

CARD No. 22

Quality Assurance

22.A.1 BACKGROUND

Quality assurance (QA) is a process for enhancing the reliability of the technical data and analyses underlying DOE's Compliance Certification Application (CCA). Section 194.22, Quality Assurance, sets requirements that apply to data and information collected in support of the CCA and as part of the WIPP program. This background section provides a general description of EPA's actions to assess DOE's compliance with the requirements of 40 CFR 194.22.

The first assessment for compliance with the QA requirements was for EPA to determine if DOE correctly executed QA programs for the items and activities listed in 194.22(a)(2). The second assessment was to determine if DOE qualified all data, including existing data that were collected prior to the implementation of QA programs (Section 194.22(b)&(d)). The third assessment was to determine if DOE assessed the application's data for their quality characteristics (Section 194.22(c)).

EPA took two general steps to perform each of the three assessments mentioned above. First, EPA reviewed the QA chapter of the CCA (Chapter 5) and associated references to determine if DOE provided a satisfactory description of compliance with the QA requirements. During this stage EPA requested and reviewed additional information from DOE. In the second step, EPA conducted audits at several WIPP-related facilities to verify compliance with the requirements of 40 CFR 194.22 (see Sections 194.22(e) and 194.21). For example, EPA conducted audits to verify the proper execution of QA programs at DOE's Carlsbad Area Office (CAO), Sandia National Laboratories (SNL), and Westinghouse's Waste Isolation Division (WID). This CARD contains only the general results of these audits, and it references the detailed audit reports that are available in the public docket for the certification rulemaking (Air Docket A-93-02).

Four documents are referenced in 40 CFR 194.22 and throughout this CARD, and the reader may wish to obtain copies of these referenced documents. These documents are available in the public docket (Air Docket A-93-02) or from the addresses noted below:

- ◆□ Three (3) standards for nuclear quality assurance (NQA) are referenced in 40 CFR 194.22(a)(1). The NQA standards contain numerous QA requirements for the WIPP that are not repeated in 40 CFR 194 or in this CARD. These documents are available in the public docket (Category II-G, Item 1, CCA Reference Numbers 9, 10, and 11) or from:

The American Society of Mechanical Engineers Service Center
22 Law Drive, P.O. Box 2900
Fairfield, New Jersey 07707-2900
(800) 843-2763

- ◆ □ NUREG-1297, Peer Review for High Level Nuclear Waste Repositories, is referenced in 40 CFR 194.22(b). NUREG-1297 provides guidelines for conducting peer review, one of the methodologies used for data qualification. NUREG-1297 is available in the public docket (Docket A-93-02, Item III-B-1h) or from:

United States Nuclear Regulatory Commission
Public Document Room
Washington, D.C. 20555
(202) 634-3273, (800) 397-4209

Inspections and audits of WIPP facilities were performed by EPA to verify compliance with the QA requirements. The audits of QA programs were performed in accordance with written checklists that are based on the NQA requirements. For example, NQA-1 basic element #16, entitled Corrective Action, begins, “Conditions adverse to quality shall be identified promptly and corrected as soon as practical.” Correspondingly, EPA’s audit checklist contains the following question: “Are conditions adverse to quality identified promptly and corrected as soon as practical?” The auditors reviewed the WIPP facilities’ procedures to determine if this requirement had been *established*, and then the auditors selected random samples of WIPP reports, entitled Corrective Action Reports, to verify that this requirement had been *implemented/executed*. Completed checklists are provided as an attachment to each audit report. For a list of audit reports generated by EPA, see Section 194.22(e) below.

The results of an audit are based on the severity of the “findings.” A “finding” is an instance of noncompliance with the establishment or implementation of a NQA requirement. A QA program is found satisfactory to the extent that findings are isolated (i.e., not representative) and of low consequence (i.e., not essential for compliance).

EPA conducted an audit of CAO’s quality assurance program on December 9-13, 1996 (EPA 1997a) and determined that CAO QA organization adhered to the requirements of NQA-1 element #18, entitled Audits. EPA thus determined that CAO’s QA organization can perform audits properly. Based on that determination, EPA found it acceptable to employ DOE audits to verify the proper execution of QA programs at the facilities of some waste generator sites. In other words, the Agency performed inspections of DOE audits at the facilities of waste generators to verify the proper execution of QA programs. EPA retains full authority under Section 194.21 to conduct its own audits.

It is important to note that the CCA alone does not provide all the documentation necessary to verify the proper execution of a QA program for the items and activities listed in Section 194.22(a)(2). Section Section 194.22(e) requires EPA to verify that DOE has properly executed a QA program for the areas indicated in Section 194.22(a)(2). Most of the “objective evidence” for determining whether or not a QA program has been properly executed exists at the WIPP-related facilities and waste generator sites, and is examined during EPA field audits or EPA inspections of DOE field audits. The function of audits is to examine objective evidence to determine compliance of the QA programs with the applicable NQA standards. This CARD

serves to highlight EPA's audits and inspections of DOE's audits under which such "objective evidence" was examined at WIPP-related facilities.

EPA's Compliance Application Guidance for 40 CFR Part 194 (CAG) called for DOE to provide much of the required QA documentation in the CCA. Because of the voluminous nature of these QA records, however, EPA found that it was impracticable to expect DOE to provide in the CCA all QA records identified in the CAG. EPA recognized that it was more efficient to review these records during field inspections and audits. Further, the CAG is intended solely as guidance, and it does not establish compliance criteria or any other binding rights or duties.

22.A.2 REQUIREMENT

(a)(1) "As soon as practicable after April 9, 1996, the Department shall adhere to a quality assurance program that implements the requirements of the ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda, part 2.7, to ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition [excluding Section 2.1 (b) and (c), and Section 17.1]. (Incorporated by reference as specified in § 194.5)."

22.A.3 ABSTRACT

Chapter 5 of the CCA discusses DOE's QA program. EPA reviewed Chapter 5 and referenced documents and determined that DOE provided an adequate description of compliance with the NQA requirements. The Carlsbad Area Office's (CAO) Quality Assurance Program Document (CAO QAPD), dated April 22, 1996, was included with the CCA as Appendix QAPD and incorporates the requirements of ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda, part 2.7, to ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1 (b) and (c), and Section 17.1). EPA conducted an audit of CAO's quality assurance program on December 9-13, 1996 (EPA 1997a). The audit determined that CAO adhered to a QA program that implements the requirements of 40 CFR 194.22(a)(1), including that CAO adhered to the requirements of NQA-1 element #18, entitled Audits. CAO performed audits of its lower-tier organizations, such as Sandia National Laboratories, to enforce the flow down of the NQA requirements from the CAO QAPD. EPA will perform periodic audits (referred to as "maintenance audits") to verify that CAO's QA program is maintained in accordance with NQA requirements. Section 40 CFR 194.22(a)(2) discusses EPA's verification activities of the QA programs of the lower-tier organizations.

22.A.4 COMPLIANCE REVIEW CRITERIA

The requirements of NQA-1, NQA-2, part 2.7, and NQA-3 provide the basis for EPA audit checklists to verify if an appropriate QA program has been established and executed. The Agency required DOE's QA program to meet the requirements of:

- ◆ □ American Society of Mechanical Engineers (ASME) "Quality Assurance Program Requirements for Nuclear Facilities" (NQA-1-1989). This document sets forth requirements for the establishment and execution of quality assurance programs for the siting, design, construction, operation,

and decommissioning of nuclear facilities. NQA-1 contains 18 basic requirements along with supplements. This arrangement of basic and supplementary requirements of standards permit the application of the entire standard or only portions of the standard. The extent of this application depends upon the scope of the work being performed and the relative importance of the items being produced or services being provided.

- ◆ ASME's "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications" (part 2.7 of NQA-2a-1990, addendum to ASME NQA-2-1989). 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. It supplements the requirements of ASME NQA-1 and is used in conjunction with applicable Basic and Supplementary Sections of ASME NQA-1 when and to the extent specified by the organization invoking Part 2.7.
- ◆ ASME's "Quality Assurance Requirements for the Collection of Scientific and Technical Information on Site Characterization of High-Level Nuclear Waste Repositories" (NQA-3-1989), excluding sections 2.1(b), 2.1(c) and 17.1. ASME NQA-3 is used in conjunction with NQA-1 to set forth Quality Assurance Program requirements and nonmandatory guidance for data used to characterize sites for high-level nuclear waste repositories.

22.A.5 DOE METHODOLOGY AND CONCLUSIONS

The CAO QAPD establishes and describes the QA program requirements that apply to programs and projects managed by DOE's CAO. The program-wide requirements in this document establish the controls applicable to all participants within DOE's management infrastructure. The CAO QAPD addresses the eighteen (18) basic requirements, including supplemental requirements, established by NQA-1; the computer software requirements established by NQA-2a, part 2.7; and the requirement for collection of scientific and technical information for site characterization of high level nuclear waste repositories established by NQA-3(1989).

