2. Quality Assurance Program

2.1 INTRODUCTION

Quality assurance is the set of planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service (ASM89a). Standard "good practice" may lead to a quality outcome and it is possible that quality outcomes will result without the imposition of a formal program. However, formalizing this process helps to assure a quality outcome and the lack of formality can impede the demonstration of the outcome's inherent quality. Because of the need to provide confidence that the WIPP will comply with federal and state disposal standards, a carefully structured quality assurance (QA) program is essential.

DOE's ability to demonstrate compliance with the regulatory requirements of 40 CFR part 191 Subpart B, Environmental Standards for Disposal, and Subpart C, Environmental Standards for Ground Water Protection, depends in large part on the adequacy of its quality assurance (QA) program. Demonstration of an appropriately implemented QA program can provide confidence in the soundness of information and scientific data, thus enabling greater defensibility for the technical basis of those measures intended to ensure waste isolation. This is especially true in relation to establishing and maintaining the integrity of data and models which form the technical basis of the WIPP's performance assessment (PA) process. In §194.22, EPA has specified criteria aimed at ensuring the soundness of DOE's QA program for modeling and data collection and analysis. Specific items which the QA program must address include:

- waste characterization activities and assumptions;
- environmental monitoring, monitoring of the performance of the disposal system, and sampling and analysis activities;
- field measurements of geologic factors, groundwater, meteorologic, and topographic characteristics;
- computations, computer codes, models, and methods used to demonstrate compliance with the disposal regulations;
- procedures for implementation of expert judgment elicitations used to support applications for certification or re-certification of compliance;

- design of the disposal system and actions taken to ensure compliance with design specifications;
- collection of data and information used to support compliance applications; and
- other systems, structures, components, and activities important to the containment of waste in the disposal system.

40 CFR part 191 establishes the disposal system's performance requirements by specifying criteria for containment, assurance of performance, individual protection, and groundwater protection, but does not specify requirements for "Quality Assurance." However, §191.13(b) requires a "reasonable expectation" that compliance with the requirements will be achieved based upon the total record before the implementing agency. This statement implicitly requires a mechanism to (1) produce such a record, and (2) to provide a basis for that record to support the concept of "reasonable expectation." Quality assurance is an integral element in the formalization of this mechanism. A fully implemented quality assurance program that is in compliance with the appropriate requirements justifies a high level of confidence in the scientific protocols and data which form the basis for waste isolation estimates.

To ensure that calculations of compliance with 40 CFR part 191 are based on sound data and information, EPA requires in 40 CFR part 194 that DOE implement a QA program that meets the requirements of the following documents:

- American Society of Mechanical Engineers' (ASME) "Quality Assurance Program Requirements for Nuclear Facilities" (NQA-1-1989 edition) (ASM89a);
- ASME's "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications" (NQA-2a-1990 addenda (part 2.7) to ASME NQA-2-1989 edition) (ASM89b); and
- ASME's "Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories" (NQA-3-1989 edition excluding Section 2.1(b) and (c)) (ASM89c).

The ASME national consensus standards are well established within the U.S. nuclear industry. They have a long history of use and provide extensive supplemental guidance. EPA believes the use of these standards offers the most comprehensive/credible and specific set of QA requirements for all compliance-related elements of the disposal system. For example:

- NQA-1 sets forth requirements for the "establishment and execution of quality assurance programs for the siting, design, construction, operation, and decommissioning of nuclear facilities."

- NQA-2 (part 2.7) establishes requirements for "the development, procurement, maintenance, and use of computer software, as applied to the design, construction, operation, modification, repair, and maintenance of nuclear facilities;" and applies to computer software "used to produce or manipulate data which is used directly in the design, analysis, and operation of structures, systems, and components."

- NQA-3 sets forth quality assurance requirements for "the collection of scientific and technical information for site characterization of high-level nuclear waste repositories;" and applies to "activities which could affect the quality of scientific and technical information collected as part of the site characterization phase of high-level nuclear waste repositories...[which include] as a minimum: (a) readiness reviews; (b) peer reviews; (c) data and sample management; (d) data collection and analysis; (e) coring; (f) sampling; (g) in situ testing; and (h) scientific investigations."

This chapter describes the current DOE quality assurance program for the WIPP, describes how NRC addresses similar regulatory requirements, and provides additional background on the basis for selecting the ASME NQA requirements for 40 CFR part 194.

2.2 DOE QUALITY ASSURANCE PROGRAM

2.2.1 Management and Oversight

DOE Office of Environmental Management

Within the DOE headquarters organization, the Office of Environmental Management (EM-1) is responsible for the overall management of DOE waste management programs. Under EM-1, responsibilities of the Office of Waste Management (EM-30) include programmatic management of site operations for storage, treatment, or disposal of radioactive, hazardous and mixed waste materials including defense-generated TRU waste. Additionally, EM-30 is responsible for assuring that waste is properly characterized, packaged, labeled, and transported to the WIPP in accordance with DOE priorities and objectives; and providing management direction to the waste generators.

Figure 2-1. DOE WIPP Organizational Chart

Carlsbad Area Office

The WIPP management structure contained many organizational levels among DOE headquarters and field activities until early 1994 when DOE streamlined the organizational structure. This streamlining resulted in the vesting of major responsibilities for WIPP in the Carlsbad Area Office (CAO)[1] (DOE93a, DOE93b). The current WIPP organization is illustrated in Figure 2-1 (DOE94).

