective implementation of these QA programs is discussed in Section 5.4.

5.1 Applicability

QA program requirement sources include federal requirements, DOE Orders (primarily DOE Order 5700.6C), and national consensus standards. 40 CFR § 194.22, Quality Assurance, incorporates by reference the requirements of the following:

- American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) Standard, NQA-1-1989 edition, "Quality Assurance Program Requirements for Nuclear Facilities";

- ASME NQA-2a-1990 addenda to NQA-2-1989, Part 2.7, "Requirements of Computer Software for Nuclear Facility Applications"; and

- ASME NQA-3-1989 edition, "Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories" (excluding Section 2.1[b] and [c], and Section 17.1).

These NQA requirements form the basis of the CAO QAPD. Additionally, 40 CFR § 194.22 requires that QA programs be applied to the following eight items and activities:

- Waste characterization activities and assumptions,
- Environmental monitoring, monitoring of disposal system performance, and sampling and analysis activities,
- Field measurements of geological factors, groundwater, meteorologic, and topographic characteristics,
- Computations, computer codes, models, and methods to demonstrate compliance with 40 CFR Part 194,
- Procedures for implementation of expert judgment elicitation to support the applications for certification and recertification of compliance with 40 CFR Part 194,
- Design of the disposal system and actions taken to ensure compliance with design specifications,
- Collection of data and information to support compliance application(s), and
- Other systems, structures, components, and activities important to the containment of waste in the disposal system.

The objective of the CAO QAPD is to effectively satisfy QA requirements from a variety of sources through the application of management controls appropriate to the varied activities of the DOE and participants. The CAO QAPD establishes two primary categories of requirements, identified as general requirements and additional requirements.

The sections of the CAO QAPD that do not identify specific applications are general requirements that apply to all items, activities, and processes under the cognizance of the DOE. The requirements of the CAO QAPD sections identified as additional requirements apply to the eight key areas identified above.

Additionally, the use of a graded approach supports the proper implementation of QA program requirements for items and activities important to compliance with 40 CFR Parts 191 and 194. The graded approach, described in CAO QAPD Section 1.1.2.4 and in the CAO Management Procedure (MP) 1.2, Selection of Quality Levels and Grading of QA

Requirements, is the process by which the level of analysis, documentation, verification, and other controls necessary to comply with QA program requirements is determined.

The extent of management and QA controls applied to an item or activity varies as a function of the degree of confidence needed to achieve the desired quality. The grading process provides the flexibility to design and implement controls that best suit the facility or activity but is not intended to reduce or in any way degrade the full implementation of DOE implementing procedures requirements.

As discussed above, the DOE provides the overall QA program requirements for WIPP principal participants through the CAO QAPD. The CAO QAPD requirements are further supported and amplified by the next tier of QA program documents which include the DOE TRU Waste Characterization Quality Assurance Program Plan (TRU QAPP), the SNL Implementing Procedures, and the WID Quality Assurance Program Description. As generator sites initiate activities to ship waste, the DOE will perform audits and surveillances to qualify generator site QA programs. General QA program documents and implementing procedures are identified in Section 5.3.

In addition to identifying applicable QA requirements through QA program documents, the DOE, SNL, and WID conduct the following activities in support of the QA program:

- audits and surveillances (external and internal) to evaluate the adequacy and effectiveness of implementation of the applicable QA requirements.

- development and issuance of their own implementing documents, and the review and approval of lower-tier implementing documents.

40 CFR Part 194 stipulates that the DOE apply QA controls to eight areas. These quality affecting areas are discussed in detail in the following sections and are implemented in accordance with the QA program discussed in this chapter.

5.1.1 Waste Characterization Activities and Assumptions

The Transuranic Waste Baseline Inventory Report (TWBIR) (see Appendix BIR) is the inventory source document that provides the waste data used in the performance assessment and is presented in tabular form in Chapter 4.0. The TWBIR was prepared in compliance with the CAO QAPD and this activity was audited by the DOE QA Program on September 5 and 6, 1995. Quality assurance of the use of these waste data (by SNL) for performance assessment is addressed in Sections 5.1.4 and 5.1.7.

The Waste Acceptance Criteria (WAC) serve as the primary directive for ensuring that only waste that can be transported, handled, and disposed of in the WIPP are shipped and for ensuring that these wastes are certified by the generator and storage sites. The WAC was written and reviewed in compliance with the CAO QAPD. Each of the DOE source

documents for the WAC was written, reviewed, and approved in accordance with a DOE-approved QA program. The WAC requires generation and storage sites to enter waste characterization data into the WIPP Waste Information System (WWIS) prior to shipment.

The TRU QAPP describes the QA and quality control requirements for characterization of TRU waste coming to the WIPP. The TRU QAPP was written and reviewed in compliance with CAO QAPD requirements. The TRU QAPP includes both management and technical aspects of program implementation and the data-quality requirements that each DOE facility must meet in characterizing TRU wastes intended for disposal at the WIPP facility. The TRU QAPP also identifies the performance-based QA and quality control requirements with which each facility participating in the program must comply and the performance criteria for the preparation, review, and approval of site Quality Assurance Project Plans (QAPjPs).

The DOE verifies program implementation at participating sites through audits and assessments to ensure that WIPP waste characterization activities comply with applicable QAPjPs and standard operating procedures (SOPs).

Each generator and storage site submits a QAPjP for review and approval by the DOE/CAO. These QAPjPs identify QA and quality control provisions in response to the requirements in the TRU QAPP.

The Performance Demonstration Program evaluates the capability of generator and storage sites to perform TRU waste characterization within acceptable limits.

The following identifies the applicable quality-affecting activities, QA documents, and examples of subcontractors for the principal participants.

DOE Activities:

1. Prepare TWBIR

DOE QA Documents:

CAO QAPD	
MP 10.3	Audits
MP 3.1	Corrective Actions

SNL Activities:

Addressed in Sections 5.1.4 and 5.1.7.

WID Activities: None

WID QA Documents: None

Generator Site Activities:

1. Characterize TRU waste.

Generator Site QA Documents:

The following sites have Generator Site QAPjPs that have been approved by the DOE:

- Los Alamos National Laboratory
- Oak Ridge National Laboratory
- Lawrence Livermore National Laboratory
- Rocky Flats Environmental Technology Site
- Idaho National Engineering Laboratory
  - Site Project Office
  - Environmental Chemistry Laboratory
  - Radioactive Material Analytical Laboratory
  - Radioactive Waste Management Complex
  - Argonne National Laboratory-West

5.1.2 Environmental Monitoring, Monitoring of the Performance of the Disposal System, and Sampling and Analysis Activities

The monitoring plans required by 40 CFR § 194.42 detail the disposal system monitoring program that will be implemented during pre- and postclosure of the WIPP. This program will be implemented by the WID under the QA program described in this chapter.

SNL Activities: None.

WID Activities: Conduct performance monitoring.

WID Documents: Reference Appendices MON and EMP.

5.1.3 Field Measurements of Geological Factors, Groundwater, Meteorologic, and Topographic Characteristics

The current WIPP activities related to field measurements are conducted by the WID and include several areas. Measurements of geologic factors include surface subsidence measurements, which provide a baseline for evaluating long-term change in elevation, and an

ongoing program of underground monitoring to provide data on rock mass performance. Underground monitoring includes measurement of salt creep rates and local area fracturing. Seismic monitoring is also conducted to verify site characterization accuracy with regard to seismicity.

In 1989, the EPA reviewed and commented on much of the data collected by the DOE during the site selection and site characterization program. After this review by EPA geologists, hydrologists, and other scientists, the EPA reached conclusions regarding the adequacy of the DOE's site characterization program and the reasonableness of the site characterization activities. The EPA's independent reviews and conclusions regarding the adequacy of the data were supplemented by the independent reviews conducted by the National Academy of Sciences. Therefore, the DOE considers the adequacy of the QA programs and the data collected during site selection and site characterization to be satisfactory.

Topographic characteristics were characterized early in the site characterization phase of the WIPP project, and the QA of data from that period is addressed in detail in Section 5.4.2.2. The continuing subsidence measurements discussed above are the only current efforts in this area.

See Appendix EMP for QA controls applied to monitoring activities of groundwater well levels.

The following identifies the applicable quality-affecting activities, QA documents, and examples of subcontractors for the principal participants.

SNL Activities: None.

WID Activities:

1. Conduct geomechanical monitoring.
2. Conduct groundwater-level monitoring.
3. Conduct seismic monitoring.

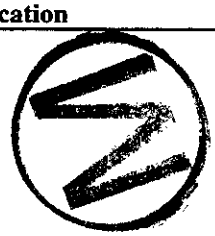
WID QA Documents:

WP 07-1	WIPP Geotechnical Engineering Quality Assurance Program
WP 02-1	WIPP Groundwater Monitoring Quality Assurance Plan

Examples of WID Subcontractors:

Servco Industrial Division Corona, California
Servco Industrial Division Costa Mesa, California

Gage Lab Corp.
New Mexico Institute of Mining and Technology
Garwin Group



Generator Site Activities: None.

5.1.4 Computations, Computer Codes, Models, and Methods to Demonstrate Compliance

Computations and computer codes used to demonstrate compliance with 40 CFR Parts 191 and 194 are controlled as described in Section 5.3.20. Models and methods are controlled by the SNL Quality Assurance Procedures (QAPs) listed below. Software supporting compliance fall into one of three categories: (1) performance assessment scientific and engineering software (PA SES), which apply to the disposal system; (2) performance assessment nonscientific and engineering software (PA NON-SES), which apply to performing calculations; and (3) nonperformance assessment scientific and engineering software (NON-PA SES), which provide parameters used in the calculations. Table 5-1 lists the compliance software according to category.

SNL QAP 9-2, Quality Assurance Requirements for the Selection and Documentation of Parameter Values Used in WIPP Performance Assessment, establishes the method for the selection and documentation of parameter values used in compliance-level performance assessment modeling performed by SNL. This document applies to categories of parameters that are relied upon to make design, analytical, operational, or regulatory-compliance decisions affecting the WIPP. The four parameter categories that are used in current compliance calculations are

1. parameters derived from experimental data (measurements collected in the field and/or in a laboratory) or that are derived through a combination of experimental data and modeling (parameters that do not fall into categories 2 through 4);

2. parameters representing the inventory of the waste to be emplaced in the WIPP, as defined in the TWBIR;

3. parameters representing physical constants; and

4. parameters that are model configuration parameters or that are assigned based on assumed correlation of properties between similar materials.

A set of screening efforts, comprised of calculations and reasoned arguments, has been identified to help define and build confidence in assumptions, data sets, and conceptual and numerical models on which the performance assessment in this application is based. Assessing the effects of features, events, and processes (FEPs) on system performance is a primary component in conceptual model development. The results of screening efforts are

Table 5-1. Computer Software and Codes

PA SES[a,c]	PA NON-SES	NON-PA SES[a]
BRAGFLO	ALGEBRACDB	COLUMN
CCDFGF	BLOTCDB[b]	EPAUNI
CUTTINGS_S	CAMCON_LIB[b]	EQ3/6
BRAGFLO_DBR	CAMDAT_LIB[b]	FMT
GENII_A[b]	CAMSUPES_LIB[b]	GRASP-INV
NUTS	CCD2STEP	GTFM-PC
PANEL	CCDFSUM	NONLIN
SECOFL2D	GENMESH	ORIGEN2
SECOTP2D	GROPECDB[b]	SANTOS
	ICSET	SPECTROM-32
	LHS	SPECTROM-41
	LHS2STEP	SWIFTII
	MATSET	THEMM
	NUCPLOT[b]	TOUGH28W
	PCCSRC[b]	
	PLT_LIB[b]	
	POSTBRAG	
	POSTGENII[b]	
	POSTLHS	
	POSTSECOFL2D	
	POSTSECOTP2D	
	PREBRAG	
	PREGENII[b]	
	PRELHS	
	PRESECOFL2D	
	PRESECOTP2D	
	RELATE	
	SDBREAD_LIB[b]	
	SPLAT[b]	
	STEPWISE[b]	
	SUMMARIZE	

[a] PA SES codes model physical processes that describe the behavior of the repository system. NON-PA SES codes provide parameters for use in the performance assessment calculation. Most NON-PA SES codes provide their parameters to the performance assessment parameters database; however, GRASP-INV and SANTOS provide their outputs directly to the performance assessment codes, as described in Appendix CODELINK.