Chapter 5.1 (pp. 5-1 to 5-3) of the CCA states that DOE provides the overall QA program requirements for WIPP via the CAO QAPD. The CAO QAPD requirements are further supported and amplified by the next tier of QA program documents, which includes the Sandia National Laboratories (SNL) implementing procedures (SNL QAP), Westinghouse's Waste Isolation Division (WID) Quality Assurance Program Description, and the quality assurance program plans (QAPPs) for the individual waste generator sites¹.

¹ To date only one waste generator site, the Los Alamos site, has been found by EPA to have appropriately established and executed a documented quality assurance program (see also Section 194.22(a)(2)(i) of this CARD). EPA audited the Los Alamos site and determined that the Site Certification Quality Assurance Plan (SCQAP) and Quality Assurance Project Plan (QAPjP) demonstrate a quality assurance program that accords with the NQA

DOE, SNL, and WID conduct audits, surveillance, and management assessments to verify the adequacy, implementation, and effectiveness of the QA documents. The CCA, Chapter 5.4 (pp. 5-45 to 5-48), discusses the implementation of the documents and lists CAO audit and surveillance dates that determined that QA documents were properly implemented.

22.A.6 EPA COMPLIANCE REVIEW

To measure compliance, EPA first reviewed Chapter 5 and the CAO QAPD to determine the documents' adequacy for compliance with the requirements of Section 194.22(a)(1). In order to verify implementation of the requirements of Section 194.22(a)(1), EPA conducted an audit of the CAO quality assurance program on December 9-13, 1996 (EPA 1997a). The CAO is located in Carlsbad, New Mexico, and is responsible for the management of the WIPP. The purpose of the audit was to verify the appropriate execution of the requirements of 40 CFR 194.22(a)(1). This audit also served to verify that the top-tier CAO QA document (QAPD) incorporated the requirements of 194.22(a)(1) and that the quality assurance program described in Chapter 5 of the WIPP Compliance Certification Application (CCA) was properly implemented at CAO.

The scope of the audit included all activities under the purview of the CAO QA program. EPA's audit included an extensive review of CAO's implementing procedures and the records resulting from those procedures. EPA conducted extensive interviews with CAO staff and contractors responsible for the implementation and management of CAO's quality assurance program and its procedures. The five-day audit resulted in four findings, all of which were isolated and of low consequence. Three of the findings were associated with CAO Team Procedure (TP) 10.5. TP 10.5 is the procedure used to execute the Peer Review Process. One of these three findings was corrected during the audit. To address concerns associated with the other two findings, EPA conducted a separate audit of the peer review process on February 10-12, 1997 (EPA 1997d). A more detailed discussion of EPA's peer review audit is provided in **CARD 27—Peer Review**. The remaining finding was a non-compliance with NQA-1, Requirement 2. Requirement 2 calls for regular assessments of the adequacy of the QA program; however, the implementing CAO procedure did not contain this provision. The CAO procedure to address this requirement was under revision during the audit and has been changed to address this finding. All findings were corrected within 30 days of the audit.

22.B.1 REQUIREMENT

(a)(2)(i): "Any compliance application shall include information which demonstrates that the quality assurance program required pursuant to paragraph (a)(1) of this section has been established and executed for waste characterization activities and assumptions."

standards. The two Los Alamos documents combined are the equivalent of a quality assurance program plan (QAPP) required by element #2 of the NQA-1 standard, entitled "Quality Assurance Program." EPA will audit (or inspect DOE audits of) each of the remaining generator sites to verify the establishment and execution of QA programs that are in accordance with NQA.

22.B.2 ABSTRACT

Waste characterization activities (WCA) are essential for determining whether or not the WIPP will comply with the radioactive waste disposal regulations. Therefore, EPA requires that QA programs be applied to WCA. WCA must be conducted at individual DOE waste generator sites (henceforth referred to as “sites”) prior to shipment of waste from those sites. The ten major sites are the Nevada Test Site, Mound Plant (Ohio), Lawrence Livermore National Laboratory (California), Argonne National Laboratory East (Illinois), Idaho site, Rocky Flats site (Colorado), Los Alamos site (New Mexico), Oak Ridge site (Tennessee), Hanford site (Washington), and the Savannah River site (South Carolina). WCA includes the use of analyses, sampling, computations, computer codes, use of process knowledge and the system of controls described in 40 CFR 194.24(c)(4). Waste generator sites’ compliance with the QA requirements of 194.22(a)(2)(ii) and (iv) and 194.24(c)(3) and (5) are addressed in this section of the CARD.

DOE informed EPA that the Los Alamos site (LANL) was ready for EPA to verify the appropriate establishment and execution of a QA program. EPA reviewed the QA program plan (QAPP) for LANL (comprised of both the Site Certification Quality Assurance Plan and Quality Assurance Project Plan-QAPjP) and inspected the site during CAO audits and demonstrations of WCA. Based on the reviews and inspections, EPA determined that LANL had properly established and executed a QA program for WCA. The inspection of CAO’s audit at LANL verified the proper execution of a QA program for WCA, assumptions, sampling, analyses, computations and computer codes, use of process knowledge, and the system of controls described in paragraph 194.24(c)(4). Therefore, where LANL complies with 194.22(a)(2)(i) for WCA, it also complies with the QA requirements of 194.22(a)(ii)&(iv) and 194.24(c)(3)&(5). The remaining generator sites and mobile units will require EPA reviews of their individual QAPPs, and will also require EPA audits or inspections of CAO audits to verify the appropriate executions of QA programs. EPA will periodically audit or inspect all sites and mobile unit to verify that the QA programs are maintained in accordance with NQA requirements.

22.B.3 COMPLIANCE REVIEW CRITERIA

The requirements of NQA-1 and NQA-2, part 2.7, provide the basis for EPA’s checklists to determine if an appropriate QA program has been established and executed. (EPA does not consider the requirements of NQA-3 to be applicable to WCA.) As required by NQA element #2, entitled “Quality Assurance Program,” each site must plan, implement and maintain a documented quality assurance program that is in accordance the NQA standards. EPA will perform site-specific audits or inspections of CAO audits to determine the adequacy of the site-specific QAPPs and to determine that the QA programs are properly executed. In any instance of WCA that does not conform to any applicable requirement of 40 CFR 194, EPA expects prompt implementation of corrective action (NQA element #16) and of NQA element #15, entitled “Control of Nonconforming Items,” to prevent inadvertent installation of any nonconforming waste at the WIPP.

22.B.4 DOE METHODOLOGY AND CONCLUSIONS

Chapter 5.1.1 (p. 5-3) of the CCA states that the Transuranic Waste Baseline Inventory Report (TWBIR), found in Appendix BIR of the CCA, is the inventory source document that provides estimates of waste data used in the performance assessment. These estimates are presented in tabular form in Chapter 4.0 of the CCA. 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.

The TRU QAPP describes quality control requirements for characterization of TRU waste coming to the WIPP. The TRU QAPP also identifies the performance-based QA and quality control requirements with which each facility participating in the program must comply, as well as the performance criteria for preparation, review and approval of site QAPjP. The CCA, Chapter 5 (p. 5-5), lists generator site QAPjPs that were approved by DOE. According to the CCA, DOE verified program implementation at participating sites through audits and assessments to ensure that WIPP waste characterization activities comply with applicable QAPjPs and standard operating procedures.

22.B.5 EPA COMPLIANCE REVIEW

Section 194.22(a)(2)(i) requires DOE to include in the CCA information that demonstrates that the required QA program has been “established and executed” for WCA prior to certification. The criteria at Sections 194.24(c)(3) and 194.24(c)(5) cross-reference the QA requirements set forth at Section 194.22. The CCA states that most sites will not begin WCA until after 1997, and that it is not reasonable to establish and execute QA programs at this time for future WCA. EPA therefore attached conditions to the WIPP’s certification. One of the conditions is that each site performing WCA must demonstrate the establishment and execution of a QA program that adheres to the applicable NQA requirements. An individual site will not be allowed to ship waste to WIPP until the Agency verifies the proper execution of a QA program at the site.

CAO informed EPA that the Los Alamos site was ready for EPA inspections to verify the establishment and execution of an appropriate QA program, and EPA performed three inspections of the Los Alamos site. EPA’s inspections of Los Alamos consisted of one preliminary inspection of a CAO audit in May 12, 1997, and two full inspections of CAO audits during demonstrations of waste characterization in August 18-22 and September 10-12, 1997 (EPA 1997i)². EPA’s full inspections determined that the Los Alamos site had appropriately established and executed a QA program for WCA. The third inspection was required to verify the proper operation of a computer system, called the WIPP Waste Information System (WWIS). The WWIS will transfer WCA information from Los Alamos to the WIPP site (see the discussion under Section 194.24(c)(4) in **CARD 24—Waste Characterization**). EPA’s inspections emphasized verifying

² EPA conducts preliminary inspections of the sites to obtain information and not to verify compliance with specified requirements. The preliminary inspections assist EPA with performing full or acceptance inspections to verify compliance.

the establishment of waste assessment procedures, software management, training, and use of acceptable/process knowledge for characterizing waste.