The mission of the CAO is to integrate the national transuranic (TRU) waste generator activities and carry out the actions necessary to facilitate DOE's decision to operate the WIPP as a disposal facility (REF). Overall responsibility for the development and implementation of the CAO quality assurance program for all WIPP related activities resides with the CAO Manager who reports directly to EM-1 as shown in Figure 2-1. The activities under CAO can be assigned to three main areas, as listed below:

- WIPP site activities are performed by the WIPP Site Management and Operating Contractor, Westinghouse Waste Isolation Division (WID) located at the WIPP Site outside of Carlsbad, NM. WID fulfills the requirements of a contract managed by CAO under the direction of the CAO Manager and is responsible for WIPP site operation (including support of experiments) and maintenance and for monitoring the site environment.

- WIPP experimental programs are conducted under the direction of the WIPP Scientific Advisor, Sandia National Laboratories (SNL) located in Albuquerque, NM. SNL fulfills the requirements of a contract managed by DOE Albuquerque Operations and overseen by the CAO Manager. In this capacity, SNL is responsible for developing, confirming, and validating models used to simulate long-term disposal system performance (i.e., performance assessment); and conducting research, experiments, and tests to collect the data needed for input to the models (DOE92). SNL sets forth its QA requirements through its Sandia National Laboratories Waste Isolation Pilot Plant Quality Assurance Program Description and implementing procedures (SNL95).

- TRU Waste Generator Site activities at the TRU waste generator sites are managed by DOE Field and Site Offices, as discussed below. A detailed description of site

[1] For example, in 1991, DOE EM-1 provided policy guidance and centralized management through EM-30 to DOE Albuquerque Operations, which reported to the WIPP Project Integration Office. Policy guidance and management now flow directly from DOE EM-1 to the Manager of the DOE Carlsbad Area Office. DOE EM-30 still ensures that program plans and operations are coordinated, integrated, and consistent with DOE Headquarters.

activities is beyond the scope of this report. The TRU waste generator sites are responsible for TRU and mixed TRU waste characterization and for the waste certification programs. The National TRU Program Office (NTPO) Team Leader is responsible for the day-to-day implementation of DOE Headquarters policy and technical direction. The NTPO Team Leader is also responsible for overseeing waste characterization activities and for providing an interface between DOE field offices and CAO. NTPO is divided into two functional areas, described below:

- Waste Characterization and Technology is responsible for the development, issuance and distribution of technical documents that control the TRU Waste Characterization Program.

- Assessment and Certification is responsible for the verification of compliance with the TRU Waste Characterization Program requirements at participating TRU waste generator sites through audits (DOE94).

The CAO QA Manager has the overall responsibility to independently assess the effective implementation of the QA program. Other responsibilities of the QA Manager include:

- Interfacing with CAO technical staff on quality related matters;

- Maintaining a liaison with the QA organizations of WIPP participants and other affected organizations; and

- Review and approval of CAO procedures and contractor quality assurance program descriptions.

TRU Waste Generator Sites

Each of the DOE sites that currently generate, process or store TRU wastes intended for disposal at WIPP must comply with applicable federal and state regulations regarding waste characterization, storage, transportation, etc. While these sites vary considerably in size, complexity and function, each site prepares a site specific Quality Assurance Project Plan (QAPjP). The QAPjP translates the applicable CAO and other federal and state regulations into procedures for that site. As stated previously, the daily operations at TRU generator sites are managed by DOE field and site offices with guidance provided by NTPO. CAO assesses generator site activities through Quality Assurance audits and surveillances, focusing primarily on waste characterization activities.

2.2.2 Key Regulatory Issue

The Quality Assurance documents described in this section provide requirements for activities associated with the generation, storage, transport and characterization of TRU waste intended for disposal at WIPP. However, the ultimate compliance criterion is the determination that once the appropriate Quality Assurance practices and criteria have been identified that they are *adequately implemented*. This must be determined empirically by conducting compliance audits and surveillances at all levels of operation. DOE is currently in the process of evaluating the implementation of its QA program, identifying problem areas and preparing a documentation record of these activities. EPA must evaluate DOE's program by a thorough evaluation of records in conjunction with selected independent verification.

2.2.3 Key DOE Quality Assurance Documents

DOE has established a hierarchy of quality assurance documents consistent with the organizational framework (See Figure 2-2). Some of the major documents are described in this section.

2.2.3.1 DOE Order 5700.6C - Quality Assurance

This document establishes the basic quality assurance framework for the Department (DOE91) and includes the following:

- Placing responsibility for mission accomplishment and Quality Assurance Program (QAP) implementation with senior management;
- Training and qualification of all personnel performing assigned work; all important work will be described in documents and records will be kept;
- Performance of all work to established standards using approved instructions; all equipment used for data collection shall be calibrated and maintained;
- Verification and validation of the adequacy of all designed products by independent personnel; and
- Periodic management assessment of the QAP to assure results, and independent assessments to assess quality; all assessments conducted by personnel technically qualified and knowledgeable in the areas under assessment.