[b] PLT_LIB, CAMCON_LIB, CAMDAT_LIB, CAMSUPES_LIB, and SDBREAD_LIB are subroutine libraries used by the performance assessment codes. GROPECDB, PCCSRC, STEPWISE, PREGENII, GENII_A, POSTGENII, BLOTCDB, NUCPLOT, and SPLAT are codes that are used to postprocess compliance certification application calculation results, such as for sensitivity analysis, plotting, and humandose calculation.

[c] Appendix CODELINK describes all the codes except those in footnote b and NON-PA SES codes described in footnote a.

used to build upon and modify, when necessary, those conceptual and numerical models employed in past WIPP performance assessments.

FEP screening is phased. Phase I FEPs are those that could potentially affect conceptual and/or numerical models. Phase II FEPs are those that could impact parameter input to the numerical models. FEP screening analysis plans for Phase I and Phase II FEPs were developed and controlled in accordance with SNL QAP 9-1. A FEP screening analysis plan is used to develop the initial screening recommendation and is also used to reevaluate FEPs whenever changes in the regulatory standard occur or in light of new or revised laboratory and field data. Additionally the DOE and SNL have provided oversight of the FEPs screening process in the form of detailed audits and surveillances. See Section 5.3.18 for the location of applicable QA records.

Experimental data are acquired through the utilization of measuring and test equipment. Software is used to record instrumentation values. This data acquisition software (DAS) is controlled in accordance with SNL QAP 19-1 and the CAO QAPD. Additionally, software used for data reduction or for performing calculations and unit conversions is also controlled in accordance with the requirements of the CAO QAPD.

The WWIS is a computer database and reporting program that will track and tally the waste that comes to the WIPP. The WWIS computer program and system are being programmed and established in compliance with CAO QAPD and WID Quality Assurance Program Description requirements.

Software used to prepare, analyze, or verify WIPP facility designs are processed and controlled in accordance with the WID Quality Assurance Program Description.

A primary component of the waste characterization process is the nondestructive assay (NDA) process. NDA software is used to collect, measure, and interpret radioisotope emissions in order to define and characterize the waste. NDA software is controlled in accordance with the requirements of the CAO QAPD.

The following identifies the applicable quality-affecting activities, QA documents, and examples of subcontractors for the principal participants.

SNL Activities:

1. Develop performance assessment calculations and computer codes.

2. Develop conceptual models and numerical codes.

3. Develop and control DAS.

SNL QA Documents:

QAP 19-1	WIPP Computer Software Requirements
QAP 9-1	Quality Assurance Requirements for Conducting Analyses
QAP 9-2	Quality Assurance Requirements for the Selection and Documentation of Parameter Values Used In WIPP Performance Assessment
QAP 9-4	Quality Assurance Requirements for the Database Management of Parameter Values Used In WIPP Performance Assessment
QAP 9-5	Conducting and Documenting Routine Calculations

SNL Subcontractors:

Subcontractors that directly support performance assessment and conceptual model work follow the SNL QA program.

WID Activities: Develop and control WIPP site design and the WWIS software.

WID Documents:

WP 16-0	Software Management Plan
WP 16-117	WIPP Computer Software Quality Assurance

Generator Site Activities: Develop and control NDA software.

Generator Site Documents: Documents are site specific.

5.1.5 Expert Judgment Elicitation

No expert judgment activities have been identified.

SNL Activities: None.

WID Activities: None.

Generator Site Activities: None.

5.1.6 Design of the Disposal System and Actions Taken to Ensure Compliance with Design Specifications

5.1.6.1 WIPP Facility

Disposal system items and processes were designed using sound engineering practices, scientific principles, and applicable industry and government standards. System design descriptions, conceptual design reports, performance requirements, and regulatory requirements are included in new designs. Designs are initiated using a classification system that ensures that the proper level of design and QA requirements is employed to meet design and testing requirements.

NQA-1 Supplement 3S-1 requires that design verification be performed to verify the adequacy of design. Specifically,

> Design control measures shall be applied to verify the adequacy of design, such as by one or more of the following: the performance of design reviews, the use of alternate calculations, or the performance of qualification tests.

At the WIPP, initial design was done by Bechtel as the architectural and engineering contractor. Design verification was accomplished by a combination of Supplement 3S-1 methods.

5.1.6.2 Original Repository Design

After Bechtel turned systems over to the DOE, an extensive and comprehensive program of start-up testing was initiated by the DOE. The program tested systems and components against the requirements specified in design documents. This testing meets the requirements of Supplement 3S-1 for design verification. Start-up testing is currently described in WID Implementing Procedures WP 03-001 through WP 03-006 and has been controlled since its inception by appropriate predecessor procedures.

Brookhaven National Laboratory performed independent calculations of important design parameters (for example, structural steel stress calculations) using methods and engineering personnel independent of the original Bechtel design. This task was documented in a report commissioned by the Office of Environmental Safety and Health (EH-30) titled, "Waste Isolation Pilot Plant Safety Evaluation Report" dated August 1989, including two subsequent addenda, the last of which closed all action items, concluding the Brookhaven effort.

The combination of qualification testing and independent calculations meets the requirements of Supplement 3S-1 for design verification of the WIPP facility.

Design verification ensures compliance with identified requirements. The WID Quality Assurance Program Description (see Appendix QAPD) establishes actions and responsibilities to verify the adequacy of a design. Design controls specified in the WID Quality Assurance

Program Description are in place to track and verify the design process. These controls ensure that new designs and design changes are subject to specifications commensurate with the original design and verify that the design analyses are still valid. All changes are approved by technically qualified individuals. See Section 5.3.1.8 for the location of applicable QA records.

SNL Activities: None.

WID Activities: Design Configuration Control

WID Documents:

WP-09-9

Generator Site Activities: None.

5.1.6.3 Repository Sealing System

Design work for the repository sealing system was conducted under the SNL QA program. Two procedures are especially relevant to design work. QAP 3-1, Managing Design and Analysis Contracts, and QAP 3-2, Verification of Design Adequacy, applied to the development of the repository sealing system.

The repository sealing system design is summarized in Section 3.3.1 and Appendix SEAL. This report was extensively reviewed by DOE, SNL, WID, and CAO Technical Assistance Contractor personnel as well as independent design reviewers. All comments were resolved. Audits or surveillances were performed on each of the primary contractors. In all cases, QA requirements were properly identified and were effectively implemented. The DOE performed oversight activities to evaluate the adequacy and effectiveness of implementation of the SNL QA program as it relates to the SNL Sealing Systems Program. These oversight activities determined that the QA program was effectively implemented for the repository sealing system program, including the activities of the participating subcontractors. The DOE also determined that the procurement document process used to pass down QA requirements to subcontractors was adequate.

The following identifies the applicable quality-affecting activities, QA documents, and examples of subcontractors for the principal participants.

SNL Activities:

1. Evaluate sealing systems designs.

SNL QA Documents:

QAP 3-1	Managing Design and Analysis Contracts
QAP 3-2	Verification of Design Adequacy

Examples of SNL Subcontractors:

RE/SPEC, Inc.
Parsons-Brinkerhoff Energy Services, Inc.
Intera, Inc.

5.1.7 Collection of Data and Information to Support Compliance Application(s)

Data and information collected from experimental programs serve multiple purposes in the WIPP project: to collect data about the chemical or physical characteristics of the site; to collect data that allow estimation of the behavior of the wastes and system during the 10,000-year regulatory period; or to develop data to be used in testing alternative conceptual models and selecting the most appropriate model(s) of engineered system behavior for use in the performance assessment modeling process.

SNL Activities:

1. Collect scientific data in the following areas: rock mechanics, actinide source term, chemical transport, disposal room, gas generation, non-Salado flow and transport, Salado hydrology and transport.

SNL QA Documents:

QAP 20-1	Preparing, Reviewing, and Approving Test Plans
QAP 20-2	Preparing, Reviewing, and Approving Scientific Notebooks
QAP 20-3	Qualification of Existing Data
QAP 20-4	Preparing, Reviewing, and Approving Field Operations Plans
QAP 20-5	Preparing, Reviewing, and Approving Technology Development Descriptions
QAP 20-6	Preparing, Reviewing, and Approving Experimental Plans
QAP 2-1	Qualification and Certification of Personnel
QAP 4-1	WIPP Supplier Quality Assurance Program Requirements
QAP 5-2	Preparing, Reviewing, and Approving Drawings and Sketches
QAP 5-3	Preparing, Reviewing, and Approving Technical Operating Procedures
QAP 9-1	Quality Assurance Requirements for Conducting Analyses
QAP 13-1	Conducting and Documenting Sample Control
QAP 13-2	Chain-Of-Custody

Examples of SNL Subcontractors:

Baker Oil Tools
RE/SPEC, Inc.
Intera, Inc.
University of California
Core Laboratories, Inc.
University of New Mexico
University of Nevada Las Vegas
Northwestern University
Pacific Northwest Laboratory
Rust Geotech, Inc.
Argonne National Laboratory
Florida State University
Lovelace Inhalation Toxicology Research Institute

WID Activities: None.

Generator Site Activities: None.

5.1.8 Other Systems, Structures, Components, and Activities Important to the Containment of Waste in the Disposal System

At this time, the DOE has not identified any other systems, structures, components, or activities important to waste isolation in the disposal system that require controls to be applied as described in the CAO QAPD.

5.2 Program History

WIPP work has been performed under nuclear QA programs from 1977 to the present throughout several project phases. All DOE programs have been required to work under nuclear QA programs since the early 1980s. However, during the past 19 years, there have been changes in the scope, purpose, and regulatory responsibility for the WIPP. Changes in the state of development of the WIPP have resulted in corresponding changes in the QA program requirements. It is important to understand the evolution of the QA requirements applicable to the WIPP when assessing QA program adequacy.

From 1975, when the DOE first commenced site investigations, until late 1977, there were no DOE QA requirements imposed; no nuclear QA programs were applied to WIPP geotechnical data collection activities during this siting phase. Drilling and other related site activities were controlled by recognized industry drilling and geotechnical practices. Data collected during this phase were limited to seismic, geophysical, and hydrologic data derived from surface surveys and borehole cores and logs.

A QA program was established in late 1977 that was based on 10 CFR Part 50, Appendix B, which was applicable to engineering and construction activities that were important for the protection of public health and safety. By late 1978, DOE policy refinements had expanded the QA program to incorporate the requirements of American National Standards Institute (ANSI)/ASME N45.2 (the precursor to NQA-1) and had extended the applicability of the program to subsurface investigation activities and all earth science activities furnishing information on the possibility of radionuclide release into the biosphere.