Waste characterization activities to meet WIPP requirements have not begun at the other sites (EPA performed one preliminary inspection of a CAO audit of the Idaho site on April 21-23, 1997 (EPA 1997h)). The Compliance Criteria specifically require that QA programs be established and executed with respect to waste characterization assumptions and activities, WCA incorporating process knowledge, and the system of controls required by Section 194.24(c)(4). Individual waste generator sites must demonstrate establishment and execution of QA programs for WCA before EPA will allow individual waste generator sites to transport waste for disposal at the WIPP.

With respect to other waste generator sites, EPA will verify compliance with Section 194.22(a)(2)(i) conditioned on separate, subsequent approvals from EPA that site-specific QA programs for waste characterization activities and assumptions have been established and executed in accordance with applicable NQA requirements at each waste generator site. EPA will conduct audits and/or inspections of DOE audits to determine whether compliant QA programs have been established and executed. A minimum 30-day public comment period will be allowed in relation to audits or inspections to determine whether compliant QA programs have been established and executed. Upon a determination that a compliant QA program is in effect at a particular waste generator site, EPA will exercise its authority under Sections 194.22(e) to conduct periodic inspections of approved sites to verify continued execution of the required QA programs. The Compliance Criteria require that EPA have unfettered access to sites, and organizational freedom to: (1) identify problems, (2) verify implementation of solutions, and (3) stop further waste characterization, shipment of waste, or emplacement of waste at the WIPP until EPA verifies proper disposition of a deficiency or unsatisfactory condition.

22.C.1 REQUIREMENT

(a)(2)(ii) “Any compliance application shall include information which demonstrates that the quality assurance program required pursuant to paragraph (a)(1) of this section has been established and executed for environmental monitoring, monitoring of performance of the disposal system and sampling and analysis.”

22.C.2 ABSTRACT

Environmental monitoring, monitoring of performance of the disposal system, and sampling and analysis activities are considered by EPA to be important for the determination of whether WIPP will comply with the radioactive waste disposal regulations. Therefore, EPA requires that QA programs be applied to these activities to enhance their reliability. The QA program for sampling and analyses for WCA is discussed in Section (a)(2)(i), and the QA program for analyses for the performance assessment is discussed in Section (a)(2)(iv). The Westinghouse Waste Isolation Division (WID) is located in Carlsbad, New Mexico, and is responsible for site management of the WIPP. WID conducted the WIPP’s baseline environmental monitoring, and will be responsible for monitoring of performance of the disposal

system and sampling and analysis. WID is also responsible for implementing the QA requirements of this section.

The CAO QAPD establishes the QA requirements for WID's implementing procedures. EPA conducted an audit of the WID quality assurance program on February 10-14, 1997. No findings were developed during this audit. The results of the EPA audit included a determination that an appropriate QA program has been executed for environmental monitoring, sampling and analysis. Monitoring of performance of the disposal system has not started, but EPA has no reason to believe that the QA program for this activity will not be similar to the QA program for existing monitoring activities. EPA finds that the necessary QA program had been established and executed to meet the requirements of 194.22(a)(2)(ii), and will perform periodic audits or inspections of CAO audits of WID to verify proper maintenance of a QA program in the future.

22.C.3 COMPLIANCE REVIEW CRITERIA

The requirements of NQA-1, NQA-2, part 2.7, and NQA-3 provide the basis for EPA's audit checklists to determine if an appropriate QA program has been established and executed. The NQA requirements that are applicable must be established in the QAPD and WID's implementing procedures, and these established NQA requirements must be appropriately executed by WID's QA organization. EPA verified compliance using checklists based on the NQA requirements. EPA expected the appropriate establishment and execution of a QA program at Westinghouse's Waste Isolation Division that adheres to applicable NQA requirements

22.C.4 DOE METHODOLOGY AND CONCLUSIONS

The CAO QAPD establishes the QA requirements for WID's implementing procedures. DOE conducted audits and surveillance of the WID quality assurance program, including the environmental monitoring program. DOE's audits concluded that WID has an adequate and effectively implemented quality assurance program (see Chapter 5, Table 5-8, p. 5-54).

WID developed a WIPP Environmental Monitoring Plan (EMP), document number DOE/WIPP 96-2194, Appendix EMP. The EMP includes guidelines for radiological and non-radiological environmental monitoring. Sample handling, laboratory procedures, required records and reports, and data analyses guidelines are also included in the EMP. Section 8.0 of the EMP establishes the quality assurance procedures for the environmental monitoring program. Section 8.1 of the EMP states that the Quality Assurance practices that cover monitoring activities at the WIPP are consistent with applicable elements of ASME NQA-1.

22.C.5 EPA COMPLIANCE REVIEW

Section 22.A.6 of this CARD discusses how EPA determined that CAO has established an appropriate QA program in the QAPD. EPA verified compliance with the requirements of Section 194.22(a)(2)(ii) by reviewing Appendix EMP of the CCA and conducting an audit of the WID quality assurance program on February 10-14, 1997 (EPA 1997c). The purpose of the audit was to verify that the WID was in conformance with top-tier CAO QA documents that incorporate 194.22(a) requirements and that WID's QA program is properly implemented.

Monitoring of the performance of the disposal system and sampling and analysis activities will be implemented during the pre- and post-closure of the WIPP. EPA could not assess whether QA activities related to monitoring of the performance were properly implemented because implementation of pre-closure monitoring has not begun. However, EPA did review all QA procedures established for environmental monitoring activities to determine that the necessary QA procedures had been established to meet Section 194.22(a)(2)(ii).

The scope of EPA's audit included the waste containment activities of the WID QA program under the purview of the CAO QA program. EPA's audit of the WID QA program covered all aspects of the program, including but not limited to: quality assurance procedures (QAPs), reports from previous audits, surveillance reports, and corrective action reports (CARs). The audit assessed the adequacy and implementation of the WID quality assurance program in accordance with Section 194.22(a)(1). EPA conducted extensive interviews with WID staff responsible for the implementation and management of WID's quality assurance program and its procedures. The five-day audit resulted in no findings (EPA 1997c).

EPA reviews determined that WID has properly planned a documented QA program for all activities listed in Section 194.22(a)(2)(ii), and an EPA audit determined that WID has properly established and executed a QA program for all but one of the activities. Monitoring of performance of the disposal system has not started, but EPA has no reason to believe that the QA process for this activity will not be similar to the QA process for existing monitoring activities. In addition, EPA will perform periodic audits or inspections of CAO audits of WID to verify proper maintenance of WID's QA program in the future.

22.D.1 REQUIREMENT

(a)(2)(iii) "Any compliance application shall include information which demonstrates that the quality assurance program required pursuant to paragraph (a)(1) of this section has been established and executed for field measurements of geologic factors, groundwater, meteorologic, and topographic characteristics."

22.D.2 ABSTRACT

DOE must correctly establish and execute QA programs for activities involving field measurements of geologic factors, groundwater, meteorologic, and topographic characteristics. Some of the field measurements of geologic factors, groundwater, meteorologic, and topographic characteristics presented in the CCA were used for site characterization. Site characterization was conducted prior to issuance of EPA's Compliance Criteria for the WIPP. As specified by Section 194.22(a)(1), a QA program must be implemented as soon as practicable after April 9, 1996. Therefore, the requirements of Section 192.22(a)(2)(iii) are not applicable to the old field measurements of geologic factors, groundwater, meteorologic, and topographic characteristics presented in the CCA. The old data were evaluated under the CAO QAPD requirement for qualification of existing data. Qualification of existing data is discussed in Section 194.22(b) of this CARD.

However, after April 9, 1996, DOE must properly establish and execute QA programs for activities involving field measurements of geologic factors, groundwater, meteorologic, and topographic characteristics. DOE has conducted activities related to seismic monitoring and geologic factors. WID, under the requirements established by CAO QAPD, is responsible for conducting field measurements, underground monitoring, and seismic monitoring. EPA conducted an audit of the WID quality assurance program on February 10-14, 1997. No findings were developed during this audit.

EPA reviewed Chapter 5 of the CCA for completeness and found that it did not adequately address the application of a QA program to meteorologic characteristics. DOE subsequently demonstrated to EPA in supplementary information that meteorologic information cited in the CCA was not used in the performance assessment.

