2009 Compliance Recertification Application (2009 CRA)
Compliance Application Review Document (CARD) 194.22

Quality Assurance

22.0 BACKGROUND

Quality Assurance (QA) provides for preliminary assessments of the quality/reliability of items and activities that are important to the long-term isolation of transuranic wastes inside the Waste Isolation Pilot Plant (WIPP). The purpose of these QA assessments is to identify problems with the reliability of any item or activity that is important to isolation. These QA assessments are conducted under the authority of QA Organizations from the U.S. Department of Energy (DOE). The assessments are in the form of reviews, inspections, tests, audits, surveillances and formal peer reviews. DOE's QA Organizations are separate from DOE's operational organizations that directly produce the items or perform the activities that are important to long-term isolation. The items and activities include the technical data and analysis underlying the DOE's Compliance Certification Application (CCA), the 2004 Compliance Recertification Application (2004 CRA or CRA04), and the 2009 Compliance Recertification Application (2009 CRA or CRA09). DOE's QA assessments "qualify" WIPP's items and activities before final assessments that are conducted by the Environmental Protection Agency (EPA or the Agency). Quality Assurance is a process to enhance the quality/reliability of the WIPP's items and activities prior to the EPA's assessments.

Section 194.22, titled "Quality Assurance", invokes three specific Nuclear Quality Assurance (NQA) standards for WIPP's QA program. Paragraph (a)(1) of Section 194.22 requires DOE to establish and implement a QA program that complies with the following NQA standards of the American Society of Mechanical Engineers (ASME):

- "Quality Assurance Program Requirements for Nuclear Facilities" (NQA-1-1989).
- "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications" (part 2.7 of NQA-2a-1990, addendum to ASME NQA-2-1989).
- "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.

The main function for QA Programs is found in NQA-1-1989, Basic Requirement 1, titled "Organization", as follows:

Persons or organizations responsible for …verifying that activities affecting quality have been correctly performed shall have sufficient authority, access to work areas, and organizational freedom to:

(1) identify quality problems;

(2) initiate, recommend or provide solutions to quality problems through designated channels;

(3) verify implementation of solutions; and
(4) assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

For EPA's oversight of the WIPP, "quality" is defined as the reliability of an item or activity that is important to the long-term isolation of transuranic waste. Therefore, a "quality problem" is a problem with the reliability of any item or activity that is important to isolation. Thus, the main function of WIPP's QA Organizations is to identify problems with the reliability of any such item or activity.

A copy of the NQA standards can be obtained from:

The American Society of Mechanical Engineers
Three Park Avenue, New York, NY 10016-5990

22.1 Requirements

(a)(1) "As soon as practicable after April 9, 1996, the Department [Department of Energy] shall adhere to a quality assurance program that implements 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). (Incorporation by reference as specified in Sec. 194.5.)

(2) 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:

(i) Waste characterization activities and assumptions;

(ii) Environmental monitoring, monitoring of the performance of the disposal system, and sampling and analysis activities;

(iii) Field measurements of geologic factors, ground water, meteorologic, and topographic characteristics;

(iv) Computations, computer codes, models and methods used to demonstrate compliance with the disposal regulations in accordance with the provisions of this part;

(v) Procedures for implementation of expert judgment elicitation used to support applications for certification or recertification of compliance;

(vi) Design of the disposal system and actions taken to ensure compliance with design specifications;

(vii) The collection of data and information used to support compliance application(s); and

(viii) Other systems, structures, components, and activities important to the containment of waste in the disposal system."

(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 have 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 Sec. 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). (Incorporation by reference as specified in Sec. 194.5.)"

(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."

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

(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 reviews.”

22.2 1998 CERTIFICATION DECISION

EPA performed three types of assessments to determine compliance with §194.22: 1) determine if DOE correctly established and implemented QA Programs for items and activities important to the long-term isolation of transuranic wastes in the disposal system (Section 194.22(a); 2) determine if DOE qualified all data, including existing data that were collected prior to the implementation of QA programs {Section 194.22(b)&(d)}; and 3) determine if DOE assessed the CCA’s data for their quality characteristics (Section 194.22(c)).