Figure 2-2. Hierarchy of DOE WIPP QA Program Documents

2.2.3.2 Quality Assurance Requirements and Description Document

Based on requirements in Order 5700.6C, DOE EM developed the Quality Assurance Requirements and Description document (QARD) (DOE91a). The QARD is intended to state DOE/EM's commitment to specific requirements and to integrate their requirements, for example, ASME NQA-1, NQA-2 (part 2.7) and NQA-3; and EPA QAMS-005/80. QARD requirements include the following:

- Organizations shall develop, implement, and maintain a written Quality Assurance Program (QAP) as identified in DOE Order 5700.6C. Appropriate standards, such as ASME NQA-1 shall be used, wherever applicable, to develop and implement QAPs. The QAP Description shall delineate the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing adequacy of work.

- Personnel shall be trained and qualified to ensure they are capable of performing their assigned work. Personnel shall be provided continuing training to ensure that job proficiency is maintained.

- Organizations shall establish and implement processes to detect and prevent quality problems and to ensure quality improvement. Items and processes that do not meet established requirements shall be identified, controlled, and corrected. Correction shall include identifying the causes of problems and preventing recurrence.

- Organizations shall ensure that procured items and services meet established requirements and perform as specified. Prospective suppliers shall be evaluated and selected on the basis of specified criteria.

- Inspection and acceptance testing of specified items and processes shall be conducted using established acceptance and performance criteria. Equipment used for inspections and tests shall be calibrated and maintained.

- Senior management shall periodically assess the integrated quality assurance program and its performance. Problems that hinder organizations from achieving their objectives shall be identified and corrected.

- Planned and periodic independent assessments shall be conducted to measure item quality and process effectiveness, and to promote improvement.

2.2.3.3 Carlsbad Area Office Quality Assurance Program Description

The Carlsbad Area Office Quality Assurance Program Description (CAO QAPD) is the quality management document that identifies the federal and industry quality requirements applicable to the CAO quality assurance program (DOE 94). The CAO QAPD Revision 1.0 states that compliance to its requirements, responsibilities, and authorities "is mandatory for CAO personnel" while organizations supporting CAO are expected to use the CAO QAPD for "guidance." The federal and industry quality program requirement source documents it identifies are divided into three categories:

- Regulatory documents - these define the requirements necessary for WIPP to receive a certificate of compliance and operational permits by the federal and state governments, respectively;
- Commitment documents - these have been imposed on WIPP operations by DOE management; and
- Guidance documents - these provide additional information that may be useful in developing quality assurance programs for WIPP activities.

A listing of QAPD source documents by category is provided in Figure 2-3. The CAO QAPD provides a description of general, management, performance, and assessment requirements, as well as supplementary quality assurance requirements for specific application areas, such as Scientific Investigation Quality Assurance and Software Quality Assurance, incorporating the applicable portions of ASME NQA-3 and NQA-2, part 2.7, respectively. CAO QAPD requirements include the following:

- Identifying the responsibilities and authorities of those organizational line management positions responsible for achieving and verifying quality.
- Allowing the CAO QA Manager direct access to responsible management at a level where appropriate action can be effected.
- Performing and documenting planning to ensure work is accomplished under suitably controlled conditions.
- Establishing and implementing processes to detect and prevent adverse quality conditions and to ensure quality improvement.

REGULATORY REQUIREMENTS DOCUMENTS	TITLE
10 CFR part 830	Nuclear Safety Management
40 CFR part 261	Identification and Listing of Hazardous Waste
40 CFR part 268.6	Land Disposal Restrictions
10 CFR part 71	Subpart H, Quality Assurance, Packaging and Transportation of Radioactive Material
40 CFR part 284	Standards for Owners and Operators of Hazardous Waste Treatment Storage and Disposal Facilities
COMMITMENT DOCUMENTS	**TITLE**
DOE Order 5700.6C	Quality Assurance
EM-1 QARD	Quality Assurance Requirements and Description
ASME NQA-1 (1989), with all supplements	Quality Assurance Program Requirements for Nuclear Facilities
ASME NQA-2 (1990) Part 2.7	Quality Assurance Requirements of Computer Software for Nuclear Facility Applications
ASME NQA-3 (1989) (with exceptions)	Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Waste Repositories
NUREG-1298 (1988)	Staff Position - Qualification of Existing Data for High-Level Nuclear Waste Repositories
GUIDANCE DOCUMENTS	**TITLE**
NUREG/BR-0167 (1993)	Software Quality Assurance Program and Guidelines

Figure 2-3. DOE QAPD Source Documents by Category

- Analyzing performance data that affect quality and identifying lessons learned to improve items, activities, and processes.

- Preparing, approving, issuing, and controlling documents which prescribe processes, specify requirements, or establish design.

- Records shall be specified, prepared, reviewed, approved, controlled, and maintained to accurately reflect completed work and facility conditions and to comply with statutory or contractual requirements.

- Classifying Quality Assurance records as either "permanent" or "non-permanent."

- Performing work under controlled conditions using approved instructions, procedures, drawings or other appropriate means.

- Items and processes shall be designed using sound engineering/scientific principles and appropriate standards. The adequacy of design products shall be verified by individuals or groups other than those who performed the work.

- Ensuring that procured items and services meet established technical and quality assurance requirements and that they perform as specified. Prospective suppliers shall be evaluated and selected on the basis of documented criteria.

- Inspecting and testing specified items and processes, and calibrating and maintaining equipment used for such tests.

- Conducting planned and periodic assessments to measure management effectiveness, item quality and process effectiveness, and to promote improvement. Persons conducting assessments shall be technically qualified and knowledgeable in their assigned roles.

- Controlling and identifying samples in a manner consistent with their intended use.

- Shall be defining, controlling, verifying and documenting scientific investigations.