22.D.3 COMPLIANCE REVIEW CRITERIA

The requirements of NQA-1, NQA-2, part 2.7, and NQA-3 provide the basis for EPA checklists to determine if an appropriate QA program has been established and executed. The NQA requirements that are applicable must be established in the QAPD and WID's implementing procedures, and these established NQA requirements must be appropriately executed by WID's QA organization. EPA verified compliance using checklists based on the NQA requirements. EPA expected the appropriate establishment and execution of a QA program at Westinghouse's Waste Isolation Division that adheres to applicable NQA requirements.

22.D.4 DOE METHODOLOGY AND CONCLUSIONS

Chapter 5.1.3 (p. 5-5) of the CCA states that current WIPP activities related to field measurements are conducted by the WID and include several areas. Measurements of geologic factors include subsurface 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.

MON.8 of Appendix MON provides a discussion of the relevant QA and quality control requirements established by WID and DOE. Appendix MON states that the monitoring activities at the WIPP adhere to all DOE, NQA, and EPA quality assurance requirements. Topographic characteristics were characterized early in the site characterization phase of the WIPP project, and the data were identified as existing data and qualified accordingly. See Section 194.22(b) below.

22.D.5 EPA COMPLIANCE REVIEW

In a letter dated December 19, 1996, EPA notified DOE that Chapter 5 did not adequately address the application of a QA program to meteorologic characteristics (Docket A-93-02, Item II-I-01). Supplementary information sent by DOE on January 24, 1997, demonstrated to EPA that the measured meteorologic information in Chapter 2 (pp. 2-178 to 2-180) of the CCA was not used in the performance assessment (PA). DOE demonstrated that the PA instead used

meteorological information obtained from geological data and information (Docket A-93-02, Item II-I-03).

Additionally, most of the field measurements of geologic factors, groundwater, meteorologic, and topographic characteristics presented in the CCA were used for site characterization. Site characterization was conducted prior to issuance of the Compliance Criteria. As specified by Section 194.22(a)(1), a QA program must be implemented as soon as practicable after April 9, 1996. Therefore, the requirements of 192.22(a)(2)(iii) are not applicable to the field measurements of geologic factors, groundwater, meteorologic, and topographic characteristics presented in the CCA. Qualification of data that was generated prior to the implementation of a QA program is discussed in Section 22.J of this CARD.

EPA verified compliance with the requirements of Section 194.22(a)(2)(iii) by conducting an audit of the WID quality assurance program on February 10-14, 1997 (EPA 1997c). The objective of the audit was to verify the proper execution of WID's QA program, and its scope included field measurements of geologic factors, groundwater, meteorologic, and topographic characteristics.

EPA's audit of the WID QA program covered all aspects of the program including, but not limited to, quality assurance procedures (QAPs), reports from previous audits, surveillance reports, and corrective action reports (CARs). The audit assessed the adequacy and implementation of the WID quality assurance program in accordance with Section 194.22(a)(1). EPA determined that the QAPD and Westinghouse procedures incorporate the NQA requirements applicable to the activities of this section, and that the WID QA program was properly executed.

22.E.1 REQUIREMENT

(a)(2)(iv) "Any compliance application shall include information which demonstrates that the quality assurance program required pursuant to paragraph (a)(1) of this section has been established and executed for computations, computer codes, model and methods used to demonstrate compliance with the disposal regulations in accordance with the provisions of this part."

22.E.2 ABSTRACT

Computations and computer codes used to demonstrate compliance are evaluated and controlled in accordance with requirements established by the CAO QAPD. Software development and management are controlled in accordance with criteria established by SNL software QAPs and WID QAPD. EPA considered the establishment and execution of QA programs for waste characterization software as part of the review described in Section 22.B.5 of this CARD.
used by the waste generator sites.

EPA conducted an audit of the SNL quality assurance program on January 13-24, 1997. The audit resulted in eight findings, all of which were corrected within 30 days of the audit. EPA

conducted an audit of the WID quality assurance program on February 10-14, 1997, and conducted two follow-up inspections for the WID audit June 24-25, 1997, and September 11, 1997 (see EPA 1997c for a detailed description of the audit and inspections). There were no findings from the audit and inspections of WID.

22.E.3 COMPLIANCE REVIEW CRITERIA

Computation and computer codes are utilized throughout every aspect of the disposal system. They are used to generate the performance assessments and to maintain data used in the characterization and inventory of TRU waste. Therefore, EPA requires that QA programs be applied to these activities. Section 194.22(a)(2)(iv) requires that DOE implement a QA program that meets the computer software requirements for nuclear facilities applications of NQA-2, part 2.7. EPA expected DOE to establish and execute the applicable requirements of the NQA standards.

22.E.4 DOE METHODOLOGY AND CONCLUSIONS

Chapter 5, Sections 5.1.4 (pp. 5-7 to 5-10) and 5.3.20 (pp. 5-40 to 5-41), discusses software QA. The description of DOE's QA program below is taken from Chapter 5.

Software QA controls include inventory and classification of 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 the CAO QAPD. When accepted, the software is placed under configuration control prior to use.

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

- ◆□ Definition of requirements.
- ◆□ Design.
- ◆□ Implementation.
- ◆□ Testing, including certification and validation tests.
- ◆□ Installation and checkout.

- ◆□ Operations and maintenance, including in use tests.
- ◆□ Retirement.

Verification and validation of the software, including a review of software activities, documentation, and tests, are 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 phase 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 the appropriate version of the software is used. Configuration management includes the maintenance of unique identification, configuration change control, configuration status accounting, and access control.

Software documentation that is generated and retained includes:

- ◆□ Procurement documentation of procured software.
- ◆□ Software requirements documentation.
- ◆□ Design and implementation documentation.
- ◆□ Verification and validation documentation.
- ◆□ Any change documentation.
- ◆□ User documentation.
- ◆□ 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 requires significant modification to the software are identified.

Models and methods are controlled by SNL Quality Assurance Procedure 9-2 (QAP 9-2). Software supporting compliance falls 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.

SNL QAP 9-2, “Quality Assurance Requirements for the Selection and Documentation of Parameter Values Used in the 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 WIPP Waste Information System (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 the CAO QAPD and WID QAPD requirements. See the discussion of Section 194.24(c)(4) in **CARD 24—Waste Characterization** for further information on the WWIS.

Software used to prepare, analyze, or verify WIPP facility designs is processed and controlled in accordance with the WID QAPD.

22.E.5 EPA COMPLIANCE REVIEW

EPA reviewed Section 6.0 of the CAO QAPD and found that it incorporated the requirements of NQA-2a, part 2.7. EPA then conducted audits of the SNL and WID quality assurance programs for computations, computer codes, methods and models. EPA's audits of SNL and WID covered all aspects of the programs, including but not limited to: the adoption of the CAO QAPD, quality assurance procedures (QAPs), reports from previous audits, surveillance reports, and corrective action reports (CARs). The audits assessed the adequacy and implementation of the SNL and WID quality assurance programs in accordance with Section 194.22(a)(1). EPA also reviewed QA programs to determine their application to these activities and the flow down of NQA requirements to the procedures supporting the QA programs (EPA 1997b, 1997c).

The verification activities discussed above also served to ensure compliance with the requirements of Section 194.23(b) (see **CARD 23—Models and Computer Codes**). Section 194.23(b) requires that computer codes be documented in accordance with the quality assurance requirements established by Section 194.22. CARD 23 provides a description of the conceptual models and the computer codes used to develop and support the models.

EPA concluded that Section 6.0 of the CAO QAPD complied with the computer software requirements as established by NQA-2a, part 2.7, and that SNL and WID software QAPs were established and implemented in accordance with Section 6.0 of the CAO QAPD. Since the SNL and WID software QAPs incorporate all of the requirements of NQA-2a, part 2.7, EPA determined that the software quality assurance program as established by CAO QAPD and implemented by SNL and WID adequately addressed the requirements of Section 194.22(a)(2)(iv) and Section 194.23(b). EPA's audits of SNL and WID concluded that the quality assurance programs were properly executed.

22.F.1 REQUIREMENT

(a)(2)(v) "Any compliance application shall include information which demonstrates that the quality assurance program required pursuant to paragraph (a)(1) of this section has been

established and executed for procedures for implementation of expert judgment elicitation used to support applications for certification or re-certification of compliance.”

22.F.2 ABSTRACT

Section 194.22(a)(2)(v) is intended to enhance the reliability of procedures for implementation of the expert judgment elicitation process required by Section 194.26, Expert Judgment. The CCA states in Chapter 5 (p. 5-10) that no expert judgment activities were identified that called for the application of a QA program. However, after submitting the CCA on October 29, 1996, the CAO conducted one expert judgment elicitation on May 5-9, 1997.