Public Law 96-164, passed by Congress in late 1979, authorized the DOE to proceed with the WIPP construction project as a research & development (R&D) facility to demonstrate the safe disposal of the radioactive wastes resulting from U.S. defense activities exempted from regulation by the Nuclear Regulatory Commission (NRC). The WIPP QA program was revised to meet the DOE/Albuquerque Operations Manual (Chapter WIPP), which was equivalent to the requirements of ANSI/ASME NQA-1-1979.

Over the next 12 years (1980 to 1992), the WIPP QA program was revised to reflect the changes resulting from DOE and WIPP management reorganizations and the changes in upper-tier QA program documents NQA-1-1979 to NQA-1-1989 and DOE Orders 5700.6A, 5700.6B, and 5700.6C.

The following summarizes the QA program requirements in force during the various phases of the WIPP development.

1975-1977	Siting Phase. Recognized potash and petroleum industry drilling and geotechnical practices formed the basis of the QA effort.
1977-1980	Site and Characterization Phase. The earliest WIPP QA programs were based on the nuclear power plant QA requirements of 10 CFR Part 50, Appendix B, and ANSI/ASME N45.2 (the precursor to NQA-1). The ASME NQA-1 standards were issued in 1979 and began to be incorporated into the WIPP QA program.
1980-1983	Site and Preliminary Design Validation Phase. NQA-1 requirements, as suggested by DOE Order 5700.6A, were the basis for WIPP QA programs.
1983-1989	Construction Phase. NQA-1 continued to be recognized as the preferred standard for QA through DOE Order 5700.6B.
1989-1993	Test Phase. The WIPP QA programs began to incorporate program elements from DOE Order 5700.6C while retaining the requirements of NQA-1.

1994-Present Preoperational Phase. The current requirements are taken from 40 CFR Part 194, which incorporates the NQA requirements referenced in Section 5.1, DOE Order 5700.6C, and 10 CFR Subpart 830.120.

5.3 Adequacy

The adequacy of a QA program is measured by the extent to which QA requirements, both external and internal, are incorporated in QA program documents and in implementing procedures. An adequate QA program contains detailed instructions for each process or activity in a manner that provides traceability, replication, and accountability.

From May 1993 to March 1994, DOE Headquarters, Division of Waste Isolation Pilot Plant Program, Office of Environmental Management (EM-342), assessed the quality of the WIPP data acquisition process for performance assessment. The assessment was conducted to determine whether these data were collected under approved QA programs that met DOE requirements or whether acceptable alternative methods were used to ensure data quality in the absence of approved QA programs. The team concluded that the DOE needed to reevaluate all experimental program data used to support performance assessment.

The adequacy of the current DOE QA program is ensured by passing down requirements (see Section 5.3.5) to principal participants (SNL, WID, and the generator sites) with the directive that applicable requirements then be passed down to lower-tier organizations. The DOE QA Manager assesses the adequacy of QA program documents for the DOE and the principal participant organizations. The responsibility for oversight of QA program documents for lower-tier organizations and contractors is delegated to the principal organizations. Lower-tier organizations prepare, issue, and maintain QAPs or QAPjPs, as appropriate, for specific projects. Figure 5-1 illustrates the hierarchy of QA program documents for 40 CFR Parts 191 and 194 compliance activities, and Figure 5-2 illustrates the hierarchy of QA program documents for waste characterization activities.

Adequacy of QA program requirements are initially verified by the DOE through the review of lower-tier QA program documents prior to their implementation by the organizations. These document reviews focus on the proper transmission of requirements into lower-tier documents. These documents are not approved for use until their adequacy has been determined to be acceptable. Formal document review forms are used to document this process (see Section 5.3.18 for discussion of QA records).

The audits, surveillances, and management assessments conducted by DOE, SNL, WID, and the generator sites at the various organizational levels also assess the adequacy and effectiveness of those documents applicable to the assessed areas. Any inadequacies in QA program documents that are identified during audits or other assessments are documented and tracked until the condition has been corrected, verified, and closed (refer to Section 5.3.17).

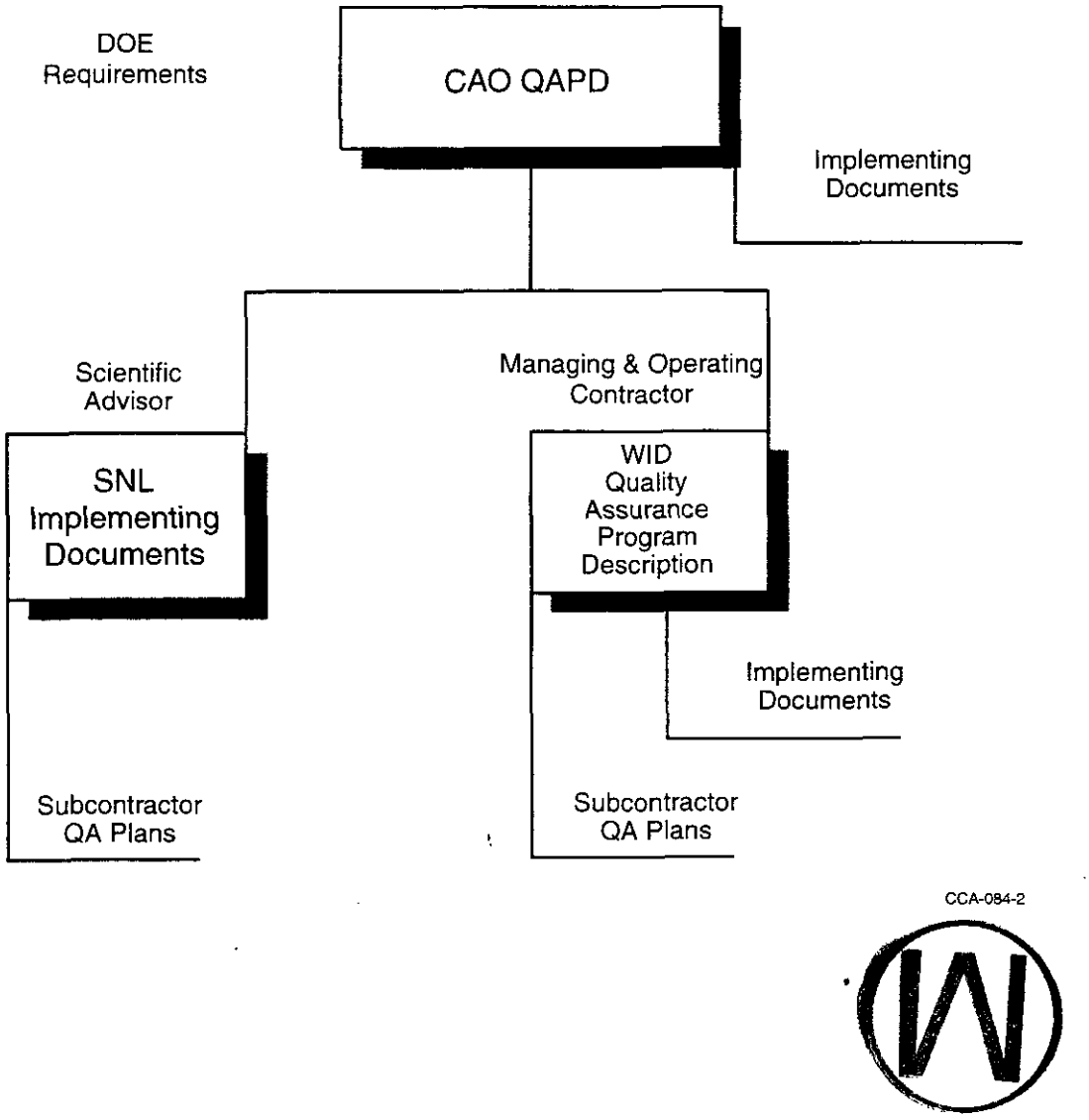


Figure 5-1. Document Hierarchy for 40 CFR Part 194 Compliance

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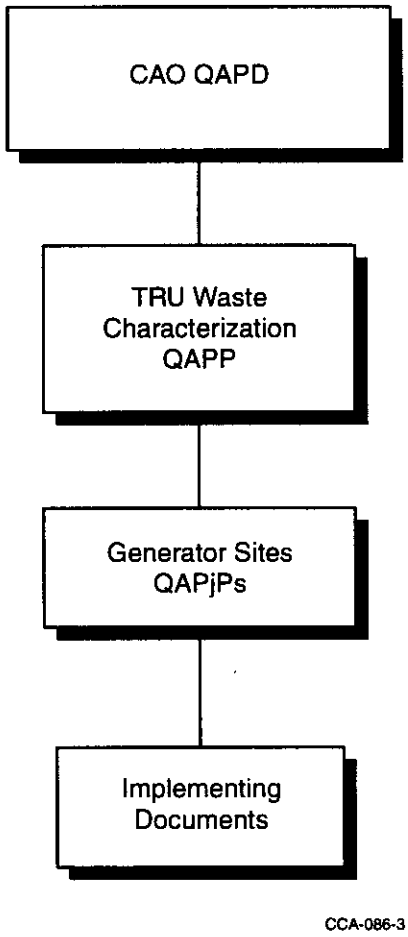

Figure 5-2. QA Document Hierarchy for Waste Characterization

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The DOE has also prepared matrices tracing the applicable NQA requirements referenced in Section 5.1 to the CAO QAPD. WID and SNL likewise are required to prepare and maintain matrices that identify all current and applicable documents that serve to implement the applicable CAO QAPD requirements. These matrices provide sufficient detail to identify documents that implement each applicable CAO QAPD requirement and are submitted to the DOE QA Manager for review. The matrices are required to be updated as implementation procedures are revised. The matrices are designated to demonstrate that the DOE, SNL, and WID QA programs are adequate and address all applicable requirements.

The DOE, SNL, and WID perform assessments that include the review of implementing documents for adequacy. These assessments verify that all appropriate upper-tier requirements have been addressed. These assessments (see Section 5.4) and the resulting corrective actions have determined that the DOE, SNL, and WID QA programs have adequately included upper-tier requirements. Ongoing audits and surveillances by these organizations ensure that QA programs continue to address the requirements adequately.

5.3.1 QA Program Description

The current CAO QAPD addresses QA requirements from multiple sources. The present DOE QA program is described in the CAO QAPD.

5.3.2 Organization and Interfaces

The DOE and WIPP organizational structures, primary interfaces, functional responsibilities, and levels of authority for activities affecting quality are described and documented in the CAO QAPD. The organizational interfaces are illustrated in Figure 5-3.

DOE Headquarters: Within the DOE headquarters, the Office of Environmental Management (EM-1) is responsible for the overall management of the DOE waste management programs. Responsibilities of the Office of Waste Management (EM-30) include establishing the DOE policy and issuing policy guidelines, setting the overall budget, and integrating TRU-waste activities with other waste-type activities.

CAO Manager: The CAO Manager reports directly to the DOE Assistant Secretary, Office of Environmental Management (EM-1), and has the responsibility for management of the WIPP, including the overall responsibility for the DOE QA program.

The DOE QA Manager has been delegated the authority for execution of the QA function by the CAO Manager. The DOE QA Manager has the authority and overall responsibility to independently assess the effective implementation of the DOE QA Program, within both the DOE organization and participant organizations. The DOE QA Manager reports through the Office of Program Support and Assurance for administrative matters. Participant QA

management has the authority and responsibility to independently assess the effective implementation of the DOE QA Program, within both the participant organization and lower-tier organizations.

Responsibilities of the WIPP principal participants are as follows:

- The DOE is responsible for WIPP QA program development, implementation, and assessment. The DOE reviews and approves the WIPP-related QA program documents of SNL, WID, and the TRU waste generator sites. The DOE performs QA audits and surveillances of these organizations to verify compliance to QA program requirements.