EPA applied two evaluation processes to perform each of the three assessments mentioned above. For one evaluation process, the Agency reviewed the CCA and associated references to determine if DOE provided a satisfactory description of compliance with the QA requirements. During this evaluation process, the Agency requested and reviewed additional information. In the second evaluation process, the EPA conducted formal audits at WIPP-related facilities to verify compliance with the requirements of 40 CFR 194.22. These two processes were not taken sequentially; EPA conducted many audits before DOE’s submission of the CCA. These EPA audits were conducted under the authority of §194.22(e), and were essential to verify implementation of the QA requirements. Each WIPP-related facility generated much activity and documentation, and it was not practicable to witness proper implementation of QA programs away from each facility, based solely on documents provided by DOE. Therefore, EPA auditors went to four DOE facilities to witness the proper implementation of the QA requirements of 40 CFR 194.22. As a result of the audits, the EPA approved the WIPP’s QA programs at DOE’s Carlsbad Field Office (CBFO), WIPP site or Washington TRU Solutions (WTS), Sandia National Laboratories (Sandia) and the Los Alamos National Laboratories (LANL). These four WIPP-related facilities are located in New Mexico.

At that time, other WIPP-related facilities located outside of New Mexico could not be approved by the EPA. Section 194.22(a)(2)(i) requires DOE to apply QA programs for waste characterization (WC) activities prior to certification. The criteria at §194.24(c)(3) and § 194.24(c)(5) cross-reference the QA requirements set forth at §194.22(a)(2)(i). The CCA indicated that *waste generator sites* outside New Mexico would not begin WC until after 1997, and that it was not reasonable to implement QA programs at that time for future WC. The Agency applied a condition to the approval of the CCA that sites without approved QA programs could not dispose of transuranic waste at the WIPP. Under Section 194.8(a), each unapproved site would have to be audited after the approval of the CCA to verify compliance, prior to shipment of wastes from each unapproved site.

The Agency did audit the application of QA for WC at one waste generator site as part of the CCA review. DOE informed EPA that the LANL was ready for an EPA audit to verify the appropriate establishment and implementation of a QA program. EPA auditors reviewed LANL's QA Plan to verify establishment of QA requirements, and later verified the proper implementation QA Plan at LANL. Based on the audit samples taken, the EPA determined that LANL had properly established and implemented a QA program for its WC. The other waste generator sites required EPA audits of their individual QA programs before EPA could allow sending the site's waste to the WIPP.

After the Agency's approval of the CCA, EPA conducted periodic audits at the four approved facilities to verify continued compliance. EPA also began to audit other facilities that had not been ready for to perform work at the time of the CCA.

A complete description of EPA's 1998 Certification Decision for Section 194.22 can be obtained from EPA Air Docket, A-93-02, Items V-A-1 and V-B-2.

22.3 CHANGES IN THE 2004 CRA

Chapter 5 of the 2004 CRA, like Chapter 5 in the previous CCA, discussed the QA programs for the WIPP. Changes in the 2004 CRA were mostly in format to better match each specific requirement of the NQA standards. (DOE revised its QA Plan to more clearly establish each of the applicable NQA elements, and to update DOE's organizational structure.) The substantive changes to the QA portions of the 2004 CRA reflected a maturing and expansion of the WIPP's QA programs since the CCA. The QA programs that were approved at the time of the CCA increased their effectiveness over time. New waste generator sites were added under Section 194.8(a), thus adding more QA programs.