EPA assessed compliance with Section 194.22(a)(2)(v) by conducting an audit of CAO's QA program and later observing CAO's control over the development and approval of a CAO procedure to implement the expert judgement elicitation conducted on May 5-9, 1997. EPA determined that CAO's QA program was properly established and executed, and that CAO's QA organization appropriately controlled the development, approval, and use of the CAO procedure to implement an expert judgment elicitation.

22.F.3 COMPLIANCE REVIEW CRITERIA

EPA verified the appropriate establishment and execution of a QA program at CAO. EPA expected that CAO's QA program will control the development, approval and use of any procedures for implementation of expert judgment elicitation to assure that any expert judgment elicitation is conducted in accordance with Section 194.26. See **CARD 26—Expert Judgment** for further discussion of expert judgment procedures.

22.F.4 DOE METHODOLOGY AND CONCLUSIONS

The CCA states in Chapter 5 (p. 5-10) that no expert judgment activities were conducted. The CCA also states that the CAO established and executed a QA program in compliance with NQA requirements for all items and activities important to the containment of waste in the isolation system, including procedures that may be developed for implementation of future expert judgment elicitations. Subsequent to submission of the CCA on October 29, 1996, DOE prepared procedures for an expert judgment elicitation conducted on March 5-9, 1997.

22.F.5 EPA COMPLIANCE REVIEW

EPA conducted an audit of the CAO quality assurance program on December 9-13, 1996, to verify the establishment and execution of a QA program for all items and activities affecting the quality of waste isolation. EPA determined that the CAO's QA program could be applied to any future expert judgment elicitation if required, including control of the implementing procedure.

EPA required that DOE conduct an expert elicitation for WIPP Waste Particle Diameter Size Distribution(s) during the 10,000-year regulatory time frame. The elicitation was conducted by DOE on May 5-9, 1997. EPA audited the proceedings to verify that the CAO QA program had properly controlled the development, approval and use of the procedure. EPA then reviewed

the elicitation records generated from the proceedings on June 24-25, 1997, to verify that Requirement #17 of NQA, titled Quality Assurance Records, had been properly implemented (EPA 1997e). EPA's evaluation of the elicitation is discussed further in **CARD 26—Expert Judgment**.

EPA determined that a QA program was properly established and executed for procedures for the implementation of the expert judgment elicitation used to support the application.

22.G.1 REQUIREMENT

(a)(2)(vi) “Any compliance application shall include information which demonstrates that the quality assurance program required pursuant to paragraph (a)(1) of this section has been established and executed for design of the disposal system and actions taken to ensure compliance with the design specifications.”

22.G.2 ABSTRACT

The CCA states that the initial design of the WIPP was done by Bechtel as an architectural and engineering contractor. The design verification was accomplished by a combination of NQA-1 Supplement 3S-1 methods. The WID QAPD establishes actions and responsibilities to verify the adequacy of design for the original repository design. The design work for the repository sealing system was conducted under the SNL QA program.

EPA conducted an audit of SNL on January 13-24, 1997. The audit results included eight findings. None of the findings was associated with the design of the disposal system. All findings were corrected within 30 days of the audit. EPA conducted an audit of the WID quality assurance program on February 10-14, 1997. No findings were developed from this audit.

22.G.3 COMPLIANCE REVIEW CRITERIA

Design of the disposal system and actions taken to ensure compliance with the design specifications are considered by EPA to be important for the determination of whether the WIPP will comply with the radioactive waste disposal regulations. Therefore, EPA requires that QA programs be applied to these activities to enhance the reliability of the activities' data and analysis. The requirements of Section 194.22(a)(1) and NQA-1 provided the guidelines to determine if an appropriate QA system has been applied.

22.G.4 DOE METHODOLOGY AND CONCLUSIONS

Chapter 5.1.6 states that the 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 the new designs. Designs are initiated using a classification system that ensures that the proper level of design and QA requirements are employed to meet design and testing requirements.

The initial design of the disposal system was performed by Bechtel. After Bechtel turned systems over to DOE, an extensive and comprehensive program of start-up testing was initiated. The program tested systems and components against the requirements specified in the design documents. This testing meets the requirements of NQA-1, Supplement 3S-1 for design verification.

The WID QAPD establishes actions and responsibilities to verify the adequacy of a design. Design controls specified by the WID QAPD are in place to track and verify the design process. These controls ensure that new design changes are subject to specification commensurate with the original design and verify that the design analyses are still valid.

Design work for the repository sealing system was conducted under the SNL QA program. The repository seal system design was extensively reviewed by DOE, SNL, WID, and CAO Technical Assistance Contractor (CTAC) personnel, as well as independent design reviewers. Audits and surveillance were performed on each of the primary contractors. In all cases, QA requirements were properly identified and effectively implemented. 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.

22.G.5 EPA COMPLIANCE REVIEW

Westinghouse WID, via its QAPD, is responsible for the adequacy of the design, and SNL is responsible for the design work. EPA conducted audits of WID and SNL quality assurance programs, including procedures related to design of the disposal system (EPA 1997b, 1997c). Both audits examined compliance with Section 194.22(a)(1) and, by reference, the requirements of NQA-1. No findings were developed during the WID audit. The results of the SNL audit included eight findings. None of the findings was associated with repository design. All findings were corrected within 30 days of the audit.

22.H.1 REQUIREMENT

(a)(2)(vii) “Any compliance application shall include information which demonstrates that the quality assurance program required pursuant to paragraph (a)(1) of this section has been established and executed for the collection of data and information used to support compliance applications.”

22.H.2 ABSTRACT

SNL is responsible for conducting numerous research programs in support of the WIPP. SNL collected scientific data in the areas of rock mechanics, actinide source term, chemical transport, disposal room, gas generation, non-Salado flow and transport, and Salado hydrology and transport. EPA verified DOE’s compliance with the requirements of Section 194.22(a)(1) by reviewing the CAO QAPD and conducting audits of CAO and SNL quality assurance programs.

For data collected for any other activities listed in Section 194.22(a)(2), the QA program is discussed in the corresponding section.

Data collected prior to the promulgation 40 CFR Part 194, but used to support the compliance application is qualified as existing data. Refer to Section 22.J of CARD 22 for a discussion of existing data.

22.H.3 COMPLIANCE REVIEW CRITERIA

EPA requires that QA programs be applied to the collection of data and information used to support the CCA to enhance the reliability of the data and information. The requirements of NQA-1, NQA-2, part 2.7, and NQA-3 provide the guidelines to determine if an appropriate QA program has been applied.

22.H.4 DOE METHODOLOGY AND CONCLUSIONS

SNL is responsible for the collection of data and information to support compliance applications. Numerous SNL QAPs were developed and implemented in accordance with the requirements of the CAO QAPD. DOE audits concluded that the SNL QA program has been effectively implemented (see Table 5-4, p. 5-47).

22.H.5 EPA COMPLIANCE REVIEW

EPA conducted the audits listed in Section 22.M of this CARD to verify the proper execution of QA programs at DOE's Carlsbad Area Office (CAO), Sandia National Laboratories (SNL), and Westinghouse's Waste Isolation Division (WID) (EPA 1997a, 1997b, 1997c). EPA also conducted inspections of CAO's audits of quality assurance programs at Idaho National Energy and Environmental Laboratory and the Los Alamos National Laboratory.

EPA conducted an audit of the SNL quality assurance program on January 13-24, 1997. Audit results included eight findings. However, none of the findings was of sufficient impact to lead EPA to conclude the program was inadequate. EPA's audit of SNL concluded that the quality assurance program was adequately implemented.

22.I.1 REQUIREMENT

(a)(2)(viii) "Any compliance application shall include information which demonstrates that the quality assurance program required pursuant to paragraph (a)(1) of this section has been established and executed for other systems, structures, components, and activities important to the containment of waste in the disposal system."

22.I.2 ABSTRACT

DOE did not identify any other system, structure, component, or activity important to waste isolation in the disposal system. EPA also did not identify other containment apparatus or activities that require the establishment and execution of QA controls beyond those discussed

above. EPA found that the QA programs of CAO, WID, SNL and the Los Alamos site provide adequate coverage within their organizations to identify any other possible items and activities important to the containment of waste.

22.I.3 COMPLIANCE REVIEW CRITERIA

EPA determines whether items or activities important to the containment of waste exist for which DOE has not adequately established and executed QA controls by means of audits and inspections.

22.I.4 DOE METHODOLOGY AND CONCLUSIONS

Chapter 5.1.8 (p. 5-14) states, “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.”

22.I.5 EPA COMPLIANCE REVIEW

EPA searched for other items or activities important to the containment of waste that were not included under the activities listed in 194.22(a)(2), but did not identify other containment apparatus or activities that require the establishment and execution of QA controls beyond those discussed above. EPA found that the QA programs of CAO, WID, SNL and the Los Alamos site provide adequate coverage within their organizations to identify any other possible items and activities important to the containment of waste.