- The WID is responsible for establishing and implementing the QA program for the WIPP site operation and maintenance, for monitoring the site environment, and for receipt of waste.

- SNL is responsible for establishing and implementing QA programs for activities involved in the development, confirmation, and verification of models used to simulate long-term repository performance. SNL's QA program covers research, experiments, and tests to collect the data needed for input to the models.

- The TRU waste generator sites are responsible for establishing and implementing a QA program for TRU and TRU-mixed waste characterization and for the implementation of waste certification programs.

5.3.3 QA Program (Grading, QA Program Documents, Qualification and Training, and Management Assessment)

The CAO QAPD reflects the WIPP QA requirements, lists sources of program requirements and guidance, and describes the organizational interfaces and responsibilities. Independent assessors are responsible for measuring and evaluating the adequacy and effectiveness of implementation of the DOE QA program throughout the DOE and participant organizations.

5.3.3.1 Grading

The rigor of QA controls is commensurate with, but not limited to, the following criteria:

- function or end-use of the item,

- importance and end-use of the data generated,

- probability of failure,

- complexity or uniqueness of the design, fabrication, or implementation,

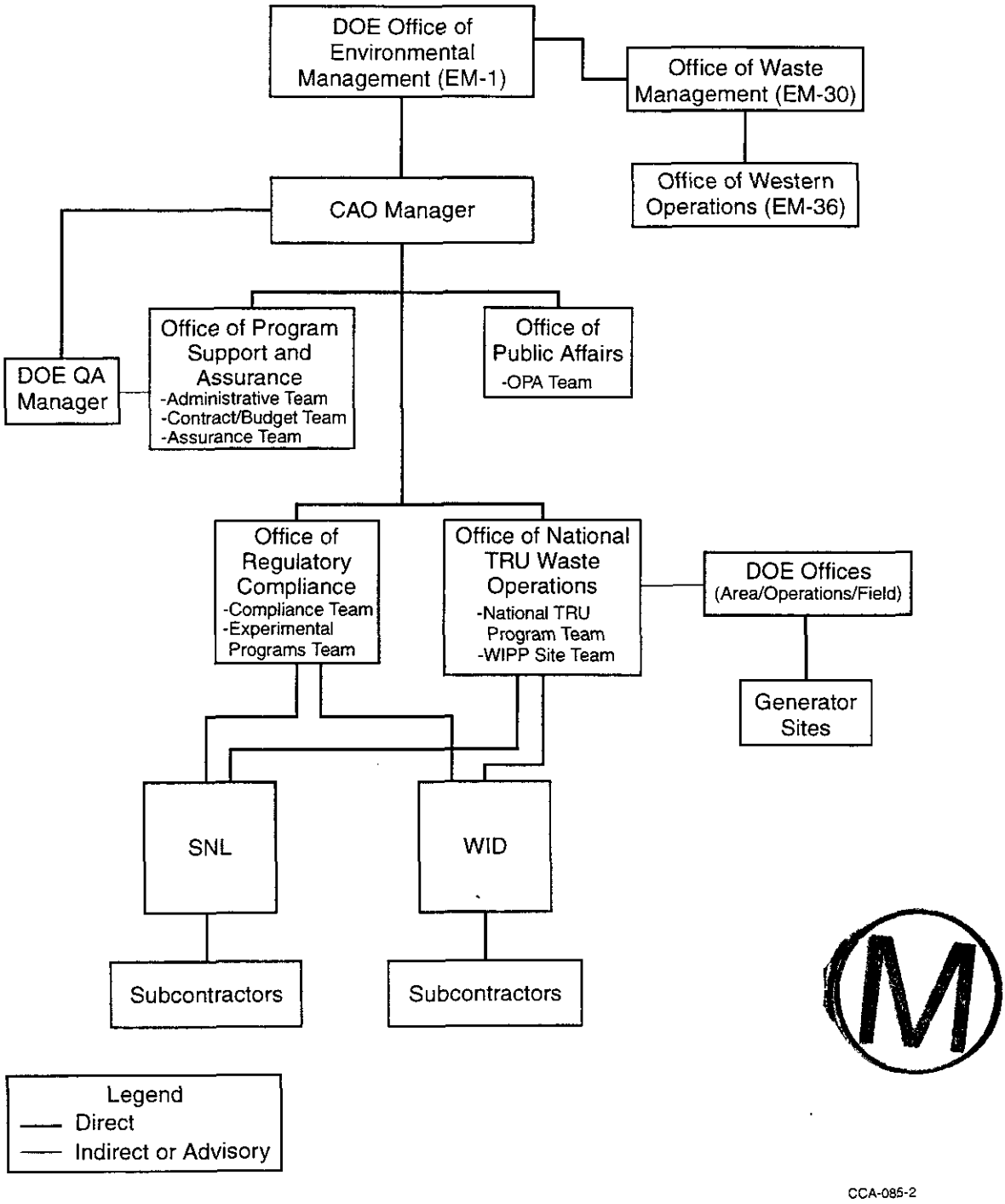

Figure 5-3. Organizational Interfaces

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- reproducibility of the results,
- history of the item or service quality,
- necessity for special controls or processes, and
- ability to demonstrate functional compliance with applicable regulations.

DOE Implementing Document:

MP 1.2	Selection of Quality Levels and Grading of QA Requirements

SNL Implementing Documents:

QAP 2-4	Preparing, Reviewing, and Approving Quality Assurance Project Plans
QAP 2-7	Preparing, Reviewing, and Approving Activity Authorizations

WID Implementing Document:

WP13-QA3501	Graded Approach

5.3.3.2 QA Program Documents

The DOE and principal participants implement the requirements of the CAO QAPD internally through QA program documents and implementing procedures prepared and maintained by their organizations (see the document hierarchy illustrated in Figures 5-1 and 5-2).

WID has issued and maintains a Quality Assurance Program Description (see Appendix QAPD), approved by the DOE, that incorporates the requirements of the CAO QAPD. SNL is currently working directly in accordance with the CAO QAPD requirements. The TRU QAPP has been prepared and is maintained by the DOE to supplement CAO QAPD requirements and prescribe program-specific QA and quality control provisions applicable to the waste generator sites for characterization of TRU waste.

Documents implementing the requirements of the DOE QA Program elements are

WIPP QA Program Documents:

CAO Quality Assurance Program Document
CAO TRU Waste Characterization Quality Assurance Program Plan
WID Quality Assurance Program Description
Generator/Storage Site Quality Assurance Project Plans

5.3.3.3 Qualification and Training

Personnel performing work are qualified and capable of performing their assigned tasks. Participants have established formal methods for the evaluation, selection, indoctrination, training, and qualification of personnel performing work that comply with the requirements of the CAO QAPD.

DOE QA Program Implementing Document:

MP 2.1	Training and Qualification

SNL QA Program Implementing Documents:

QAP 2-1	Qualification and Certification of Personnel
QAP 2-2	Orientation and Training Program
QAP 2-3	Qualification and Certification of Quality Assurance Audit Personnel

WID QA Program Implementing Documents:

Quality Assurance	
WP 13-QA.02	Quality and Regulatory Assurance Department Training Program
WP 14-TR	WIPP Technical Training Procedures Manual

5.3.3.4 Management Assessments

Management personnel of DOE participants perform assessments of the portions of the program for which they are responsible to assist in ensuring effective implementation of QA requirements.

DOE Implementing Document:

MP 9.1	Management Assessment

SNL Implementing Document:

QAP 2-8	Conducting and Documenting Management Assessments

WID Implementing Document:

MP 1.20	Assessments

5.3.4 Design Control

Design work, including changes, incorporates appropriate requirements such as general design criteria and design bases. Design interfaces are identified and controlled. The adequacy of design products is verified by individuals or groups independent from those who perform the work. Verification is completed prior to approval and implementation of the design. Control of design functions also extends to design reviews and qualification testing.

DOE Implementing Documents:

Not applicable.

SNL Implementing Documents:

QAP 3-1	Managing Design and Analysis Contracts
QAP 3-2	Verification of Design Adequacy

WID Implementing Documents:

WP 09-9	Configuration Management Plan
WP 09-CN3007	Engineering and Design Document Preparation and Change Control
WP 09-010	Design Development Testing
WP 09-CN3018	Design Verification
WP 09-CN3031	Engineering Calculations

5.3.5 Procurement Document Control

Procurement documents include the following, as applicable: scope of work; technical requirements, design bases, appropriate codes, standards, regulations, procedures, instructions, tests, inspections, hold points, and acceptance criteria; QA requirements; and documentation requirements.

The requirements of the CAO QAPD are transmitted from the DOE to its contractors. In addition, each contractor is required to transmit the appropriate CAO QAPD requirements to its subcontractors. Audits and surveillances are performed on quality-affecting vendors and subcontractors to verify that the requirements are being met.

Selected procurement documents are reviewed by knowledgeable and qualified technical and QA representatives and are approved by the appropriate management.

DOE Implementing Document:

MP 7.1	QA Requirements for Procurement of Goods and Services

SNL Implementing Document:

QAP 4-1	WIPP Supplier Quality Assurance Program Requirements

WID Implementing Document:

WP 13-QA3012	Supplier Evaluation/Qualification

5.3.6 Instructions, Procedures, and Drawings

Activities affecting quality are prescribed by and performed in accordance with the appropriate established, documented, and approved instructions, procedures, or drawings. Instructions, procedures, and drawings are developed, reviewed, and approved by technically competent personnel. They contain specific information appropriate to the work to be performed, including the following required elements:

- responsibilities,
- program requirements,
- description of the work,
- acceptance criteria,
- prerequisites, limits, precautions, process parameters, and environmental conditions,
- special qualifications and training requirements,
- verification and hold points,
- methods for demonstrating that the activity was performed as required, and
- identification and classification of QA records to be generated.

DOE Implementing Documents:

MP 4.1	Preparation and Maintenance of CAO Procedures
MP 4.4	Document Preparation and Control

SNL Implementing Documents:

QAP 5-1	Preparing, Reviewing, and Approving Quality Assurance Procedures and Abstracts
QAP 5-2	Preparing, Reviewing, and Approving Drawings and Sketches

QAP 5-3	Preparing, Reviewing, and Approving Technical Operating Procedures

WID Implementing Documents:

WP 15-PS.1	Management Control Procedures Writer's Guide
WP 15-PS.2	Technical Procedures Writer's Guide
WP 15-PS.3002	Review, Approval, and Cancellation of WID Procedures

5.3.7 Document Control

Documents affecting quality that specify requirements, prescribe processes, or establish designs important to compliance with 40 CFR Parts 191 and 194, such as instructions, procedures, drawings, test plans, and management plans, are controlled to ensure that correct documents are being employed. Prior to approval and issuance, controlled documents are reviewed by competent personnel using specified criteria for adequacy, correctness, and completeness. Review comments are formally resolved. Review comment documentation is maintained by the originating organization. Responsibilities for document preparation are specified, and the documents are controlled during the preparation, review, approval, issuance, use, and revision processes.

DOE Implementing Documents:

MP 4.2	Document Review
MP 4.4	Document Preparation and Control

SNL Implementing Documents:

QAP 6-1	Document Control System
QAP 6-2	Preparing, Reviewing, and Approving Technical Information Documents
QAP 6-3	Conducting and Documenting Reviews of Documents

WID Implementing Documents:

WP 15-PS3103	Document Distribution
WP 09-CN3022	Engineering Document Control and Distribution

5.3.8 Control of Purchased Items and Services

Controls are established to ensure that procured items and services meet applicable technical and QA requirements and performance specifications. Prospective suppliers are evaluated and selected on the basis of documented criteria. Procurement controls are in place to ensure that

approved suppliers continue to provide acceptable items and services. These procurement controls extend to the following areas:

- procurement planning,
- supplier selection and performance evaluation,
- proposal and bid evaluation,
- procurement documents,
- source verification and supplier certificate of conformance,
- receipt inspections and post-installation testing,
- control of supplier nonconformances, and
- commercial grade items.