The new QA programs of waste generator sites approved under Section 194.8(a) were as follows:

1. Nevada Test Site
2. Hanford Site in Washington State
3. Rocky Flats site in Colorado
4. Idaho National Engineering and Environmental Laboratory
5. Idaho's Advanced Mixed Waste Treatment Project
6. Savannah River Site in South Carolina

22.3.1 EVALUATION OF COMPLIANCE FOR 2004 RECERTIFICATION

EPA's evaluation process to recertify WIPP's QA Programs in 2004 was similar to the EPA process to certify in 1998 (described above under section 2.22, titled "1998 Certification Decision.") EPA reviewed documents provided by DOE for the 2004 Recertification Decision, and EPA conducted formal audits at DOE facilities because it was not possible to verify proper implementation of QA requirements based solely on documents provided by DOE. The EPA audits were conducted periodically after the 1998 CCA (i.e., before the 2004 CRA) to verify continued compliance leading up to the 2004 CRA.

DOE's QA Plan that establishes the NQA standards for the WIPP is titled "Quality Assurance Program Document" (QAPD). Appendix QAPD of the 2004 CRA, like in the CCA, contained the QAPD. DOE revised the QAPD to more clearly establish each of the applicable NQA elements, and to update DOE's organizational structure. Since the CCA, the EPA periodically reviewed the QAPD to verify the continued proper establishment of the NQA standards.

Appendices PEER and AUD of the 2004 CRA were updated for DOE peer-reviews and DOE audits performed since the CCA. EPA found that the 2004 CRA provided information which described how all data used to support the compliance application were assessed for their quality characteristics. The 2004 CRA also provided information on how all data are qualified for use in the demonstration of compliance.

EPA did not receive any public comments on DOE's continued compliance with the quality assurance requirements of Section 194.22 or Section 194.8(a).

22.3.2 2004 RECERTIFICATION DECISION

Based on the results of reviews of DOE documents and of formal EPA audits, EPA determined that DOE continued to comply with the requirements for Section 194.22 and Section 194.8(a).

22.4 Changes in the 2009 CRA

The QA documents provided by DOE for the 2009 Recertification reference much information provided for the 2004 Recertification. For the 2009 CRA, EPA revisited much of the QA information provided in 2004 CRA. For example, the 2009 CRA refers to the information provided in the 2004 CRA to describe how all data have been assessed for accuracy, precision, representativeness, completeness, and comparability. The QA Programs have changed little in form since the 2004 CRA.

The biggest change to WIPP's QA Programs since the 2004 Recertification was the

expansion of the QA Program of the Central Characterization Project (CCP QA). The QA Programs for most waste generator sites are now under CCP QA, whose main office is located at Carlsbad NM. The EPA believes that this change has improved the consistency of the waste generators' QA Programs. The number of EPA QA audits were reduced from many different waste generators to fewer audits focused on the CCP.

In general, the QA Program staff continued to increase their experience, along with increasing their effectiveness at identifying quality problems. Also, the DOE QA Manager at Carlsbad was promoted to have direct access to DOE's Field Office Manager. And, QA organizations appeared to generally increase their independence from operational groups that are responsible for providing much documentation and other objective evidence to EPA.

New waste generator sites were added thus adding more QA programs. Since the CRA-2004, new QA Programs for new TRU waste generator sites have been approved under Section 194.8(a).

22.4.1 EVALUATION OF COMPLIANCE FOR 2009 RECERTIFICATION

The EPA evaluation process to recertify the WIPP's QA Programs in 2009 was similar to the prior EPA evaluation processes to recertify in 2004 and to certify in 1998. The EPA reviewed documents provided by DOE for the 2009 Recertification Decision and conducted formal audits at DOE facilities because it was not possible to verify proper implementation of QA requirements based solely on documents provided by DOE. Prior to the 2009 Recertification, the EPA increased its surveillance of the QA Programs' performance to identify problems with the quality of items and activities that are important to isolation. EPA also increased its surveillance of the QA Programs' independence from cost and schedule considerations.