- Verification of software shall include reviews that ensure that the requirements are complete and correct, and shall include the appropriate testing.

EPA Office of Radiation and Indoor Air (ORIA) has conducted two formal reviews of the CAO QAPD and transmitted comments on Revisions 0 and 1 to DOE CAO. DOE appears to be revising the QAPD to address EPA concerns.

2.2.3.4 TRU Waste Characterization Quality Assurance Program Plan (TRU QAPP)

The TRU QAPP presents detailed technical information focusing on analytical techniques for the collection and analysis of samples at a stated, statistically derived confidence interval for physical, chemical and radiological parameters. In addition to technical information, the TRU QAPP provides Quality Assurance information, much of which overlaps with areas covered in the CAO QAPD (DOE95). The TRU QAPP identifies the quality of data necessary and the techniques designed to attain and ensure the required quality to meet the objectives of the WIPP Waste Characterization Program (DOE94), and also contains specific Quality Assurance Objectives for TRU waste. The waste characterization requirements presented in the TRU QAPP focus on the Resource Conservation and Recovery Act (RCRA) and Department of Transportation (DOT) regulations (DOE94). §194.24 requires DOE to perform an analysis which identifies waste characteristics influencing waste containment within the disposal system. Once DOE has completed the analysis, the QAPP should be revised to address the requirements of 40 CFR part 194. According to CAO, the TRU QAPP addresses all of the basic requirements of ASME NQA-1 (DOE94); any exceptions to ASME NQA-1 requirements must be noted in each site's QAPjP. Each TRU generator site's QAPjP must integrate the TRU QAPP's requirements for all TRU waste intended for shipment to WIPP, which is accomplished by NTPO/CAO reviewing and approving the generator site QAPjPs (DOE94).

2.2.4 Key WIPP Scientific Advisor Documents

In their capacity as the WIPP Scientific Advisor, Sandia National Laboratories (SNL) has developed the SNL WIPP Quality Assurance Program Description (SNL QAPD) (SNL95b) and an extensive list of implementing procedures to address specific WIPP related Quality Assurance and technical activities. These activities are generally classified as experimental programs and they cover a wide range of technical and QA activities from certifying pressure relief valves to Root Cause Analysis. As of 9-14-95, SNL lists forty one Quality Assurance Procedures as "Active WIPP Controlled Documents" (REF). EPA needs to determine the conformance of these SNL documents to the ASME NQA standards and the degree of their implementation.

2.2.5 Management and Operating Contractor Documents

Westinghouse Waste Isolation Division (WID) functions in the capacity of the WIPP Site Management and Operations Contractor. As such, WID is required to comply with all applicable federal and state regulations. These requirements are integrated in the WID Quality Assurance Program Description (WID92) and associated implementing procedures and instructions.

2.2.6 TRU Waste Generator Sites

There are approximately ten major TRU generator sites. Each site is required to develop a site specific Quality Assurance Project Plan (QAPjP) and supporting procedures. These documents are the means whereby the site translates CAO and other federal requirements into operating procedures. The TRU generator site QAPjPs must be approved by CAO (DOE94).

2.2.7 Qualification of Existing Data

2.2.7.1 Background

An important factor in performance assessment is the use of data that were not generated under a Quality Assurance Program that complies with the requirements of ASME NQA-1.[2] These data are referred to as *existing data* or *old data*[3]. The majority of the early experimental work performed under and above ground at the WIPP was conducted by the SNL, beginning in the early 1980's. SNL has only recently begun to configure its Quality Assurance Program to be consistent with ASME NQA-1, and therefore many of the technical data generated since the early 1980s in support of various scientific investigations concerning waste isolation are considered existing data. Under 40 CFR part 194, data that were not

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[2] In the context of Section 2.2.7, ASME NQA-1 means ASME-NQA-1-1988, ASME NQA-2A-1990, addenda part 2.7 to ASME NQA-1-1989, and ASME NQA-3-1989 [excluding Section 2.1(b) and (c) in Section 17.1].

[3] "Existing data is data developed prior to the implementation of an NQA-1, -2, -3 QA program by SNL and its contractors, or data developed outside the SNL-WIPP program, such as by oil companies, national laboratories, universities, or data published in technical or scientific publications. Existing data does not include information that is accepted by the scientific and engineering community as established fact (e.g., engineering handbooks, density tables, gravitational laws, etc.)." (SNL95)

generated under an ASME NQA-1 quality assurance program must be qualified in a manner consistent with one of the following four approaches:

- peer review
- confirmatory testing
- use of corroborating data
- a quality assurance program that is equivalent in effect to ASME NQA-1

Additionally, the specific methodology used must be approved by the administrator.

In commenting on EPA's Advance Notice of Proposed Rule-making on compliance criteria, DOE proposed the following steps to verify data used in compliance assessment (DOE93c):

- The data will be examined against currently approved QA procedures. This examination will be directed to show that if the data had been obtained under current QA practices, the results would be equivalent to the ongoing data collection.

- If QA equivalency of the data cannot be shown, and the data are crucial to compliance demonstration, an independent peer review group will be established to assess the validity of the data, and DOE will submit the findings to EPA.

- If an acceptable QA level cannot be demonstrated to EPA, and the data are crucial to compliance, DOE will do statistical resampling to establish the quality of the data or initiate an activity to reacquire the needed data. However, the original data will not be discarded. Instead, they will be evaluated for use as confirmation of the newly acquired data.