DOE Implementing Documents:

MP 7.1	QA Requirements for Goods and Services

SNL Implementing Documents:

QAP 4-1	WIPP Supplier QA Program Requirements

WID Implementing Documents:

WP 15-609	Procurement Process
WP 13-QA10003	Quality Assurance Inspections

5.3.9 Identification and Control of Items

Items used in systems supporting compliance with 40 CFR Parts 191and 194 are identified and controlled. Processes have been established to identify, control, and maintain items from receipt through installation and end-use. Item identification ensures the appropriate traceability as specified in design documents, codes, standards, specifications, and implementing procedures. Identification is placed on the item or is located in documents traceable to the item. Acceptable methods and materials for characteristics and markings are prescribed, and the authority for applying and removing status characteristics and markings is specified.

WID Implementing Documents:

WP 15-PM3517	Stores Inventory Control

5.3.10 Control of Processes

Work processes that support compliance with 40 CFR Parts 191 and 194 are performed in accordance with established, approved, and documented technical standards and administrative controls. Work is planned, authorized, and accomplished under controlled conditions using approved instructions, procedures, drawings, or other appropriate means. Implementing procedures are developed, reviewed, and approved by technically competent personnel and contain information, including the following elements, appropriate for the work being performed:

- prerequisites, limits, precautions, process parameters, and conditions necessary for accomplishment of the process, including calibration requirements;
- special qualifications and training requirements; and
- acceptance criteria, including applicable codes and standards.

Personnel performing work are responsible for complying with appropriate instructions, which include or reference procedure, personnel, and equipment qualification requirements. Handling, storage, cleaning, shipping, and other means of preserving, transporting, and packaging of items are conducted in accordance with established work and inspection procedures, shipping instructions, or other specified documents.

DOE Implementing Documents: None

SNL Implementing Documents:

QAP 9-1	QA Requirements for Conducting Analyses
QAP 9-2	QA Requirements for the Selection and Documentation of Parameter Values Used in WIPP Performance Assessment
QAP 9-4	QA Requirements for the Database Management of Parameter Values Used in WIPP Performance Assessment
QAP 9-5	Conducting and Documenting Routine Calculations

WID Implementing Documents:

WP 13-QA10001	Liquid Penetrant Examination–Visible, Solvent–Removable Penetrant Technique
WP 13-QA10002	Visual Inspection
WP 13-QA10004	Magnetic Particle Examination

WP 13-QA10005	Penetrant Examination–Visible, Water–Washable Penetrant Technique

5.3.11 Inspection

Inspections determine acceptance or rejection of a process, product, or service. Inspection documentation for DOE participants includes the following:

- approved implementing procedures;
- identification of the items and processes to be inspected, the parameters or characteristics to be evaluated, the techniques to be used, the acceptance criteria, and any hold points;
- the acceptance of items and processes by qualified and authorized persons; and
- identification of any equipment to be used, including the equipment identification number and the calibration due date.

DOE Implementing Documents: None

SNL Implementing Documents: None

WID Implementing Documents:

QAI 2-5	Qualification and Certification of Inspection Personnel
WP 13-007	Hold Tag Issuance
WP 13-013	Inspection Points

5.3.12 Test Control

Tests determine the capability of an item to meet specified requirements by subjecting the item to a set of operating conditions. Tests included as part of scientific investigations are conducted in accordance with the QA methods described in Section 5.3.21. Test planning includes the following:

- procedures and related requirements documents used to control and perform the test (for example, test plans);
- identification of the item to be tested, test requirements, and acceptance criteria;
- identification of the measuring and test equipment (including the type, range, accuracy, and tolerance);

- test prerequisites and provisions to ensure that all test requirements and objectives have been met;
- any designated hold points; and
- recording methods used to collect and record the data.

In addition to the above, documentation of test results identifies the test date, the personnel performing the test, the data collected and the results of the tests, the actual measuring and test equipment used, the actions taken when unexpected results are obtained, and the persons evaluating the test results. A qualified person evaluates the results to ensure that all test requirements are met.

DOE Implementing Documents: None

SNL Implementing Documents: None

WID Implementing Documents:

WP 03-001	Preparation, Release, and Cancellation of Start-up Test Procedures

5.3.13 Control of Measuring and Test Equipment

The control system for monitoring, measuring, testing, and using data collection equipment prevents the use of suspect and out-of-tolerance equipment in activities that could affect quality. If such equipment is inadvertently used, the control system provides for segregation of the defective equipment and evaluation of the data obtained using the out-of-tolerance or defective equipment. In addition, the calibration system includes provisions for

- using documented procedures that describe the calibration system and the detailed calibration methods;
- using qualified calibration services that meet the requirements of the CAO QAPD;
- developing a schedule for the initial calibration of measuring and test equipment and for periodic recalibration to ensure acceptable reliability;
- documenting the results of the calibration;
- labeling and identifying all measuring and test equipment to provide information needed for recalibration and to ensure that adequate standards are traceable to the measuring and test equipment;

- identifying any needed precautions for handling, storing, and transporting equipment to prevent damage or out-of-tolerance conditions;

- providing the environment needed to calibrate the measuring and test equipment and to take measurements; and

- using calibration standards traceable to nationally recognized standards or physical constants. (When such standards do not exist, the bases for calibration are documented.)

DOE Implementing Documents: None

SNL Implementing Document:

QAP 12-2	WIPP Calibration Laboratory Quality Assurance Program

WID Implementing Document:

WP 10-AD0.1	Metrology Program

5.3.14 Handling, Storage, and Shipping

Items supporting compliance with 40 CFR Parts 191 and 194 are handled, stored, and shipped using approved and documented methods designed to prevent damage or loss and to minimize deterioration. Precautions taken include the following:

- preparing procedures that describe the methods to be applied, the proper controls, and the records to be generated;

- using and documenting special equipment and environments when required; and

- creating and maintaining markings and labeling that identify the item, any special environments required, and the need for any other special controls as necessary.

DOE Implementing Documents: None

SNL Implementing Documents: None

WID Implementing Documents:

WP 15-525	Preparation and Processing of Shipping Authorization
WP 15-PM3500	Equipment Held for Future Projects
WP 15-PM3517	Spares Inventory Control

5.3.15 Inspection, Test, and Operating Status

Authorized persons apply and remove status indicators on items, as appropriate. These status indicators help prevent inadvertent installation, use, or operation of items that have not passed the required inspections or tests. The specific status indicators, their use, and the authority to apply or remove them are delineated in applicable QA plans or implementing procedures. Status indicator processes include provisions for

- using and maintaining status indicators to indicate if an item has completed the required inspections or tests and to indicate the operating status of items;
- placing status indicators on the items or in documents traceable to the items;
- using tags, markings, labels, stamps, travelers, inspection and test records, or other appropriate means as status indicators; and
- using and maintaining a lockout/tagout system for setting and maintaining specific conditions.

DOE Implementing Documents: None

SNL Implementing Documents: None

WID Implementing Document:

WP 13-007	Hold Tag Issuances

5.3.16 Control of Nonconforming Items

Items that do not conform to specified requirements are controlled to prevent their installation, use, or operation prior to correction. Nonconforming items may be identified at any time by anyone, although they are identified primarily during inspections, tests, and operations.

When appropriate, further work on the item is halted by senior management until the appropriate actions have been taken and have been verified. The nonconformance control process is documented in applicable QA plans or implementing procedures. The process in place to control nonconforming items includes provisions for

- identifying nonconforming items, using methods that do not adversely affect the end-use of the item;
- segregating nonconforming items, when practical;
- assigning the responsibility to halt or control further work on the item;

- evaluating and dispositioning nonconforming items by authorized persons; and

- reexamination of the item to verify acceptability after the item has been reworked or repaired, and subsequent dispositioning of the item.

In addition, suppliers are required to identify items that do not meet the requirements of the procurement documents, to document the nonconforming condition and the proposed disposition, and to provide technical justification for the disposition. The purchaser evaluates and dispositions the supplier recommendations and verifies implementation of the disposition.

WID Implementing Document:

WP 13-007	Hold Tag Issuance

5.3.17 Corrective Action

All personnel are responsible for identifying conditions adverse to quality. Conditions adverse to quality are evaluated, the appropriate corrective action is defined and taken, and the completion and effectiveness of corrective action is verified. If a condition adverse to quality is determined to be significant, the root cause is determined and appropriate actions are taken to preclude recurrence. A significant condition adverse to quality is defined as a condition that, if not corrected, could have a serious effect on compliance with 40 CFR Parts 191 and 194.

When appropriate, further work on the item, activity, or process is halted by senior management until the appropriate actions have been taken and verified. The corrective action process for conditions adverse to quality is documented in appropriate QA plans and implementing procedures. The process used to identify and control conditions adverse to quality includes provisions for

- identifying and documenting conditions adverse to quality;

- assigning the responsibility to halt or control further work on the item, activity, or process;

- evaluating and dispositioning conditions adverse to quality by authorized persons;

- notifying management of the results of evaluations of significant conditions adverse to quality;

- preparing corrective action plans that include remedial actions, investigative actions, root cause determinations, expected completion dates, and responsible persons, as appropriate;

- evaluating the corrective action plans and verifying the completion and effectiveness of the corrective actions taken; and

- assigning unique numbers to each Correction Action Request generated, maintaining a log of the specific status of each request until it is finally closed, and regularly reporting and reviewing the status of all open corrective action requests.

Minor software problems are documented by software problem reports or other resolution mechanisms as discussed in Section 5.3.20. If a software problem is determined to be a condition adverse to quality, it is documented and resolved as described in this section.

DOE Implementing Document:

MP 3.1	Corrective Action

SNL Implementing Documents:

QAP 16-1	Trend Analysis Program
QAP 16-2	Conditions Adverse to Quality and Corrective Action
QAP 16-3	Root Cause Analysis

WID Implementing Documents:

WP 12-135	Root Cause Analysis Investigation Procedure
WP 13-QA3003	Corrective Actions Program
WP 13-QA.04	Quality and Regulatory Assurance Department Administrative Program

5.3.18 QA Records

Records generated under the QA program are specified, prepared, reviewed, approved, maintained, and disposed of in accordance with the CAO QAPD. The CAO QAPD provides reference for DOE participants in meeting QA records management requirements. Records provide evidence of the work quality and evidence that the QA program has been followed in work performance. The records management system is documented in appropriate QA plans and implementing procedures. The records management process includes provisions for

- identifying those documents that become QA records and identifying the organizations responsible for submitting the QA records to the records system;

- generating records that are legible, accurate, and complete;

- protecting documents that will become QA records during generation and use;

- authenticating the QA record;
- indexing QA records to ensure retrievability and to identify record retention times and the location of the record within the records system;
- classifying QA records as either lifetime, nonpermanent, or postclosure;
- designating the organization that receives and controls QA records;
- storing QA records, using methods and facilities that meet the requirements of the CAO QAPD; and
- correcting, replacing, restoring, and substituting records for any incorrect, lost, or damaged QA records in the QA records system.

The generation and retention of QA records are controlled by appropriate QA plans or records-related procedures. These records are maintained by the proper organization for approved disposition. DOE QA records are retained in the document services storage facility in Carlsbad, New Mexico. SNL QA records are retained in the SNL WIPP Central Files located in Albuquerque, New Mexico, and Carlsbad. WID QA records are retained in the WID WIPP Files located in Carlsbad. Generator site QA records are retained in NQA-1 storage facilities at each site.