2009 CRA Information on the Establishment of QA Requirements

DOE provided information on the establishment of QA requirements in two ways. First, DOE referenced the information provided in the 2004 CRA Chapter 5, and secondly, DOE provided its QA Plan. DOE's QA Plan, which establishes the NQA standards for the WIPP, is titled "Quality Assurance Program Document" (QAPD). Appendix QAPD of the 2009 CRA, like in the 2004 CRA and CCA, contains the QAPD. Since the CCA, EPA has audited the QAPD several times to verify the continued proper establishment of the NQA standards. The following paragraphs are general descriptions of the establishment of the applicable requirements of each NQA "Element" or "Basic Requirement" in Appendix QAPD of the 2009 CRA:

NQA-1 Element 1, *Organization*, is properly established in Section QAPD-2.1.1, titled "Organization", of Appendix QAPD. CBFO's organization is structured so that operational organizations performing the work are responsible for achieving quality. CBFO's QA

Organization has the authority and organizational freedom to properly verify the achievement of quality. CBFO's requirement for *Organization* is established, and the organizational structure is defined. The responsibilities and authority of the CBFO QA Manager are described. The current organizational chart for CBFO is available through its QA records.

NQA-1 Element 2, *Quality Assurance Program*, is properly established in Table QAPD-1, titled "QA Program Documents", and in Sections QAPD-2.1.2 through QAPD-2.1.2.4. The referenced table lists the source documents used for planning and maintaining the QAPD, and the NQA standards are listed. Section QAPD-2.1.2 identifies items and activities to which the QAPD applies. CBFO is required to plan work, provide for personnel training and qualification. And, for compliance with NQA-3-1989, CBFO will provide for management assessments.

QA Grading was used to identify the levels of QA assessments to be applied to items and activities. Grading was based upon an evaluation of the complexity and importance of the item or activity. Based on the results of the evaluation, appropriate QA assessments and controls are identified. The grading process provides the flexibility to optimize QA controls to a specific item or activity.

NQA-1 Element 3, *Design Control*, is properly established in Section QAPD-3.2, titled "Design Control." CBFO's QA Organization requires that design work, including changes, incorporates appropriate controls and requirements such as general design criteria, design bases, and control of inputs. Design interfaces must be identified and controlled. The adequacy of design products must be verified by individuals or groups independent from those who performed the work. Verification must be completed before approval and implementation of the design. The control of design activities also includes design reviews and qualification testing.

NQA-1 Element 4, *Procurement Document Control*, is properly established in Section QAPD-3.3.4, titled "Procurement Document Requirements." CBFO's QA Organization requires that procurement documents address the scope of work, technical requirements, design bases, appropriate codes, standards, regulations, procedures, instructions, tests, inspections, hold points, acceptance criteria, and documentation requirements. Procurement documents must be reviewed to verify that the documents include appropriate provisions for ensuring that items and services meet the prescribed requirements. These procurement documents must be reviewed by QA personnel. The reviewers are required to have access to pertinent information and an adequate understanding of the requirements and scope of the procurement.

NQA-1 Element 5, *Instructions, Procedures, and Drawings*, is properly established in Section QAPD-3.1.2, titled "Implementing Procedures." CBFO's QA Organization requires that activities affecting quality are prescribed by and performed in accordance with the appropriate established, documented, and approved instructions, procedures, or drawings. Instructions, procedures, and drawings must be developed, reviewed, and approved by technically competent personnel. Each of the program participants must develop implementing documents that address the quality activities applicable to his or her QA program requirements and work scope.