2.2.7.2 SNL Program For Qualifying Existing Data

In 1994, SNL began to address the issue of *qualifying existing data* (QED). The process initially followed the approach outlined by the US NRC (NRC88a) and consisted of three main areas:

- Identifying those data necessary for compliance calculations, for settlement of compliance issues or for submission of DOE's certificate of compliance and organizing them into groups called Data Records Packages (DRPs);

- Determining whether the selected DRPs are acceptable with respect to technical and Quality Assurance criteria through the use of a team of qualified, independent

personnel with expertise in the areas of interest, called Independent Review Teams (IRT). Each data package is evaluated by an IRT that determines whether the data were collected under a QA program equivalent to ASME NQA-1, and whether the Technical/Scientific Protocols employed during data collection are acceptable when evaluated against a pre-established check list.

- Remediating those data that were judged to be unacceptable by virtue of technical and/or Quality Assurance flaws by IRT assessment. If a DRP is determined to be inadequate for technical and/or Quality Assurance reasons by an IRT, alternative methods for qualifying the data are to be identified by a Qualification Methods Team (QMT). Such methods include the use of corroborating data, confirmatory testing and peer review. Data that cannot be suitably qualified must be abandoned.

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- Determining whether the selected DRPs are acceptable with respect to technical and quality assurance criteria through the use of a team of qualified, independent personnel with expertise in the areas of interest, called Independent Review Teams (IRT). Each data package is evaluated by an IRT that determines whether the data were collected under a QA program equivalent to ASME NQA-1. and whether the Technical/Scientific Protocols employed during data collection are acceptable when evaluated against a pre-established check list.

- Remediating those data that were judged to be unacceptable by virtue of technical and/or quality assurance flaws by IRT assessment. If a DRP is determined to be inadequate for technical and/or quality assurance reasons by an IRT, alternative methods for qualifying the data are to be identified by a Qualification Methods Team (QMT). Such methods include the use of corroborating data, confirmatory testing and peer review. Data that cannot be suitably qualified must be abandoned.

2.2.7.4 Current Status

The assessment of existing data focused on data in four technical areas: natural barriers, disposal system design and engineered barriers, waste interactions, and human initiated processes and events. As of August 30, 1995, 46 DRPs had been identified as high priority , meaning that it was likely that DOE would use them in whole or part for the submission of their compliance application. Of these, 26 were assessed as not adequate to support compliance; 20 were assessed as adequate to support compliance. Of the 26 DRPs assessed as not adequate, 23 were pending QMT review.

SNL began the QED process by evaluating DRPs in November 1994, and has made considerable progress to date, as discussed previously. Personnel from EPA Office of Radiation and Indoor Air-Las Vegas Facility and their technical support contractor have observed IRT assessments of approximately ten DRPs, some as late as June, 1995. Additionally, CAO performed a Quality Assurance Audit of the SNL QED process in September, 1995 (DOE CAO Audit A-95-05). These observations have provided EPA with insight into SNL's approach to the QED process. The governing document for the QED process (SNL QAP 20-3) (SNL95a) has been evolving as SNL has progressed through the QED process. Once SNL's methodology is completed, it would be presented to EPA for approval.

2.2.8 Quality Assurance for Models and Codes

Sandia National Laboratories is conducting iterative performance assessments to provide interim guidance prior to preparing a final compliance evaluation (SNL92). These performance assessments describe the conceptual basis for consequence modeling and performance assessment methodology, including the selection of scenarios for analysis, the determination of scenario probabilities, and the estimation of scenario consequences (SNL92).

The modeling process described in references SNL92 and SNL92a includes significant participation of peer review groups external to Sandia. The iterative nature of the work leads to a constant updating of models. If, during review of a compliance application, it is determined that one or more parts of the model(s) is based upon data obtained in the early stages of the WIPP program when a less stringent QA program was used, the model's validity could become an issue. If found to exist, such issues must be settled using the QA standards

and criteria applicable to the performance assessment process itself.

WIPP procedure No. PAP02, Computer Software Supporting Performance Assessments of the Waste Isolation Pilot Plant, describes four classes of software:

- A- Adjudicated (full QA status)
- C- Candidate (partial QA status, possibly undergoing continued refinement)
- D- Dormant (obsolete software formerly in Class A or C)
- X- Experimental (entry level, software in early stages of development or experimentation, no QA requirements)

A Software Review Committee decides whether to classify software as Class A. It is SNL policy to use only Class A software for the performance assessment to support the application for certification of compliance. This procedure is not as rigorous as that specified in NQA-2 (part 2.7).

2.3 SUMMARY OF U.S. NRC REQUIREMENTS

The purpose of this section is to identify the NRC QA requirements for data gathering, analyses, and modeling applicable to high-level radioactive waste disposal systems.[4] Useful parallels may be drawn between NRC and EPA requirements since both involve modeling of geologic nuclear waste repositories.

Quality assurance requirements for disposal of high-level radioactive wastes in geologic repositories are specified in Subpart G of 10 CFR part 60. Subpart G requires DOE to implement a QA program based on the criteria of Appendix B of 10 CFR part 50 as applicable[5], and which is appropriately supplemented by additional criteria. Specific QA criteria which the NRC staff use to review the DOE QA program are provided in "Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions" (NRC89). This document provides NRC's position on the meaning of the term "as applicable" as used in Appendix 2B of the disposal system program.