22.J.1 REQUIREMENT

(b) “Any compliance application shall include information which demonstrates that data and information collected prior to the implementation of the quality assurance program required pursuant to paragraph (a)(1) of this section has been qualified in accordance with an alternate methodology, approved by the Administrator or the Administrator’s authorized representative, that employs one or more of the following methods: Peer review, conducted in a manner that is compatible with NUREG-1297, “Peer Review for High-Level Nuclear Waste Repositories,” published February 1988 (incorporation by reference as specified in § 194.5); corroborating data; confirmatory testing; or a quality assurance program that is equivalent in effect to ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda, part 2.7, to ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1(b) and (c) and Section 17.1).”

22.J.2 ABSTRACT

Chapter 5 of the CCA (Table 5-5 on page 5-51) identifies data packages that were reviewed by DOE Independent Review Teams (IRT) and determined to have been collected under NQA-equivalent controls. DOE also used the T=0 process to determine which data were considered “existing” data. The purpose of T=0 is to establish the earliest date when data collection was performed under appropriate NQA equivalent controls. Data collected without NQA equivalent controls are considered “existing data” and were qualified by peer reviews.

Based on a sample of data reviewed by EPA auditors, EPA determined that: (1) the T=0 process is acceptable to identify “existing” data; (2) the IRT data package reviews and T=0 processes are acceptable methodologies to determine equivalent NQA controls; (3) peer reviews employed by DOE were acceptable; and (4) all existing data had been qualified.

22.J.3 COMPLIANCE REVIEW CRITERIA

EPA requires DOE to identify “existing” data, i.e., data used to support the CCA that were collected before the implementation NQA programs. EPA also requires that “existing” data be qualified via an EPA approved methodology. The requirements applicable to the qualification of data contained in NQA-1, NQA-2, part 2.7, NQA-3 and NUREG-1297 provide the guidelines to determine if the existing data were qualified properly. EPA expected that a representative sample of existing data could reasonably demonstrate that all existing data were properly qualified.

22.J.4 DOE METHODOLOGY AND CONCLUSIONS

Qualification of existing data (QED) is discussed in Chapter 5, Sections 5.4.2.1 (pp. 5-48 to 5-50) and 5.4.2.2 (pp. 5-50 to 5-52). Any data collected prior to DOE’s approval of the overall SNL QA program were qualified by the T=0 process. A qualification date (T=0) is documented in reports in QA files at SNL Records Center. The process described in SNL QAP 20-3 was used to qualify existing data (obtained prior to 1992).

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 DOE
- ◆☐ Collected after the qualifications of a subcontractor QA Program by SNL
- ◆☐ Qualified by an Independent Review Team (IRT), or
- ◆☐ Qualified by the Peer Review process.

Chapter 9 and Appendix PEER of the CCA contain documentation of three peer reviews conducted by DOE for qualification of existing data. The Engineered Systems, Natural Barriers, and Waste Form and Disposal Room Data Qualification Peer Reviews were conducted to comply with the requirements of Section 194.22(b). **CARD 27—Peer Review** addresses DOE’s process for conducting peer review process and its compliance with NUREG-1297.

22.J.5 EPA COMPLIANCE REVIEW

EPA verified DOE’s compliance with Section 194.22(b) by tracing parameters and data to the qualifying source, conducting an audit of the SNL quality assurance program (including QED), conducting an audit of the T=0 process for qualifying SNL subcontractors, and conducting an audit of the peer review process.

EPA conducted audits at SNL on April 16-18, 1997, and May 12-16, 1997. The purpose of these audits was to trace parameters and data to the qualifying source. EPA reviewed pre-existing data records packages that were used in compliance records packages located in the SNL Records Center. EPA also reviewed documents governing qualification of existing data that included procedures and management plans for independent review, peer review, and equivalent QA procedures, scientific notebooks, checklists, peer review process documentation, parameter value determination records and memos. SNL generated a table providing information of how all parameters and data were qualified. All of the parameters and data reviewed were traceable and qualified (EPA 1997f).

An audit of the SNL quality assurance program, including QED, was conducted on January 13-24, 1997. The audit covered all aspects of the program, including but not limited to the adoption of the CAO QAPD, quality assurance procedures (QAPs), reports from previous audits, surveillance reports, and corrective action reports (CARs). EPA's audit assessed the adequacy and implementation of the SNL quality assurance program in accordance with the requirements of Section 194.22(a)(1). Audit results included eight findings (EPA 1997b). None of the findings was related to the qualification of existing data, and all findings were corrected within 30 days.

EPA's audit of SNL's QA program included an evaluation of QED and the Independent Review Team. An audit of the T=0 process for SNL subcontractors was conducted June 2-6, 1997. No findings resulted from this audit (EPA 1997g).

DOE conducted three peer reviews for the purpose of qualifying existing data: Natural Barriers Peer Review, Engineered Systems Peer Review, and Waste Form/Disposal Room Peer Review. The scope and findings of these peer reviews are addressed in Section 194.23(c)(4) of **CARD 23—Models and Computer Codes**. EPA conducted an audit of DOE's peer review process on February 9-11, 1997. The audit results included seven findings (EPA 1997d). Six of the findings were due to lack of documentation in the files reviewed. The remaining finding was associated with documentation of conflict of interest among panel members. All findings were corrected within 30 days of the audit and none was sufficient to deem the process incompatible with the requirements of NUREG-1297. **CARD 27—Peer Review** addresses DOE's process for conducting peer review process and its compliance with NUREG-1297.

22.K.1 REQUIREMENT

(c) "Any compliance application shall provide, to the extent practicable, information which describes how all data used to support the compliance application have been assessed for their quality characteristics, including:

- (1) Data accuracy, i.e., the degree to which data agree with an accepted reference or true value;
- (2) Data precision, i.e., a measure of the mutual agreement between comparable data gathered or developed under similar conditions expressed in terms of a standard deviation;

- (3) Data representativeness, i.e., the degree to which data accurately and precisely represent a characteristic of a population, a parameter, variations at a sampling point, or environmental conditions;
- (4) Data completeness, i.e., a measure of the amount of valid data obtained compared to the amount that was expected; and
- (5) Data comparability, i.e., a measure of the confidence with which one data set can be compared to another.”

22.K.2 ABSTRACT

DOE was required by Section 194.22(c) to show to the extent practicable that data supporting the CCA had been assessed for data quality characteristics (DQCs), i.e., accuracy, precision, representativeness, completeness, and comparability. DOE stated in the CCA that “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.” Upon EPA’s request for clarification of this position, DOE provided supplementary information that stated that DQCs could not be assessed principally because the data quality objectives by which DQCs are assessed could not be applied retroactively.

To assess compliance with this regulatory requirement, EPA independently reviewed DOE’s data records packages and the results of data qualification peer reviews conducted by DOE. EPA concluded as a result of this review that DOE had in fact assessed DQCs to the extent practicable in the development of the compliance application.

22.K.3 COMPLIANCE REVIEW CRITERIA

Assessment of the data quality characteristics (DQCs) identified in Section 194.22(c)—accuracy, precision, representativeness, completeness and comparability (PARCC)—identifies uncertainties associated with the data and thus may assist with the qualification of the data. Therefore, EPA requires all data used to support the CCA be assessed for their quality characteristics to the extent practicable.

Section 194.22(c) requires that DOE apply DQCs to “all data used to support the compliance application,” not just to data used to support the performance assessment. Again, the purpose of this requirement is to establish that data may be considered to be reliable since they have been subjected to controls over their acceptability, as represented by DQCs. EPA believes that it is important that DOE assess any measured data for DQCs, if such data will be used to demonstrate the WIPP’s compliance with the Compliance Criteria. For example, DOE should be able to show that enough useful data will result from waste drum sampling to draw conclusions about the contents of the waste stream that originated the drum (data completeness). Likewise, DOE should be able to show that measurements of groundwater flow around the disposal system will be checked against baseline values (data accuracy).

EPA has recognized that it may not be practicable to assess the DQCs for some data:

The rigor of the analysis may differ according to the intended use of the data, as indicated by Section 194.22(d) and the NQA standards. The EPA recognizes that the evaluation of some data quality characteristics is difficult to apply to “old data” or to apply over a 10,000 year regulatory time frame. Thus, EPA has stated in the final rule [40 CFR Part 194] that such documentation of these characteristics must be provided *to the extent practicable*, and has also clarified that all data must be qualified *with a rigor that is commensurate with the intended use of the data* in any compliance demonstration [emphasis added]. (Response to Comments Document for 40 CFR Part 194, p. 4-8)

As an alternative to evaluating the specific characteristics in Section 194.22(c), EPA permitted DOE to specify the degree of uncertainty that is tolerable in data to attain the required degree of confidence in the results of the performance assessment (CAG, pp. 20-21).