NQA-1 Element 6, *Document Control*, is properly established in Section QAPD-2.4, titled "Documents." CBFO's QA Organization requires that documents that specify quality requirements or prescribe activities affecting quality, such as instructions, procedures, drawings, test plans, and management plans, are controlled to assure that the correct documents are being employed. Controlled documents must be reviewed by competent personnel, using specified criteria for adequacy, correctness, and completeness before approval and issuance. Review comment documentation must be maintained by the originating organization. Responsibilities for document preparation must be specified and the documents must be controlled during the preparation, review, approval, issuance, use, and revision processes

NQA-1 Element 7, *Control of Purchased Items and Services*, is properly established in Section QAPD Sections 3.3.2, 3.3.6, and 3.3.7. CBFO's QA Organization requires that controls must be established to ensure that procured items and services meet performance specifications. Prospective suppliers must be evaluated and selected on the basis of documented criteria. Procurement controls must be in place to ensure that approved suppliers continue to provide acceptable items and services.

NQA-1 Element 8, *Identification and Control of Items*, is properly established in Section QAPD-3.1.3, titled "Item Identification and Control." CBFO's QA Organization requires that processes must be used to identify, control, and maintain items from receipt through installation and end-use. Item identification must ensure the appropriate traceability as specified in design documents, codes, standards, specifications, and implementing procedures. An identification marking must be placed on the item or in documents traceable to the item. Acceptable methods and materials for characteristics and markings must be prescribed, and the authority for applying and removing status indicators and markings must also be specified.

NQA-1 Element 9, *Control of Processes*, is properly established in Section QAPD-3.1.4, titled "Special Processes." CBFO's QA Organization requires that work processes must be performed in accordance with established, approved, and documented technical standards and administrative controls. Work must be planned, authorized, and performed under controlled conditions using approved instructions, procedures, drawings, or other appropriate means. Implementing procedures must be developed, reviewed, and approved by qualified and competent personnel. Personnel performing work must be responsible for complying with appropriate instructions

NQA-1 Element 10, *Inspections*, is properly established in Section QAPD-3.4.1, QAPD-3.4.3.6, and QAPD-3.4. CBFO's QA Organization requires inspections to determine acceptance or rejection of an item or activity. Inspection documentation required of program participants includes:

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

- identification of any measuring and test equipment used, including the equipment.

NQA-1 Element 11, *Test Control*, is properly established in Sections QAPD-3.4 and QAPD-7.6.2.4. (Software testing is established in Section 7.0 of the Appendix QAPD and will be addressed below under the establishment of NQA-2a-1990) CBFO's QA Organization requires tests to determine the capability of an item to meet specified requirements by subjecting the item to a set of defined operating conditions. Test planning is required and includes:

- identification of the procedures and related requirements documents used to control and perform the test (for example, test plans);
- identification of the item to be tested, test requirements, and acceptance criteria;
- identification of the measuring and test equipment (M&TE) including the type, range, accuracy, and tolerance;
- test prerequisites and provisions to ensure that all test requirements and objectives have been met;
- any designated hold points; and
- recording methods used to collect and record the data.

NQA-1 Element 12, *Control of Measuring and Test Equipment*, is properly established in Section QAPD-3.4.6. CBFO's QA Organization requires the use of control systems for measuring and test equipment to ensure that suspect and out-of-tolerance equipment are not used.

NQA-1 Element 13, *Handling, Storage, and Shipping*, is properly established in Section QAPD-3.1.5. Handling, storage, cleaning, packaging, shipping, and preservation of items must be controlled to prevent damage or loss and to minimize deterioration.

NQA-1 Element 14, *Inspection, Test, and Operating Status*, is properly established in Section QAPD-3.1.3. Status indicators must be employed to help prevent inadvertent installation, use, or operation of items that have not passed the required inspections or tests. Only authorized persons can apply and remove status indicators on items, as appropriate. The specific status indicators, their use, and the authority to apply or remove them are delineated in applicable QA plans or implementing procedures

NQA-1 Element 15, *Control of Nonconforming Items*, is properly established in *Section QAPD-2.3*, titled "Nonconformances", and in Section QAPD-2.3.2.2, titled "Identifying Nonconforming Items and Data." Items that do not conform to specified requirements must be controlled to prevent their installation, use, or operation before correction. Nonconforming items can be identified at any time by anyone