DOE Implementing Document:

MP 4.5	Records Management

SNL Implementing Documents:

QAP 17-1	WIPP Quality Assurance Records Source Requirements
QAP 17-2	WIPP Quality Assurance Records Center Operations

WID Implementing Documents:

WP 15-PR	Records Management Plan
WP 15-PR3001	*Generation, Storage, and Control of Active WIPP Records*
WP 15-PR3002	Development and Implementation of Records Inventory and Disposition Schedule
WP 15-PR3003	Disposal of Nonpermanent Records
WP 15-PR3005	Records Transfer and Retrieval

5.3.19 Audits and Surveillances

Audits and surveillances verify that the various QA programs adequately reflect the requirements of the CAO QAPD and that they are being effectively implemented.

The DOE has designated specific meaning to the assessment terms adequacy, implementing, and effectiveness. Adequacy refers to the flowdown of requirements contained in upper-tier documents into implementing procedures. An adequate procedure is one that contains all appropriate upper-tier requirements. Implementation refers to the performance of the process steps identified in the procedures. An implemented procedure is one where all steps have been completed as identified within the procedure. Effectiveness refers to a process that produces the desired (specified) end product or end service. These terms are used to describe assessment activities throughout this chapter.

The management and control of audits and surveillances are documented in QA plans or implementing procedures. The audit and surveillance processes include provisions for

- scheduling audits and surveillances;
- using qualified, certified, and independent personnel;
- reporting results to the management of the audited or surveilled organization and to any other affected organizations;
- requiring a written response to any noted conditions adverse to quality; and
- ensuring that the audited or surveilled organization verifies that appropriate corrective actions have been taken and are effective.

DOE Implementing Documents:

MP 10.1	Qualification and Certification of Audit Personnel
MP 10.2	Surveillances
MP 10.3	Audits

SNL Implementing Documents:

QAP 18-1	Quality Assurance Audit Requirements
QAP 18-2	Quality Assurance Surveillance Requirements

WID Implementing Documents:

WP 13-QA1003	Quality Assurance Inspection
WP 13-QA3012	Supplier Evaluation/Qualification

5.3.20 Computer Software QA

Software quality assurance controls ensure that the software meets its intended use and is controlled. These controls apply to software that manipulates or produces data that are, in turn, used to process, gather, or generate information and whose output is relied upon to make design, analytical, operational, or compliance-related decisions affecting the performance of the waste isolation or waste characterization processes. The application of these requirements is prescribed in written plan(s), policies, procedures, or instructions.

Software QA controls include inventorying and classifying appropriate software. Plans are prepared at the start of the software life cycle to document the software basis and objectives of the software to meet its intended use.

The sponsoring organization for the software procurement and related services verifies the software's capability and the acceptability of the supporting documentation. Any software errors and failures are reported to the sponsoring organization for analysis and then forwarded to the supplier, if applicable.

Software not developed under a QA program meeting CAO QAPD requirements, including preexisting software, is evaluated, uniquely identified, and controlled in accordance with the requirements of CAO QAPD, Section 6.0. When accepted, the software is placed under configuration control prior to use. QA records (for software) are controlled and stored as described in Section 5.3.18.

Software controls use an iterative or sequential approach during the following phases:

- definition of requirements,
- design,
- implementation,
- testing, including verification and validation test,
- installation and checkout,
- operations and maintenance, including in-use tests, and
- retirement.

Verification and validation of the software, including a review of software activities, documentation, and tests is performed to ensure that the software adequately and correctly performs all intended functions and does not perform any unintended functions, in accordance with the requirements of the CAO QAPD. Software verification is performed during the

software development phases to verify that the requirements of the previous phase are fulfilled. Software validation is performed to ensure that the software satisfies requirements.

Controlled software is placed under configuration management to ensure that changes are controlled and that the appropriate version of the software is used. Configuration management includes the maintenance of unique identification, configuration change control, and configuration status accounting. When appropriate, access is controlled.

Software documentation that is generated and retained includes

- procurement documentation for procured software,
- software requirements documentation,
- design and implementation documentation,
- verification and validation documentation,
- any change documentation,
- user documentation, and
- any errors and disposition documentation.

For released versions, software problems are documented, evaluated, and, if appropriate, corrected. Evaluation of software problems includes the impact on previous use and any appropriate corrective action. Problems that significantly impact decisions based upon prior use or that require significant modification to the software are identified. Errors that qualify as a condition adverse to quality are controlled as described in Section 5.3.17.

DOE Implementing Documents: None

SNL Implementing Documents:

QAP 9-1	Quality Assurance Requirements for Conducting Analyses
QAP 9-5	Conducting and Documenting Routine Calculations
QAP 19-1	WIPP Computer Software Requirements

WID Implementing Documents:

WP 16-0	Software Management Plan
WP 16-117	WIPP Computer Software Quality Assurance

5.3.21 Scientific Investigations

Technical investigations and design-development data collection activities performed in support of this application are defined, controlled, verified, and documented. Process variables affecting scientific investigations are measured and controlled as described in Section 5.3.13. Planning for scientific investigations ensures that the appropriate information is collected and that outside factors are eliminated or their effects are minimized. Planning is coordinated with other organizations that provide input or use the results. Planning for scientific investigations includes provisions for

- identifying and appropriately controlling variables that affect interrelated scientific investigations;
- documenting the intended use of the data before collection;
- considering the compatibility of data processing with any conceptual or mathematical models used at each applicable stage;
- reviewing and approving the technical adequacy of procedures;
- reviewing and approving the documented development activities used to establish new methods or procedures;
- establishing acceptance criteria for the data quality evaluation;
- identifying known sources of error and uncertainty; and
- identifying input data that are suspect or whose quality is beyond the control of the performing organizations.

Scientific investigations are performed according to requirements documented in scientific notebooks or technical implementation documents or both. If no nationally recognized test standard exists, special test procedures are developed and used. Scientific notebooks contain the results of the investigations, and they are periodically reviewed by a qualified individual for completeness.

Methods used in the investigations are reviewed to ensure that they are technically sound and have been properly selected. Data collection and analysis are controlled by procedures that allow the processes to be replicated. Test media are characterized and controlled in accordance with test procedures.

Data are recorded, identified, and traceable to the scientific investigation from which they were generated. Data collection and analysis are critically reviewed and questions resolved

before the results are used or reported. Uncertainty limits are assigned to the data prior to their use. Data are controlled to

- prevent data loss and permit data retrievability;
- maintain data integrity and security;
- ensure error-free transfer, reduction, and change of expression or quantity of data; and
- prevent the use of erroneous, rejected, superseded, or otherwise unsuitable data.

Data used for compliance with 40 CFR Parts 191 and 194 that were not collected under a QA program meeting CAO QAPD requirements are qualified through one or a combination of five methods detailed in Section 5.4.2.1. If peer reviews are necessary, the DOE uses procedure Team Procedure (TP) 10.5 to conduct them.

DOE Implementing Document:

TP 10.5	CAO Office of Regulatory Compliance (ORC) Team Procedure for Peer Review

SNL Implementing Documents:

QAP 13-1	Conducting and Documenting Sample Control
QAP 13-2	Chain-Of-Custody
QAP 20-1	Preparing, Reviewing, and Approving Test Plans
QAP 20-2	Preparing, Reviewing, and Approving Scientific Notebooks
QAP 20-3	Qualification of Existing Data
QAP 20-4	Preparing, Reviewing, and Approving Field Operations Plans
QAP 20-5	Preparing, Reviewing, and Approving Technology Development Descriptions (TDDs)
QAP 20-6	Preparing, Reviewing, and Approving Experimental Plans

WID Implementing Documents: None

5.3.21.1 Data Quality Characteristics

40 CFR § 194.22(c) states that to the extent practicable, data used to support compliance will be assessed according to their accuracy, precision, representativeness, completeness, and comparability. The DOE believes that these data quality characteristics are applicable to tasks involving the quantification through sampling and analysis of specific constituents in an environmental medium. The DOE also believes that these requirements are intended to address activities such as the determination of the presence or absence of pollutants in waste streams. Waste characterization and environmental monitoring are examples of the types of

activities at the WIPP in which data quality characteristics apply. In these cases, the performance measurement is the concentration of the constituent of interest.

In performance assessments that address compliance with 40 CFR Part 191, Subpart B, the performance measure is cumulative release of radionuclides to the accessible environment over the next 10,000 years. This measure is estimated using mathematical models rather than being determined by direct measurement. The performance assessment process requires the use of mathematical models for the repository, which, in general, require that numbers (here called parameters) be assigned to geologic formation and waste properties. Since many of these parameters are not amenable to direct measurement, they must be treated as uncertain variables, rather than precisely determined quantities, and characterized by probability distributions.

Data are used to develop conceptual models for disposal system performance that are implemented as computational models in the performance assessment. Data are also used to support distributions for parameter values used in the computational models. Between the point of data collection and the final computational model, uncertainty is introduced (for example, experimental design, extrapolation of the experimental results to spatial or temporal scales, etc.). These parameter distributions may span several orders of magnitude, and many parameters derived from data measurements need be known only within orders of magnitude of their true value. Efforts to reduce the range do not necessarily improve model accuracy.

Uncertainty and sensitivity analyses respectively assess the uncertainty in system performance measures and identify modeling areas and parameters in which reductions in uncertainty can increase confidence. If the uncertainty of a parameter is of significant importance to the performance of the WIPP, more data could possibly be collected to reduce uncertainty.

It is often not practicable for the DOE to document the above data quality characteristics for the scientific investigation and characterization of natural systems. As an example, data accuracy would be very difficult to assess for geologic site characterization activities because reference or true values do not exist.

Instead of the above quality characteristics, other steps ensure that data are of adequate quality. Upper-tier quality requirements documents specifically define QA requirements for the collection of scientific and technical information. Section 5 of the CAO QAPD, Scientific Investigation Requirements, identifies the current requirements for data collection. For inclusion in compliance calculations, the data must be collected under an approved QA plan or be otherwise qualified (see Section 5.4.2.1).

In summary, it is not practicable to apply data quality characteristics to most scientific investigations used to support a performance assessment in which there is uncertainty in the conceptual models and the resultant ranges of parameters. Instead, controls established by the QA program provide the necessary quality.

5.4 Implementation

The DOE, SNL, and WID QA programs have been determined to be effectively implemented in accordance with adequate procedures that meet the CAO QAPD. Specific details are described in Sections 5.4.1, 5.4.2, and 5.4.3.

The DOE maintains and implements an assessment schedule to assess continuing DOE, SNL, WID, and generator site QA program adequacy, implementation, and effectiveness. The scheduling of assessments is a dynamic process that requires frequent changes to respond to DOE and participant needs. The DOE assessment schedule is issued quarterly with distribution to WIPP participants and stakeholders. The assessment schedule accommodates the routine, recurring, and any focused or special purpose assessments that are deemed appropriate by management. An example of a typical assessment schedule is illustrated in Table 5-2.

5.4.1 DOE QA Program Implementation

Controlling QA documents for the DOE audit, surveillance, and corrective action programs were revised, reissued, and implemented in October 1994. These included DOE Branch Procedure (BP) 10.3, *Audits*; BP 10.2, *Surveillances*; BP 10.1, *Qualification and Certification of QA Audit Personnel*; and BP 3.1, *Corrective Action.* Subsequently, assessment 95EM34-AS-01 conducted by DOE EM-34 in March 1995, characterized these four documents as a particularly commendable aspect of the QA program and did not identify any deficiencies in the DOE audit and surveillance activities conducted in accordance with these documents.