22.K.4 DOE METHODOLOGY AND CONCLUSIONS

In Section 5.3.21.1 of the CCA, DOE stated, “It is often not practicable for the DOE to document. . . data quality characteristics for the scientific investigation and characterization of natural systems. . . Instead. . . 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” (p. 5-44).

In a letter dated March 19, 1997, EPA required DOE to submit additional documentation in support of this argument that uses specific measured data points as examples (Docket A-93-02, Item II-I-17). In response to this request, DOE submitted a short document that explained why DOE considered the assessment of DQCs to be impracticable (Docket A-93-02, Item II-I-24, Comment No. 2). Specifically, DOE stated, “[The] performance assessment simulates many complex, highly interactive processes using more than 1500 parameters. It would be impracticable to work backwards through the probabilistic simulations of the performance assessment to develop data quality objectives for these parameters” (p. 2). The document also stated that data uncertainties “make a relatively small contribution to compliance uncertainty,” and that “[technical reviews and other activities, such as Data Qualification Peer Reviews and reviews by the Independent Review Team, assure the overall quality of the performance assessment” (pp. 2-3). DOE sent an additional letter, dated August 15, 1997, that did not depart from DOE’s earlier position but added a case study of data quality characteristics for distribution coefficients (Docket A-93-02, Item II-I-52).

DOE stated in the case study submitted to EPA, “To establish compliance-based DQOs [i.e., Data Quality Objectives, against which data may be assessed for DQCs] for the WIPP PA, one would need to start with the compliance calculation and work backwards to the DQCs for the individual data sets used in the WIPP PA. . . [O]ne would start with the calculated [CCDF] which integrates the results of many coupled process calculations, and then attempt to untangle

the impact of an individual data characteristic on that integrated result.” Docket A-93-02, Item II-I-52, p. 2.

DOE did observe, however, that data quality received considerable attention from peer reviewers and Independent Review Teams assembled by DOE, and was subject to NQA requirements as specified in the Quality Assurance Program Document (QAPD) (Docket A-93-02, Item II-I-24, p. 5). DOE was obliged to comply with Section 194.22(a), which requires DOE to implement NQA-3-1989 in its quality assurance program. NQA-3-1989 states, “Planning shall establish provisions for data quality evaluation to assure data generated are valid, comparable, complete, representative, and of known precision and accuracy.” NQA-3-1989, p. 11. This requirement was incorporated in Section 5 of the QAPD, which is the quality assurance “master” document that establishes QA requirements for all activities overseen by the DOE Carlsbad Area Office (the QAPD constitutes Appendix QAPD of the CCA).

22.K.5 EPA COMPLIANCE REVIEW

EPA reviewed Chapter 5 of the CCA and the supplementary information on DQCs submitted by DOE. EPA did not find that DOE had documented its assessment of DQCs or adequately justified why such assessment was impracticable in all cases. EPA added the words “to the extent practicable” to the final criterion directly in response to comments from DOE and others that DQC requirements need not be applied retroactively or to the assessment of a heterogeneous natural system’s performance over 10,000 years: “EPA recognizes that the evaluation of some data quality characteristics is difficult to apply to ‘old data’ or . . . over a 10,000-year regulatory time frame. Thus, EPA has stated in the final rule that such documentation of these characteristics must be provided to the extent practicable, and has also clarified that all data must be qualified with a rigor that is commensurate with the intended use of the data in any compliance demonstration” (Response to Comments Document for 40 CFR 194, p. 4-8). In other words, EPA acknowledged that it would not be reasonable to expect DOE to develop documentation of DQCs long after data had been collected and used, or to attempt to apply DQCs to uncertain parameters. Nevertheless, EPA still expected that DOE should be able to demonstrate that data serving an important function relative to compliance in any area have been or will be subjected to rigorous review against objective standards.

EPA independently examined whether DOE records revealed the extent to which data supporting parameter development had been assessed for the DQCs identified in Section 194.22(c). The Agency sought evidence that DOE had evaluated the acceptability of parameter data prior to employing them in the performance assessment (e.g., were data that were used to represent a geological feature of the disposal system assessed for their representativeness?). EPA reviewed data record packages, laboratory notebooks, and other documents and found that newer data (less than ten years old) were supported by a great deal of documentation related to DQCs. EPA also found that documentation for older data (more than ten years old) was less voluminous but still adequate to give the Agency confidence that DOE had considered DQCs.

More recent data (five to ten years old) were supported by a great deal of documentation related to DQCs. Most of the packages for more recent data contained experimental program plans that describe the required accuracy and precision of instrumentation and equipment used to take measurements. For example, measurements of pressure in the Castile Formation were

required to meet a certain level of accuracy. EPA also found evidence that DOE sufficiently considered data precision, representativeness, completeness, and comparability. Laboratory notebooks that were used to document measurements generally show that DQCs were considered during data measurement and collection. EPA found numerous instances in which DOE took measurements again after questions arose about the accuracy or quality of an instrument.

Older existing data (i.e., collected prior to the establishment of the required quality assurance program) were supported by less documentation of DQCs. Older data did not always have a well documented experimental program plan, but the laboratory notebooks often contained information related to the quality of measurements (e.g., how well DOE's measured values compared with values found in peer reviewed publications). EPA found that documentation of such concerns was adequate to demonstrate that DOE had considered DQCs for existing data used in support of PA parameters to the extent practicable. EPA's evaluation of DOE's qualification of existing data supports this conclusion.

In summary, EPA based its determination of compliance for Section 194.22(c) on the following conclusions: (1) DOE's quality assurance program adequately provides for the qualification of data; (2) Data obtained before the implementation of the QA program were properly qualified for their use; and (3) Given the Agency's independent consideration of parameter development in particular, DOE satisfactorily demonstrated in its documentation that DQCs had been applied in the manner that EPA intended.

22.L.1 REQUIREMENT

(d) "Any compliance application shall provide information which demonstrates how all data are qualified for use in the demonstration of compliance."

22.L.2 ABSTRACT

Chapter 5 of the CCA addresses how data are qualified. The CCA lists existing data that were reviewed by an Independent Review Team (IRT) and found to have been collected under an NQA-equivalent QA program. DOE also used the T=0 process to determine which data constituted "existing" data. The purpose of T=0 is to establish the earliest date when data collection was performed under conditions equivalent to those of a qualified Quality Assurance (QA) program. Data collected prior to the proper implementation of QA program are considered "existing data" and had to be qualified by an acceptable Qualification of Existing Data (QED) process. Finally, DOE conducted three peer reviews to qualify existing data. **CARD 27—Peer Review** discusses DOE's peer review process and its compliance with NUREG-1297.

EPA conducted an audit of the Peer Review Process on February 10-12, 1997. The audit results included seven findings. The audit of SNL's QA program included an evaluation of QED and IRT. An audit of the T=0 process for SNL subcontractors was conducted June 2-6, 1997. No findings were developed from this audit.

22.L.3 COMPLIANCE REVIEW CRITERIA

Chapter 5.4.2.1 (pp. 5-48 to 5-50) of the CCA discusses data qualification. The CCA states that data can be qualified by any of five methods:

- ◆□ Data are obtained under an approved QA program that implements the NQA requirements.
- ◆□ 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.
- ◆□ Existing data are qualified by peer review conducted in a manner compatible with NUREG-1297, Peer Reviews for High-Level Nuclear Waste Repositories.
- ◆□ Corroborating data are collected.
- ◆□ Confirmatory testing is performed.

EPA considers it important to ensure the quality and reliability of all data used to support the CCA. Therefore, EPA requires that all data used to support compliance be qualified. The requirements of NQA-1, NQA-2, part 2.7, NQA-3, and NUREG-1297 provided guidelines to determine if all data were qualified.

22.L.4 DOE METHODOLOGY AND CONCLUSIONS

Data collected prior to the DOE approval of the overall SNL QA program were qualified by the T=0 process. A qualification date (T=0) is documented in summary reports that provide rationale and pointers to supporting information. 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.

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 DOE
- ◆ Collected after the qualifications of a subcontractor QA Program by SNL
- ◆ Qualified by an Independent Review Team (IRT), or
- ◆ Qualified by the Peer Review process.

Data that were not qualified by one of these methods were not used for demonstrating compliance.

22.L.5 EPA COMPLIANCE REVIEW

EPA verified DOE's compliance with Section 194.22(d) by tracing parameters and data to the qualifying source, conducting an audit of the SNL quality assurance program (including QED), conducting an audit of the T=0 process for qualifying SNL subcontractors, and conducting an audit of the Peer Review process.