NQA-1 Element 16, *Corrective Action*, is properly established in Sections QAPD-2.3.3,

2.3.3.4, 2.3.3.5, and 2.3.3.7. "Corrective actions" are measures that are taken to rectify a condition that is adverse to quality and, where necessary, to preclude recurrence. Conditions adverse to quality must be evaluated, the appropriate corrective actions must be defined and implemented, and the completion and effectiveness of the corrective action must be verified. If the condition adverse to quality is determined to be significant, corrective action is identified, investigative action is taken, the root cause is determined, and appropriate actions are taken to preclude recurrence. A significant condition adverse to quality includes a condition, which if uncorrected, could have a bad effect on waste isolation. When appropriate, further work on the item, activity, or process must be halted until the appropriate actions have been taken and verified.

NQA-1 Element 17, *Quality Assurance Records*, is properly established in Section QAPD-2.5, titled "Records." CBFO's QA Organization requires that records must be specified, prepared, reviewed, approved, maintained, and disposed of in accordance with the CBFO QAPD. Records provide evidence of quality achievement and evidence that the QA program has been properly implemented. The records management system is documented in appropriate QA plans and implementing procedures. The generation, classification, indexing, and retention of QA records are controlled in accordance with appropriate plans and records-related procedures.

NQA-1 Element 18, *Audits*, is properly established in Section QAPD-4.2.2, titled "Audits." Audits verify that all of the WIPP's QA programs comply with the requirement of the NQA standards. The management and control of audits are documented in QA plans or implementing procedures. Audits conducted since the 2004 CRA have been rolled up into summary tables in Appendix AUD 2004. These tables reflect the extensive and comprehensive auditing efforts that CBFO's QA organization has implemented. Appendix AUD provides some objective evidence that CBFO's QA Organization has adhered to a periodic schedule of assessments of lower tier programs and suppliers as required by the NQA standards.

The NQA-2, Part 2.7, *Software Quality Assurance*, is properly established in Section QAPD-7.3, titled "Software Quality Assurance." CBFO's QA Organization requires that software QA controls are employed to ensure that the software meets its intended use and is controlled. These controls apply to software that manipulates or produces data that are, in turn, used to process, gather, or generate information and whose output is relied upon to make design, analytical, operational, or compliance-related decisions affecting the performance of the waste isolation, including waste characterization processes. The application of these requirements must be prescribed in written plans, policies, procedures, or instructions.

The 2009 CRA also refers to the 2004 CRA for information on establishment of ASME NQA-3-1989. ASME NQA-3-1989 is addressed in the CRA-2004, Chapter 5.0, Sections 5.3.21, 5.3.22, and 5.3.23. The NQA-3 requirements for *Scientific Investigation* are addressed in 2004 CRA Section 5.3.21. *Scientific Investigation* requirements are established in QAPD Section 6. Scientific investigations are defined, controlled, verified, and documented. Process variables affecting scientific investigations are measured and controlled. Planning for scientific

investigations ensures that the appropriate information is collected and that outside factors are eliminated or their effects are minimized. Planning is coordinated with other organizations that provide input or use the results. Scientific investigations are performed according to requirements and are documented in scientific notebooks or technical implementation documents or both. Methods used in the investigations are reviewed to ensure that they are technically sound and have been properly selected. Data collection and analyses are controlled by procedures that allow the processes to be replicated. Test media are characterized and controlled in accordance with test procedures. Data are recorded, identified, and traceable to the scientific investigation from which they are generated. Data collection and analysis are critically reviewed and questions are resolved before the results are used or reported. Uncertainty limits are assigned to the data before their use.