The NRC Review Plan endorses ASME NQA-1-1986 and incorporates the lessons learned

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[4] References to DOE in this section refer to DOE's Office of Civilian Radioactive Waste Management.

[5] 10 CFR Part 50 does not address requirements for software or data collection for siting such as are addressed by ASME NQA part 2.7 and ASME NQA-3.

from the Ford Study (NRC84), such as the use of technical audits and readiness reviews. This document also accounts for differences between power reactor projects and the high-level nuclear waste disposal system program and references the NRC staff's Technical Positions.

Each section of the Review Plan corresponds to one of the 18 criteria of 10 CFR part 50, Appendix B, and provides the acceptance criteria the NRC staff uses to evaluate QA program descriptions or plans. The areas addressed by each of these 18 criteria are listed below:

Criterion 1	Organization
Criterion 2	Quality Assurance Program
Criterion 3	Design Control
Criterion 4	Procurement Document Control
Criterion 5	Instructions, Procedures, and Drawings
Criterion 6	Document Control
Criterion 7	Control of Purchased Material, Equipment, Items and Services and Software
Criterion 8	Identification and Control of Items, Services, and Software
Criterion 9	Control of Special Processes
Criterion 10	Inspection
Criterion 11	Test Control
Criterion 12	Control of Measuring and Test Equipment
Criterion 13	Handling, Storage, and Shipping
Criterion 14	Inspection, Test, and Operating Status
Criterion 15	Nonconformances
Criterion 16	Corrective Action
Criterion 17	Quality Assurance Records
Criterion 18	Audits

As stated in §60.151, the QA program applies to all systems, structures, and components "important to safety," to design and characterization of barriers "important to waste isolation," and to activities related thereto. These activities include site characterization, facility and component construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities.

Section 60.2 defines the term "important to safety" as those "engineered structures, systems, and components essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area at any time until the completion of permanent closure."

NUREG-1318, "Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to QA Requirements" (NRC88b) provides guidance for the identification of items important to safety and waste isolation. The NRC QA requirements relating to data that are important to safety or to waste isolation are summarized in Sections 2.3.1, 2.3.2 and 2.3.3, below.

2.3.1 Data Gathering

Site characterization involves data gathering. As required by Subpart B of 10 CFR part 60, DOE must conduct a program of site characterization in accordance with the following:

- Investigations to obtain the required information shall be conducted in such a manner as to limit adverse effects on the long-term performance of the geologic disposal system to the extent practical.
- The number of exploratory boreholes and shafts shall be limited to the extent practical consistent with obtaining the information needed for site characterization.
- To the extent practicable, exploratory boreholes and shafts in the geologic disposal system operations area shall be located where shafts are planned for underground facility construction and operation or where large unexcavated pillars are planned.
- Subsurface exploratory drilling, excavation, and in situ testing before and during construction shall be planned and coordinated with geologic disposal system operations area design and construction.

DOE must submit to the NRC a description of the QA program to be applied during the site characterization phase. As a result of meeting the requirements of the QA Plan, Q-lists will be generated. The criteria developed in preparing Q-lists are essential to identifying quality-affecting activities and, of necessity, require a disciplined, systematic analysis of the entire project (NRC88b).

The Q-list identifies structures, systems, and components important to safety and engineered barriers important to waste isolation. A quality activities list identifies the site characterization activities that may provide data for use in assessments of the waste isolation and containment capabilities of natural and engineered barriers, those activities related to the actual assessments, and those activities that may adversely impact the waste isolation capabilities of these barriers.

Data and information needs are identified by compliance assessments, performance allocation[6] among the various components of the natural and engineered barrier systems, design, and modeling of the geologic disposal system. The need to collect additional data depends on the availability and quality of existing data. The QA criteria for data gathering are provided in Criteria 3, 5, 8, 9, 10, 11, 12, 13, 17, and 18 listed above.

2.3.2 Data Analysis

Data analysis is a design activity subject to the requirements of design control, design verification, and design changes control. The QA criteria for data analysis are provided in Criteria 3, 17 and 18.

2.3.3 Data Modeling

The data needed for construction of an adequate model of the disposal system and compliance assessments, and the associated computer modeling, are subject to 10 CFR 60 Subpart G QA requirements.

Computer programs should be developed, controlled, and used in accordance with the QA program. Guidance for documentation of computer codes is provided by NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management" (NRC83)[7]. Documentation includes five categories: software summary, description of mathematical models and numerical methods, user's manual, code assessment and support, and continuing documentation and code listing.

General recommendations for software quality assurance programs are provided in NUREG/CR-4640 "Handbook of Software Quality Assurance Techniques Applicable to the Nuclear Industry" (NRC87). The handbook is intended to be used by the nuclear power industry as an aid for structuring QA programs and assessing the adequacy of existing software practices including development and use.

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[6] Performance allocation: This term applies to the process of deriving subsystem and component performance goals from performance objectives. A systematic process of assigning confidence levels with their desired, associated performance goals for the mined geologic disposal systems, subsystems, and components (NRC88b).

[7] NUREG-0856 does not comply completely with ASME NQA Part 2.7.

Guidance for NRC organizations and NRC contractors in the development and maintenance of software for use by NRC staff is provided in NUREG/BR-0167 "Software Quality Assurance Program and Guidelines" (NRC93). Those guidelines apply to technical application software used in safety decisions by the NRC. The applicability of those guidelines depend on the purpose and use of the software and management's judgment of the cost-effectiveness of each software quality activity. Most projects incorporate verification and validation, configuration management, and documentation control activities.