The most recent audit of DOE/CAO by EM-30 (96 EM36-AU-01) was conducted in July 1996. The audit team concluded that the DOE/CAO QA Program was adequate and effective, but not completely implemented. They cited nonimplementation of two DOE procedures MP 1.2, *Selection of Quality Levels and Applicable QA Requirements*, and MP 9.1, *Management Assessment.* These procedures are now fully implemented and the overall DOE QA Program is being effectively implemented.

In addition to the audits performed by the DOE Office of Environmental Management, the DOE has performed internal surveillances to supplement the audit program in determining adequacy, implementation, and effectiveness. These surveillances are summarized in Table 5-3.

5.4.2 SNL QA Program Implementation

In May 1996, the DOE conducted audit A-96-02 of SNL. In June 1996, the DOE conducted audit A-96-03 of SNL performance assessment and software activities. The SNL QA Program was determined to be marginally adequate and marginally implemented. Areas requiring improvement were identified on Corrective Action Reports (CARs). As a result of

Table 5-2. DOE/CAO Assessment Schedule (Sample)

APPROVED BY: EXAMPLE ONLY

DOE/CAO MANAGER **DATE**

Organization and Scope	DOE/CAO Team	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	JAN	Remarks and Schedule
WID/Environmental Procedural Implementation	Assurance/WIPP Site			●										Surveillance, S-96-22, Bennington April 17 - June 14, 1996
SNL/Performance Assessment Program (includes Performance Assessment Final Calcs, Software QA, FEPs, and Parameters)	Experimental Programs					●								Audit, A-96-03, Paedon June 17-21, 1996
WID/Emergency Management	WIPP Site					●								Surveillance, S-96-39, Galle June 24-26, 1996
WID/Quality Assurance Program	Assurance					●								Audit, A-96-05, Ziemba June 24-28, 1996
CAO/QAPD Implementation	All CAO						●							Audit, A-96-10, Himpler July 15-19, 1996
WID/Work Packages (Safety Issues)	Assurance/WIPP Site						●							Surveillance, S-96-47, Lilly July 15-19, 1996
ANL-West Gas Generation	Experimental Programs						●							Audit, A-96-06, Dunhour July 22-24, 1996
LANL/Waste Characterization and Certification	National TRU Programs							o						Surveillance, S-96-48, Gilkerson August 13-16, 1996
WID/Environmental Data Control	Assurance/WIPP Site							o						Surveillance, S-96-45, Bennington August, 1996

o = Planned

● = Performed

Table 5-3. DOE Internal Surveillances

Organization and Activity	Number	Date
Compliance Team (QAPD)	CAO S-96-21	2/96
Experimental Programs Team (QAPD)	CAO S-96-25	3/96
WIPP Site Team (QAPD)	CAO S-96-27	4/96
Office of Regulatory Compliance (Peer Review)	CAO S-96-29	4/96
National TRU Program Team (QAPD)	CAO S-96-30	5/96
Administration, Contracts & Budgets, National Environment Policy Act Team (QAPD)	CAO S-96-31	5/96
Assurance Team (QAPD)	CAO S-96-28	5/96

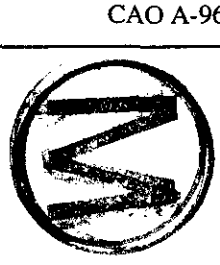
actions taken by SNL to correct the deficiencies, the SNL QA Program has been determined to be adequate and is being effectively implemented. Table 5-4 summarizes the DOE audits conducted of the SNL QA Program.

The SNL external audit program was audited by the DOE in August 1995. The audit CAO A-95-07 (see Table 5-4) examined QA records concerning SNL audits performed back to May 1994. After the implementation of specific corrective actions, SNL subcontractor QA programs, audited by the SNL audit program back to May 1994, were determined to be adequate and effectively implemented.

A primary result of the qualification of the SNL QA audit and surveillance programs was the determination of which performance assessment data provided by SNL subcontractors were collected under an approved QA program and which data required additional qualification. Currently, SNL is working directly in accordance with the CAO QAPD requirements.

Table 5-4. DOE Audits of SNL

Activity	Number	Date
QA Records Management	CAO A-95-03B	7/95
External QA Audit Program	CAO A-95-07	8/95
Qualification of Existing Data	CAO A-95-05	9/95
QA Program	CAO-A-96-02	5/96
Performance Assessment and Software QA	CAO A-96-03	6/96



Previously, SNL worked in accordance with the SNL Quality Assurance Program Description, which was in accordance with the requirements of the CAO QAPD. Since the May 1994 date for qualification of the SNL assessment programs, two revisions of the SNL Quality Assurance Program Description were implemented.

Revision P of the SNL Quality Assurance Program Description was issued in October 1992. Revision R was released in July 1995. Although Revision P was determined to be inadequate to meet the requirements of the CAO QAPD, it was also determined that the inadequate areas did not adversely affect the qualification of SNL subcontractors or data collected under Revision P. Major requirement changes from Revision P to Revision R are discussed below.

- Resolution of QA Disputes. QAP 2-9 was added to address the requirements for the resolution of disputes. Previously, QA disputes were normally handled through the nonconformance reporting process, described in SNL Quality Assurance Program Description, Rev. P, Section 15.

- Stop Work Orders. QAP 2-5 was added to address the requirements for stopping work because of quality concerns. Previously, stopping work was considered a part of the process for completing a nonconformance report, described in SNL Quality Assurance Program Description, Rev. P, Section 15.

- Conditions Adverse to Quality and Corrective Action. QAP 16-2 was added to address the corrective action reporting process. Previously, corrective action documentation, resolution, and verification was documented on a nonconformance report, described in SNL Quality Assurance Program Description, Rev. P, Section 15.

- Scientific Investigation. Many of the requirements under scientific investigations were already in the program and implemented through various QAPs (for example, earlier revisions of QAP 6-1 included the requirements for writing, approving, revising, and issuing test plans, field operation plans, procedures, and other documents describing scientific investigations). QAP 20-2 was added to address scientific notebooks. QAP 20-3 was added to address the qualification of existing data (QED). Previously, existing data was qualified by the review of planning, implementing, and reporting documentation.

- Software. QAP 19-1 was revised to address the considerably different software requirements.

5.4.2.1 Data Qualification

An SNL audit Internal Audit [IA] 95-03 (see Table AUD-3 in Appendix AUD) was conducted in August 1995 to verify the adequacy and effective implementation of QA requirements. The scope of the audit included the 11 experimental areas of the program. The audit resulted in 14 findings in the areas of calibration, procedures, training, experimental planning, test records,

and equipment and data acquisition. All the resulting corrective actions have been completed and verified. Two positive observations were made: (1) efficient organization of data used in the demonstration of compliance and (2) noticeably strong commitment to quality by management and staff. The audit concluded that, with the exception of the Corrective Action Requests, there was evidence that SNL QA controls were in place and that they were adequate and effectively implemented.

Data can be qualified for use by one of five methods:

(1) data used in performance assessment were obtained under an approved QA program that implements the NQA requirements referenced in Section 5.1;

(2) existing data collected before the implementation of a qualified QA program are qualified by showing that the data were obtained under a QA program that is equivalent to one satisfying the NQA requirements referenced in Section 5.1;

(3) existing data are qualified by peer review conducted in a manner compatible with NUREG-1297, Peer Reviews for High-Level Nuclear Waste Repositories;

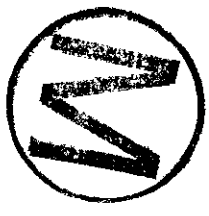
(4) corroborating data are collected; and

(5) confirmatory testing is performed.

For data qualified by implementation of a QA program meeting the requirements of 40 CFR Part 194 (Method 1), the supporting documents include the QA plan, audits and surveillances of the work that produced the data, and other objective evidence of QA implementation. If the audits show the program to be adequate and effectively implemented, then the data can be qualified back to the earliest date of the objective evidence reviewed during the audits. If audits identify significant deficiencies, then data whose quality is affected by those deficiencies are not qualified until impact assessments are completed and corrective actions have been implemented and verified.

For data collected prior to the DOE approval of the overall SNL QA program, another process was used to qualify data. A qualification date (T=0) is documented in summary reports that provide rationale and pointers to supporting information (see Section 5.4.2.3). For new and existing data (work completed prior to 1992), the QED process, as described in SNL QAP 20-3, was used to qualify the data to determine if the QA program in effect met the requirements of 40 CFR Part 194 (Method 2). The results of the QED process are documented in Statements of Condition.

Data collected by SNL and its subcontractors to support compliance were used if the data were



- collected after August 1, 1995 when SNL QA program was qualified by the DOE (Method 1),
- collected after the qualification of a subcontractor QA Program by SNL (Method 1),
- qualified by an Independent Review Team (IRT) (Method 2), or
- qualified by the Peer Review process (Method 3).

Data that did not fall into one of these four categories were not used in compliance.

5.4.2.2 Qualification of Existing Data (Methods 2 and 3)

Existing data are those data collected prior to the implementation of a QA program satisfying the requirements identified in 40 CFR § 194.22. Existing data, used as input to support computer codes and models, have been used to support the development of parameter values and distributions used in the performance assessment calculations. SNL QAP 9-2, Quality Assurance Requirements for the Selection and Documentation of Parameter Values Used in WIPP Performance Assessment, describes the process for selecting parameter values used in performance assessment. To ensure that data are used as intended, the scientific investigator and the performance assessment analyst must concur on Form 464 (WIPP Parameter Entry Form) that the proposed parameter is appropriate and the supporting documentation is sufficient. To qualify existing data to support the compliance application, a process following the guidelines of NUREG-1298 (NRC 1988) was developed.

The QED process, as described in SNL QAP 20-3, includes three major steps. The first step identifies the packages to be qualified by identifying those data packages that support the performance assessment calculations. The second step includes provisions for the evaluation of the QA requirements and technical status of the data packages by an IRT. If the QA requirements applicable to the data package are determined to be acceptable, the data are considered qualified. If the QA requirements are determined to be unacceptable, a third step is followed in which the data are qualified by peer review, confirmatory testing, or the use of corroborating data. Otherwise, the data are not used.

The experiments reviewed by the QED process have been diverse, including the thermal-structural interaction tests conducted underground in the WIPP, the gas generation tests conducted at other national laboratories, the surface and underground hydrologic testing in the vicinity of the WIPP, the laboratory testing of salt properties, and others. The previous work reviewed was performed from 1984 to 1992. Each data package corresponded to a test plan or other test control document. Table 5-5 identifies the 14 packages reviewed by the IRT and determined to have been collected under an equivalent QA program.

Peer reviews are performed when necessary to verify the technical adequacy of work done and to qualify data. The peer review process and peer reviews conducted to support data

Table 5-5. QED Data Packages Qualified by IRT (in accordance with SNL QAP 20-3)

Review Group	Data Package
Salado testing activities (two packages)	Salado in situ permeability
Creep and fracture tests	Clean and argillaceous salt
Salt compaction	Hydrostatic and shear consolidation
Corrosion	Steel
Microbial	Cellulosics, plastics, and rubbers
Borehole tests, two or more wells (six packages)	Drilling, drill stem and hydrologic testing, well development
Hydrogeologic characterization (two packages)	Permeability and water level measurements

qualification are described in Chapter 9.0, Peer Review. All data sets not qualified by IRT or collected under a qualified QA program were qualified by the peer review process.

The QA records packages generated as a result of the IRT process described in SNL QAP 20-3 contain the following documents:

- IRT Statement of Condition, composite checklist, recommendations for improvement, etc., and
- qualifications and training documentation of IRT members.