The 2009 CRA refers to the 2004 CRA for information on the qualification of all data, including the qualification of information collected prior to implementation of a QA Program. The CRA-2004, Chapter 5.0, Section 5.3.23 provided information on how all data are qualified for use. This section provided information on how all data used are qualified by using one or more of five methods; (1) existing QA Program, (2) peer-review, (3) corroborating data, (4) confirmatory testing, or (5) equivalent QA program. *Peer Reviews* are performed when necessary to verify the technical adequacy of work done and to qualify data. The peer review process and peer reviews conducted to support data qualification are described in the 2004 CRA Chapter 9.0, *Peer Review*. CBFO's program for performing *Peer Reviews* is established in CBFO procedure MP 10.5. The EPA found that the CRA-2004 provided information describing how all data used to support the compliance application have been qualified. Therefore, the EPA determines that the DOE continues to comply with the requirements for Sections 194.22(b)&(d).

The 2009 CRA refers to the 2004 CRA for information on data quality characteristics. The CRA-2004, Chapter 5.0, Section 5.3.22 provided information that describes how all data used to support the compliance application have been assessed for accuracy, precision, representativeness, completeness, and comparability. The EPA found that the CRA-2004 provides information that describes how all data used to support the compliance application have been assessed for their quality characteristics. Therefore, the EPA determines that the DOE continues to comply with the requirements for Sections 194.22(c).

EPA finds that the information provided or referenced in the 2009 CRA provided sufficient information to describe the establishment of the QA requirements invoked under 40 CFR 194.22 and 40 CFR 194.8(a). DOE provided a satisfactory description of compliance with the QA requirements.

Audits to Verify Proper Execution of QA Programs

It is not possible to verify proper execution of QA Programs based solely on information provided by DOE. Part 194.22(e) provides EPA with the authority to conduct audits to verify the proper execution of QA Programs. Therefore, EPA conducted audits, and the EPA audit

reports are available to the public through the Agency's public dockets. Table 1 provides a list of the EPA audits of to verify the proper execution of the QA Program at DOE's Carlsbad Field Office.

Table 1 - List of EPA's Audits of DOE's QA Program Through CRA 2009

Activity	Date	Purpose
Initial Certification Audit	December 9-13, 1996 (A-93-02, II-I-4)	Initial audit of QA program for conformance with 40 CFR 194.22(a)
Audit	January 6-8, 1998 (A-93-02, IV-A-4)	Annual audit for maintenance of QA program for conformance with 40 CFR 194.22(a)
Audit	January 6-8, 1999 (A-98-49, II-A1-4)	Annual audit for maintenance of QA program for conformance with 40 CFR 194.22(a)
Audit	January 4-6, 2000 (A-98-49. II-A1-14)	Annual audit for maintenance of QA program for conformance with 40 CFR 194.22(a)
Audit	January 9-10, 2001 (A-98-49, II-A1-24)	Annual audit for maintenance of QA program for conformance with 40 CFR 194.22(a)
Audit	January 8-9, 2002 (A-98-49, II-A1-33)	Annual audit for maintenance of QA program for conformance with 40 CFR 194.22(a)
Surveillance	January 24, 2002 (A-98-49, II-A1-33)	Follow-up evaluation of findings and concerns from January 2002
Audit	February 20-21, 2002 (A-98-49, II-A1-35)	Follow-up audit to determine actions on EPA findings from January 2002 audit
Audit	May 14-16, 2002 (A-98-49, II-A1-35)	Follow-up audit to determine actions on EPA findings from January and February 2002 audits
Audit	January 7-9, 2003 (A-98-49, II-A1-44)	Annual audit for maintenance of QA program for conformance with 40 CFR 194.22(a)
Audit	December 2-4, 2003 (A-98-49, II-A1-57)	Annual audit for maintenance of QA program for conformance with 40 CFR 194.22(a)
Informational Visit	February 10-12, 2004	Follow-up visit to obtain information regarding newly established CBFO organizational chart. No report was issued.
Audit	November 16-17, 2004 (A-98-49, II-A1-66)	Follow-up audit to assess the implemented re-organization of CBFO.
Audit	February 8-9, 2005 (A-98-49, II-A1-70)	Follow-up audit to assess a corrective action by CBFO**.**
Audit	July 19-21, 2005 (A-98-49, II-A1-73)	Follow-up audit to assess a corrective action by CBFO
Audit	December 13-20, 2005 (A-98-49, II-A1-80)	Audit of CBFO auditing and corrective action processes.
Audit	February 7-9, 2006 (A-98-49, II-A1-79)	Audit of Revision 7 of CBFO QA Plan.
Audit	January 23, 2007 (A-98-49, II-A1-90)	Annual Audit of CBFO QA Program.
Audit	January 15-17, 2008 (A-98-49, II-A1-97)	Annual Audit of CBFO. Revision 9 of QA Plan.