Verification is the process of ensuring that the products and processes of each of the major life cycles' activities meet the standards for the products and the objectives of that activity. Validation is the process of demonstrating that the as-built software meets its requirements and is accomplished by review and demonstration in a live or simulated environment.

Verification and validation activities include planning, formal life cycle reviews and audits, peer inspections, and testing. Testing is the process of detecting errors and verifying performance. Testing typically includes unit integration, qualification, and acceptance testing.

Fundamental to configuration management are the concepts of a baseline and change control. A baseline is a document or software that has been formally reviewed and agreed upon by the developer and sponsor, and thereafter serves as the basis for further development. It can be changed only through formal change control procedures. Change control is the process by which a change to a baseline is proposed, evaluated, approved or rejected, scheduled, and tracked.

Peer reviews may be employed for data modeling and computer models. Guidance on the use of the peer review process is provided in NUREG-1297 "Peer Review for High-Level Nuclear Waste Repositories" (NRC88). A peer review is a documented, critical review performed by experts who are independent of the work being reviewed. NUREG-1297 provides guidance on areas where a peer review is appropriate, the acceptability of peers, and the conduct and documentation of a peer review. Peer review is discussed in greater detail in Chapter 7.

The QA criteria relating to data and computer modeling are provided in Criteria 3, 6, 8, 9, 11, 14, 15, 17 and 18 from the above list.

2.3.4 Management and Oversight

NRC QA procedures describe how DOE and prime contractors exercise responsibility for the overall QA program. DOE and its prime contractors are required to identify a management position within each respective organization that retains overall authority and responsibility for the QA program. This position must:

- Be at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality and be sufficiently independent from cost and schedule;
- Have effective communication channels with other senior management positions; and
- Have no duties or responsibilities unrelated to QA that would prevent full attention to QA matters.

Persons and organizations performing QA functions must have sufficient authority and organizational freedom to:

- Identify quality problems;
- Initiate, recommend, or provide solutions through designated channels;
- Verify implementation of solutions; and
- Assure that further processing, delivery, installation, or operation is controlled until a nonconformance, deficiency, or unsatisfactory condition has been corrected.

The QA program should provide control over all activities affecting the quality of the identified activities, structures, systems, and components to an extent consistent with their required performance (NRC88b).

The QA criteria related to management and oversight are provided in Criteria 1, 2, 15, 16, and 18.

2.3.5 Qualification of Older Data

Data pertinent to waste isolation systems and/or components may exist that were developed before the implementation of a 10 CFR part 60 Subpart G QA program by DOE and its contractors. Additionally, data that were developed outside of the DOE disposal system program may be identified as pertinent and used by DOE for purposes of waste isolation, such as data generated by oil companies, national laboratories, universities, or data that have been published in technical or scientific publications. These are considered "existing data". This category does not include information accepted by the scientific and engineering community as established facts such as are found in engineering handbooks, density tables, gravitational laws.

NRC specifies that procedures should be established describing methods of reviewing and qualifying existing data. NUREG-1298 "Qualification of Existing Data for High-Level Nuclear Waste Repositories, Generic Technical Position" (NRC88a) describes four general approaches, but does not provide implementation guidance for this process.

2.4 ASME NQA-1, NQA-2, AND NQA-3 STANDARDS

EPA is requiring that DOE implement a QA program that meets the requirements of the American Society of Mechanical Engineers' "Quality Assurance Program Requirements for Nuclear Facilities" (NQA-1-1989 edition); "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications" (NQA-2a-1990 addenda (part 2.7) to ASME NQA-2-1989 edition); and "Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories" [NQA-3-1989 edition, excluding Section 2.1(b) and (c)][8]. EPA has mandated

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[8] EPA proposes the use of the ASME NQA 1989 editions instead of the ASME NQA 1994 edition for the following reasons:

- The ASME NQA 1994 edition allows a reduction in the level of structure for personnel qualification and certification for designers/verifiers, inspection personnel, testing and audit personnel to only a subjective level by supervisory analysis.
- ASME NQA-3-1989 contains added amplification requirements related to Scientific and Technical Data (S&TD) applications to support the WIPP that are not included in ASME NQA 1994 edition. These areas include: (1) planning,quality standards and criteria for the collection of S&TD; (2) surveillance, including in-process, deficiencies, and follow-up; (4) communication; (5) design control; (6) peer reviews; (7) data processing; and (8) qualification of existing data.

the use of the ASME standards because these national consensus standards offer the most comprehensive and specific set of QA requirements for all compliance-related elements of the WIPP disposal system. NRC has taken a similar approach by specifying equivalent criteria in 10 CFR part 50, Appendix B.

2.4.1 ASME NQA-1

This Standard sets forth requirements for the establishment of a quality assurance program for the siting, design, construction, operation, and decommissioning of nuclear facilities. This Standard's requirements apply to activities which could affect the quality of structures, systems, and components of nuclear facilities. These activities include:

- attaining quality objectives;
- assuring that an appropriate quality assurance program is established; and
- verifying that activities affecting quality have been correctly performed.

Activities affecting quality include siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, modifying and decommissioning (ASM89a).

2.4.2 ASME NQA-2, Part 2.7

Part 2.7 provides requirements "for the development, procurement, maintenance, and use of computer software, as applied to the design, construction, operation, modification, repair, and maintenance of nuclear facilities" (ASM89b). It supplements the requirements of NQA-1.