5.4.2.3 T=0 Process

The T=0 process implemented by SNL was used to determine the date when NQA controls were adequate and effectively implemented for subcontractor activities performed prior to the qualification of the current SNL QA program.

The process is documented in SNL procedure QAP 20-7, *Establishing T=0 for Internal and External Experiment Activity QA Programs*, and includes the following key elements:

1. The process evaluation was performed by a certified NQA-1 Lead Auditor. Results are documented in a memorandum.
2. The QA requirements identified for the work (as described in the Statement of Work), the subcontractor QA program plan, and other implementing documents, were reviewed.

3. The audit record, including audit responses and corrective actions, was reviewed to determine the requirements and objective evidence evaluated during the audit and the audit results.

4. The audit record and the associated documentary evidence were evaluated to determine when adequate controls on the work were effectively implemented. This evaluation included a review of any corrective actions and the associated responses as well as verifications of the corrective actions.

5. A determination was made of the date when adequate QA controls were applied to the work. Results of audits and surveillances were documented in a report that included the rationale and the identification of reviewed documentation.

This process provides a traceable basis for determining when adequate QA controls were applied to subcontractor activities. The results of this process are shown in Table 5-6 for SNL subcontractors supplying data to support performance assessment. Additionally, SNL conducts internal and external surveillances, the most recent of which are shown in Table 5-7. The five external surveillances in Table 5-7 supplemented and supported the findings of the SNL audits of its subcontractors. See Section 5.3.18 for discussion on control and location of associated QA records.

5.4.3 WID QA Program Implementation

The WID QA Program was determined to be adequate and effectively implemented based on DOE audit A-96-01 in December 1994. The most recent audit in June 1996, A-96-05, indicated that the WID QA Program was adequate, implemented, and marginally effective. As a result of actions taken by WID to correct the deficiencies, the WID QA Program has been determined to be adequate and effectively implemented. Tables 5-8 and 5-9 summarize the DOE audits and surveillances, respectively, of the WID QA Program.

As the WID conducts audits of internal or external organizations, an evaluation is made of past performance by that organization. In most cases, an organization's program had been in effect before a WID audit, therefore WID determines program adequacy to one year before the audit.

WID determines the adequacy of the implementation of QA requirements for both internal WID customers and external contractors. Internal determinations of adequacy of QA implementation are generally based on adherence to the WID QAPD requirements. The process includes a review of the contractor's QA program with regard to the applicable elements of the WID QAPD, nationally recognized codes and standards, and regulations. The WID has performed audits and surveillances to determine the dates when each of its supplier's and subcontractor's QA programs were considered adequate and effectively implemented. These dates and the basis for determination are shown in Table 5-10.

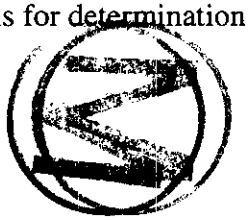


Table 5-6. T=0 for SNL Subcontractors

Subcontractor	First Qualification Date	Basis
Lawrence Berkeley National Laboratory (LBNL) (AH-5592)	9/93	EA 94-07
University of Nevada Reno (AG-4915)	1/95	IA 95-01
Florida State University (AH-5590)	7/94	EA 95-02
Battelle (AF-3339)	12/93	EA 95-01
University of Nevada Las Vegas (AJ-8745)	4/95	EA 95-04
Stanford University (AG-4979)	11/94	EA 95-05
Lawrence Livermore National Laboratory (AG-4965 and AF-3341)	4/95	EA 95-13
RE/SPEC Inc. (AF-3334)	5/94	EA 95-06
RE/SPEC Inc. (AG-4911)	4/94	EA 95-06
Parsons-Brinkerhoff (AG-4909)	3/94	EA 95-10
INTERA Inc. (AG-4910)	7/94	EA 95-11
Core Laboratories (AF-3945, AI-3669)	5/93	EA 94-04
RE/SPEC Inc. (AA-2020)	6/94	EA 94-05

Table 5-7. Additional SNL Internal and External Surveillances

Activity	Assessment Number	Date
FEPs	SR 96-01	10/95
Los Alamos National Laboratory (external)	SR 96-02	12/95
Texas A & M (external)	SR 96-03	12/95
RE/SPEC (external)	SR 96-04	2/96
INTERA, Inc. (external)	SR 96-05	2/96
Dissolved Species Program	SR 96-06	3/96
Los Alamos National Laboratory (external)	SR 96-07	3/96
Software QA	SR 96-08	4/96
Training	SR 96-09	4/96
Small-Scale Seal Performance Test	SR 96-10	7/96

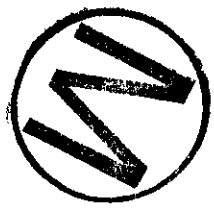


Table 5-8. DOE Audits of WID

Activity	Number	Date
QA Program	CAO A-95-01	12/94
QA Records Management	CAO A-95-03A	7/95
QA Program	CAO A-96-05	6/96

Table 5-9. DOE Surveillances of the WID Organization

Surveilled Organization	Number	Date
WID/Safety and Health Surveillance of Occupational Medical Program	S-95-07	4/95
WID/Environmental Compliance	S-95-08	5/95
WID/Environmental Compliance Program	S-95-17	10/95
WID/Equipment Safety	S-95-26	9/95
WID/Operation Maintenance	S-95-29	5/95
WID/Emergency Response/Training and Qualification	S-95-30	7/95
WID/Biennial Environmental Compliance Report Hazardous Waste Management for Generator	S-95-31	6/95
WID/Accident Analysis and Reporting Program	S-95-32	4/95
WID/Food Service Sanitation Program	S-95-32A	9/95
WID/Lockout-Tagout	S-95-33	9/95
WID/Hazardous Waste Satellite Accumulation Points	S-95-34	9/95
WID/MSDS Waste Characterization	S-96-02	11/95
WID/Mine Safety	S-96-06	12/95
WID/Spill Response and Control	S-96-12	2/96
WID/Hazard Communication	S-96-14	12/95
WID/Environmental Procedural Implementation	S-96-22	6/96
WID/Conduct of Operations	S-96-26	4/96
WID/Excavation and Trenching Safety	S-96-33	3/96
WID/Personal Protective Equipment	S-96-34	3/96
WID/Fall Protection	S-96-35	3/96
WID/Emergency Management	S-96-39	7/96
WID/Work Packages (Safety Issues)	S-96-47	7/96

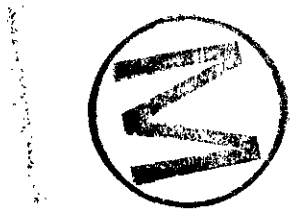
Table 5-10. T=0 for WID Subcontractors

Contractor	Qualification Data Prequalification Date for Audit	Qualification Audit Number and Date of Qualification
Shortridge Instruments	June 1993	Audit E94-04A, 06/21/94
John Fluke Mfg.	June 1993	Audit E94-05A, 06/30/94
Kinemetrics, Inc.	July 1993	Audit E94-07A, 07/14/94
Hi-Q Environmental Products	July 1993	Audit E94-08S, 07/12/94
Pacific Northwest National Laboratory - Battelle	August 1993	Audit E94-09A, 08/03/94
Quanterra Corporation	August 1993	Audit E94-10S, 08/08/94
MKS Instruments, Inc.	August 1993	Audit E94-12S, 08/04/94
GE Rental	September 1993	Audit E94-14S, 09/15/94
Haliburton NUS Environmental	September 1993	Audit E94-16A, 09/19/94
Southern California Edison Energy Services	October 1993	Audit E94-17S, 10/26/94
IT Corp., Air Quality Services, Cincinnati, Ohio	October 1993	Audit E94-18A, 10/25/94
Benchmark Environmental	February 1994	Audit E95-001A, 02/23/95
Servco Industrial Division Corona, California	March 1994	Audit E95-002A, 03/01/95
Wyle Labs	April 1992	Audit E94-003S, 04/05/94
Merrick and Company	January 1994	Audit E95-004A, 03/07/95
Quantrad Sensor	April 1994	Audit E95-005A, 04/26/95
Servco Industrial Division Costa Mesa, California	March 1994	Audit E95-006A, 03/01/95
Colorado Allstate Transportation	April 1994	Audit E95-008S, 04/18/95
Nordberg, Inc.	May 1994	Audit E95-009A, 05/05/95
Lake Shore Mining Co.	May 1994	Audit E95-010A, 05/05/95
Instrument Services Lab	May 1994	Audit E95-012A, 05/12/95
Ross Analytical Services	May 1994	Audit E95-014A, 05/11/95
Gage Lab Corporation	May 1994	Audit E95-015A, 05/23/95
EG&G Ortec	May 1994	Audit E95-016A, 05/23/95
Eberline Instruments	September 1994	Audit E95-026A, 09/26/95
IT Corp. Albuquerque, New Mexico	November 1994	Audit E95-028A, 11/30/95

An established NQA-1-based auditing process is used to ensure the integrity of the WID program. Procedures are in place that specify the qualifications for the audit team and the lead auditor in particular. Audits are conducted according to approved WID procedures. Internal audits and surveillances of the WID QA program are identified in Appendix AUD. Corrective actions resulting from an audit require action plans that identify such items as the cause of the condition found to be adverse to quality, effect on other processes, method to prevent recurrence, and scheduled dates of completion of accepted corrective actions.

5.4.4 QA Program Implementation at Other Organizations

The DOE, WID, and SNL have performed numerous additional audits and surveillances, both internal and external to their organizations, in accordance with the same procedures used to directly support this application. Lists of these audits and surveillances are included in Appendix AUD.



REFERENCES

ASME (American Society of Mechanical Engineers). 1989a.. *Quality Assurance Program Requirements for Nuclear Facilities*. ASME NQA-1-1989. September 15, 1989. The American Society of Mechanical Engineers, New York, NY.

ASME (American Society of Mechanical Engineers). 1989b. "Part 2.7 Quality Assurance Requirements of Computer Software for Nuclear Facility Applications," *Quality Assurance Requirements for Nuclear Facility Applications*. ASME NQA-2a-1990, Part 2.7. May 31, 1990. ASME, New York, NY.

ASME (American Society of Mechanical Engineers). 1989c. *Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories*. ASME NQA-3-1989. March 23, 1990. American Society of Mechanical Engineers, New York, NY.

EPA (U.S. Environmental Protection Agency). 1993. 40 CFR Part 191 Environmental Radiation Protection Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes; Final Rule. *Federal Register*, Vol. 58, No. 242, pp. 66398 – 66416, December 20, 1993. Office of Radiation and Indoor Air, Washington, D.C. WPO 39133.

EPA (U.S. Environmental Protection Agency). 1996. 40 CFR Part 194: Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations; Final Rule. *Federal Register*, Vol. 61, No 28, pp. 5224 – 5245, February 9, 1996. Office of Air and Radiation, Washington, D.C. In NWM Library as KF70.A35.C751 1996 (Reference).

NRC (U. S. Nuclear Regulatory Commission). 1988. *Qualification of Existing Data for High-Level Nuclear Waste Repositories*. NUREG-1298. February 1988.

BIBLIOGRAPHY

NRC (U. S. Nuclear Regulatory Commission). 1988a. *Peer Review for High-Level Nuclear Waste Repositories*. NUREG-1297. February 1988.

Knight, J.P. 1989. Memorandum. "Waste Isolation Pilot Plant Safety Evaluation Report," on EH-30 Safety Evaluation Report (SER) for the Waste Isolation Pilot Plant (WIPP) plus attachment.