The QA Program of CBFO audits all other WIPP-related organizations to verify that they also properly establish and implement the QA requirements. Appendix AUD of the 2009 CRA contains summaries of the CBFO QA audits of WIPP organizations. Tables AUD-1 through AUD-16 of Appendix AUD summarize CBFO's QA Organization audits performed between January 11, 2003 and January 15, 2008 of transuranic (TRU) waste sites, Sandia National Laboratories (SNL), Washington TRU Solutions (WTS), suppliers performing quality-affecting work, the Carlsbad Field Office (CBFO), and Los Alamos National Laboratory – Carlsbad Operations (LANL-CO). Some of these audits were performed prior to the end of the CRA-2004, Appendix AUD-2004 reporting date; however, the audits were not considered complete until the final report and associated regulatory approvals were documented.

EPA auditors witnessed the performance of many of the audits conducted by CBFO's QA Organization that are listed in Appendix AUD. In all the witnessed cases, the EPA determined that the CBFO QA audits were performed properly in accordance with Element 18, titled "Audits", of NQA-1. This was a focus to EPA audits; to verify that CBFO's QA Organization could properly audit lower-tier organizations. The EPA reports of CBFO QA audits are also available to the public through the Agency's public dockets. Based on a large sample of CBFO QA audits witnessed by EPA, the EPA has the following general conclusions regarding the audits listed in Appendix AUD:

1. The CBFO QA audits were properly planned and scheduled,

2. The audits were properly performed in accordance with written procedures or checklists by qualified personnel who did not have direct responsibility for performing the activities being audited.

3. The audit results were properly documented and reported to and reviewed by responsible DOE management and EPA, and

4. Follow-up actions were taken by DOE where indicated in the CBFO QA audit reports.

The EPA also directly audited the lower-tier WIPP organizations that report to CBFO. In most of these cases, the EPA QA auditors took direct audit samples while witnessing CBFO QA audits. EPA also conducted many EPA-only audits of the QA programs of lower-tier organizations, focusing on SNL, WTS and LANL-CO. The QA organization of WTS was the most audited lower-tier organization because WTS operates both the WIPP site and the Central Characterization Project at most of the waste generator sites. The EPA reports documenting EPA-only audits of lower-tier organizations are also available to the public through the Agency's public dockets.

The contact-handled TRU waste generators with EPA-approved QA programs include:

- LANL/Central Characterization Project (CCP)

- Hanford
- Idaho National Laboratory (INL)/Central Characterization Project
- Savannah River Site (SRS)/CCP
- Advanced Mixed Waste Treatment Project
- Oak Ridge National Laboratory (ORNL)/Central Characterization Project

Public Comments

EPA did not receive any public comments on DOE's continued compliance with the quality assurance requirements of Section 194.22 or Section 194.8(a).

22.4.2 2009 RECERTIFICATION DECISION

EPA finds that DOE's QA Programs continue to be effective at identifying problems with the reliability of items and activities that are important to the long-term isolation of transuranic waste. Based on EPA's review of the effectiveness of the WIPP related QA Organizations, the results of EPA audits, and the review of the 2009 CRA information, the EPA determines that DOE continues to comply with the Quality Assurance requirements of Section 194.22 and Section 194.8(a).