2.4.3 ASME NQA-3

NQA-3 was developed specifically for site characterization of high-level nuclear waste repositories. (The same QA considerations apply to repositories for transuranic wastes.) NQA-3 is to be used in conjunction with NQA-1 to set forth QA program requirements and guidance for the collection of scientific and technical information for site characterization of high-level nuclear waste repositories. "The requirements of NQA-1 and NQA-3 are intended to meet and clarify the criteria of 10 CFR 50, Appendix B, and 10 CFR 60, Subpart G, for

high-level nuclear waste repositories” (ASM89c).

2.5 REFERENCES

ASM89a American Society of Mechanical Engineers, "Quality Assurance Program Requirements for Nuclear Facilities,” ASME NQA-1-1989 Edition.

ASM89b American Society of Mechanical Engineers, "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications,” Part 2.7, ASME NQA-2-1990 Edition (First Addenda to ASME NQA-2-1989 Edition).

ASM89c American Society of Mechanical Engineers, "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 Edition.

DOE91 U.S. Department of Energy, "Quality Assurance," DOE Order 5700.6C, August 21, 1991.

DOE91a U.S. Department of Energy, Office of Environmental Restoration and Waste Management, "Quality Assurance Requirements and Description (QARD)," Revision 0, October 31, 1991.

DOE92 U.S. Department of Energy, "Quality Assurance Program Plan for the Waste Isolation Pilot Plant Experimental-Waste Characterization Program," Waste Isolation Pilot Project, DOE/EM/48063-1, Final Draft, Revision 2.0, October 1992.

DOE93a U.S. Department of Energy (M. Frei) letter dated July 9, 1993, to EPA (J. William Gunter), identification of issues.

DOE93b U.S. Department of Energy (P. D. Grimm) letter dated March 31, 1993, to U.S. Environmental Protection Agency (M. H. Shapiro), Attn: Docket No. A-92-56, comments on ANPR 58 FR 8029.

DOE94 U.S. Department of Energy, Carlsbad Area Office, "TRU Waste Characterization Quality Assurance Program Plan," CAO-94-1010, DRAFT, Revision B, July, 1994.

DOE95 U.S. Department of Energy, Carlsbad Area Office, "Quality Assurance Program Description," CAO-94-1012, DRAFT, Revision 1.0, August, 1995.

EPA80 U.S. Environmental Protection Agency Interim Guidelines and Specifications

for Preparing Quality Assurance Program Plans, QAMS-005-080.

NRC83 U.S. Nuclear Regulatory Commission, S. A. Silling, Office of Nuclear Materials Safety and Safeguards, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management," NUREG-0856, June 1983.

NRC84 U.S. Nuclear Regulatory Commission, Altman, W., et al.,"Improving Quality and the Assurance of Quality in the Design and Construction of Commercial Nuclear Power Plants, NUREG-1055, May 1984.

NRC87 U.S. Nuclear Regulatory Commission/Pacific Northwest Laboratory, J. L. Bryant, N. P. Wilburn, "Handbook of Software Quality Assurance Techniques Applicable to the Nuclear Industry," NUREG/CR-4640 (PNL-5784), August 1987.

NRC88 U.S. Nuclear Regulatory Commission, Altman, W.D., et al., "Peer Review for High-Level Nuclear Waste Repositories," NUREG-1297, February 1988.

NRC88a U.S. Nuclear Regulatory Commission, W. D. Altman, J. P. Donnelly, J. E. Kennedy, Office of Nuclear Materials Safety and Safeguards, "Qualification of Existing Data for High-Level Nuclear Waste Repositories," Generic Technical Position, NUREG-1298, February 1988.

NRC88b U.S. Nuclear Regulatory Commission, A. B. Duncan, S. J. Bilhorn, J. E. Kennedy, Office of Nuclear Materials Safety and Safeguards, "Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements," NUREG-1318, April 1988.

NRC89 U.S. Nuclear Regulatory Commission, "Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions," Revision 2, March 1989.

NRC93 U.S. Nuclear Regulatory Commission, "Software Quality Assurance Program and Guidelines," NUREG/BR-0167, February 1993.

NRC93a U.S. Nuclear Regulatory Commission (B. Youngblood) letter dated March 22, 1993, to EPA (J. W. Gunter), comments on ANPR 58 FR 8029.

SNL92 Sandia National Laboratories, WIPP Performance Assessment Department, "Preliminary Performance Assessment for the Waste Isolation Pilot Plant, December 1992, Volume 2: Technical Basis," SAND92-0700/2, December 1992.

SNL92 Sandia National Laboratories, WIPP Performance Assessment Department, "Preliminary Performance Assessment for the Waste Isolation Pilot Plant, December 1992, Volume 1: Third Comparison with 40CFR191, Subpart B," SAND92-0700/2, March 1993.

SNL95a Sandia National Laboratories, Waste Isolation Pilot Plant, Quality Assurance Procedure QAP 20-3, "Qualification of Existing Data", Revision 2, June 28, 1995.

SNL95b Sandia National Laboratories, "Waste Isolation Pilot Plant Quality Assurance Program Description," Rev. R, July, 1995.

WTA94 WTAC Independent Review Team (IRT) Desk Instruction IRT DI 1.0, Revision 1, Independent Review Team Qualifications, Selection and Roles, November, 1994.