An audit of the SNL quality assurance program, including QED was conducted January 13-24, 1997 (EPA 1997b). The audit covered all aspects of the program including, but not limited to, the adoption of the CAO QAPD, quality assurance procedures (QAPs), reports from previous audits, surveillance reports, and corrective action reports (CARs). The audit assessed the adequacy and implementation of the SNL quality assurance program in accordance with the requirements of Section 194.22(a)(1). EPA's audit of SNL's overall QA program resulted in eight minor findings which were easily corrected and it was determined that SNL has executed a quality assurance program that implements the requirements of Section 194.22 (a).

EPA conducted an audit of the process of establishing T=0 for SNL subcontractors (EPA 1997g). The T=0 date set by DOE for three SNL subcontractors, including five contracts, were reviewed during this audit. The results of EPA's T=0 audit determined that the procedures for establishing T=0 for the three subcontractors reviewed adequately addressed the requirements of 40 CFR part 194.22(b).

Peer reviews of data related to Engineered Systems, Natural Barriers, and Waste Form and Disposal Room Data Qualifications were conducted by DOE to comply with the requirements of Section 194.22(b). An audit of the peer review process was conducted February 10-12, 1997 (EPA 1997d). **CARD 27—Peer Review** discusses DOE's peer review process and its consistency with NUREG-1297.

22.M.1 REQUIREMENT

(e) "The Administrator will verify appropriate execution of quality assurance programs through inspections, record reviews and record keeping requirements, which may include, but may not be limited to, surveillance, audits and management systems review."

22.M.2 ABSTRACT

EPA conducted several audits and inspections of CAO audits to verify the appropriate execution of quality assurance programs that adhere to the requirements of Section 194.22. The scope of the audits included but was not limited to: extensive review of records, interviews with WIPP staff and contractors responsible for the implementation and management of the quality assurance program, quality assurance procedures (QAPs), reports from previous audits, surveillance reports, and corrective action reports (CARs).

22.M.3 COMPLIANCE REVIEW CRITERIA

EPA did not expect that all necessary QA documentation could be provided in the CCA because of the very large number of documents involved. Rather, EPA verified appropriate execution of quality assurance programs through inspections, record reviews, and record keeping requirements, including but not limited to surveillance, audits, and management systems review. EPA evaluated all WIPP QA programs to ensure that the programs were adequate and properly implemented. As listed below, EPA conducted audits of DOE's CAO, SNL, and WID facilities. These audits covered all aspects of each DOE facilities's QA programs, including but not limited to the quality assurance procedures (QAPs), reports from previous audits, surveillance reports, and corrective action reports (CARs).

22.M.4 DOE METHODOLOGY AND CONCLUSIONS

Not Applicable.

22.M.5 EPA COMPLIANCE REVIEW

EPA audits were planned, scheduled, and performed in accordance with written checklists by EPA staff and contractors, who are independent of DOE staff and contractors. As listed below, audits were performed of DOE and its principal WIPP Contractors (Westinghouse's Waste Isolation Division and Sandia National Laboratory) to verify the appropriate execution of QA programs. Additional audits were performed to verify the qualification of old data and to verify that the peer reviews were conducted in accordance with NUREG-1297. Inspections of CAO's audits of generator sites were also made to assess their QA programs as they relate to waste characterization activities.

EPA conducted the following activities to verify DOE's appropriate execution of quality assurance programs in accordance with the requirements of Section 194.22:

- ◆□ An audit of the DOE's Carlsbad Area Office quality assurance program, conducted December 9-13, 1996. The purpose of the audit was to verify the appropriate execution of the quality assurance practices described in the CCA (EPA 1997a).
- ◆□ An audit of Sandia National Laboratories' quality assurance program, conducted January 13-24, 1997. The audit assessed the adequacy and implementation of the SNL quality assurance program in accordance with the requirements of Section 194.22(a)(1) (EPA 1997b).
- ◆□ An audit of the Westinghouse Waste Isolation Divisions quality assurance program, conducted on February 10-14, 1997. The audit assessed the adequacy and implementation of the WID quality assurance program in accordance with the requirements of Section 194.22(a)(1) (EPA 1997c).

- ◆□ An audit of the Peer Review Process, conducted by the DOE's Carlsbad Area office, conducted on February 10-12, 1997. The audit consisted of an extensive review of DOE's QA records for peer review and interviews of DOE staff and contractors responsible for the management of the required peer reviews (EPA 1997d).
- ◆□ An audit of DOE's expert elicitation for WIPP Waste Particle Diameter Size Distribution(s) During the 10,000-Year Regulatory Post-Closure Period. The elicitation was conducted by DOE on May 5-9, 1997. EPA attended all panel proceedings and reviewed records of the elicitation on June 24-25, 1997 (EPA 1997e).
- ◆□ A records review conducted at Sandia on April 16-18, 1997 and May 12-16, 1997, to determine if parameters and data were traceable to their qualifying source (EPA 1997f).
- ◆□ An audit of SNL's process of establishing T=0 for their subcontractors, conducted June 2-6, 1997. The purpose of the audit was to verify compliance with the requirements of Section 194.22(b) (EPA 1997g).
- ◆□ A preliminary inspection of DOE's audit of Idaho National Engineering and Environmental Laboratory (INEEL), conducted on April 21-25, 1997 (EPA 1997h).
- ◆□ Three inspections of DOE audits of Los Alamos National Laboratory (LANL), conducted May 12-16, 1997, August 18-20, 1997, and September 10-11, 1997 (EPA 1997i).

22.N REFERENCES

- American Society of Mechanical Engineers (ASME). NQA-1- 1989 Edition, Quality Assurance Program Requirements for Nuclear Facilities. (CCA Reference #9)
- American Society of Mechanical Engineers (ASME). NQA-2a-1990 addenda to NQA-2-1989, Part 2.7, Requirements of Computer Software for Nuclear Facility Applications. (CCA Reference #10)
- American Society of Mechanical Engineers (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. (CCA Reference #11)
- EPA 1997a. U.S. Environmental Protection Agency. Audit of the Department of Energy Carlsbad Area Office Quality Assurance Program. 1997. (Docket A-93-02, Item II-A-43)

- EPA 1997b. U.S. Environmental Protection Agency. Audit of the Sandia National Laboratories Quality Assurance Program for Activities Associated with the Department of Energy Waste Isolation Pilot Plant. 1997. (Docket A-93-02, Item II-A-44)
- EPA 1997c. U.S. Environmental Protection Agency. Audit of the Westinghouse Waste Isolation Division Quality Assurance Program for Activities Associated with the Department of Energy Waste Isolation Pilot Plant. 1997. (Docket A-93-02, Item II-A-45)
- EPA 1997d. U.S. Environmental Protection Agency. Audit of the Department of Energy, Carlsbad Area Office—Peer Review Process. 1997. (Docket A-93-02, Item II-A-46)
- EPA 1997e. U.S. Environmental Protection Agency. Audit of the Department of Energy, Carlsbad Area Office—Expert Judgement Elicitation. 1997. (Docket A-93-02, Item II-A-47)
- EPA 1997f. U.S. Environmental Protection Agency. Audit of Parameter Traceability and Qualification of Existing Data. 1997. (Docket A-93-02, Item II-A-48)
- EPA 1997g. U.S. Environmental Protection Agency. Audit of the Sandia National Laboratories, Albuquerque, New Mexico, T=0 Process. 1997. (Docket A-93-02, Item II-A-49)
- EPA 1997h. U.S. Environmental Protection Agency. Inspection of CAO Audit of Idaho National Engineering and Environmental Laboratories. 1997. (Docket A-93-02, Item II-A-50)
- EPA 1997i. U.S. Environmental Protection Agency. Inspection of CAO Audit of Los Alamos National Laboratories. 1997. (Docket A-93-02, Item II-A-51)
- U.S. Nuclear Regulatory Commission. Peer Review for High-Level Nuclear Waste Repositories: Generic Technical Position, NUREG-1297. Washington, DC. 1988. (CCA Reference #484)

List of Acronyms and Abbreviations

ASME	American Society of Mechanical Engineers
CAG	Compliance Application Guidance for the Waste Isolation Plant
CAO	Carlsbad Area Office
CCA	Compliance Certification Application
DOE	Department of Energy
DQO	Data Quality Objective
EMP	Environmental Monitoring Plan
EPA	Environmental Protection Agency
IRT	Independent Review Team
LANL	Los Alamos National Laboratory
NQA	National Quality Assurance Program Requirements for Nuclear Facilities
QA	Quality Assurance
QAPD	Quality Assurance Program Description
QAPP	Quality Assurance Program Plan
QAPjP	Quality Assurance Project Plan
QP	Quality Procedure
SNL	Sandia National Laboratories
SCQAP	Site Certification Quality Assurance Plan
TP	Team Procedure
TRU	Transuranic Waste
WID	Westinghouse Waste Isolation Division
WIPP	Waste Isolation Pilot Plant