**Recertification CARD No. 22**
**Quality Assurance**

## 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 (TRU) waste inside the Waste Isolation Pilot Plant (WIPP). These QA assessments are conducted under the authority of QA organizations from the U.S. Department of Energy (DOE or Department). 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. The items and activities include the technical data and analysis underlying the DOE's Compliance Certification Application (CCA) and 2004 Compliance Recertification Application (2004 CRA). DOE's QA assessments "qualify" WIPP's items and activities before final assessments that are conducted by the U.S. Environmental Protection Agency (EPA or Agency). QA is an effective 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.

A copy of the NQA standards can be obtained from:
The American Society of Mechanical Engineers
Three Park Avenue, New York, NY 10016-5990

## REQUIREMENTS

to

(a)(1) "As soon as practicable after April 9, 1996, the Department shall adhere 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."

**1998 CERTIFICATION DECISION**

EPA performed three types of assessments during review of the CCA 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 TRU waste 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 took two general steps to perform each of the three assessments mentioned above. First, the Agency reviewed the CCA and associated references to determine if DOE provided a satisfactory description of compliance with the QA requirements. During this stage, the Agency requested and reviewed additional information. In the second step, the EPA conducted formal audits at WIPP-related facilities to verify compliance with the requirements of 40 CFR 194.22. 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 practical 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 (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 TRU waste at the WIPP. Each unapproved site would have to be audited after the approval of the CCA to verify compliance, prior to shipment of waste from each unapproved site.

The Agency did examine 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 Docket A-93-02, Items V-A-1 and V-B-2.

**CHANGES IN THE CRA**

Chapter 5 of the 2004 CRA, like Chapter 5 in the previous CCA, discusses the QA programs for the WIPP. DOE extensively revised Chapter 5 to make it clearly match the structure of the NQA standards and to update information. Changes to the QA portions of the 2004 CRA reflect a maturing and expansion of the WIPP's QA program since the CCA. The new QA programs at the time of the CCA increased their effectiveness over time. And, new waste generator sites were added, thus adding more QA programs.

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, contains the QAPD. DOE revised the QAPD to more clearly establish each of the applicable NQA elements, and to update DOE's organizational structure.

Appendices PEER and AUD of the 2004 CRA were updated to include peer reviews and audits performed since the CCA.

## EVALUATION OF COMPLIANCE FOR RECERTIFICATION

Information on the Establishment of NQA Standards

The 2004 CRA provides information on DOE's establishment of the NQA standards. ASME NQA-1-1989 requirements are addressed in 2004 CRA, Sections 5.3.1 through 5.3.19. ASME NQA-2a-1990 addenda part 2.7 is addressed in Section 5.3.20. ASME NQA-3-1989 is addressed in 2004 CRA, Sections 5.3.21, 5.3.22 and 5.3.23.

DOE's QA Plan that establishes the NQA standards, the QAPD, is provided as Appendix QAPD to the 2004 CRA. Since the CCA, the EPA has periodically audited the QAPD to verify the continued proper establishment of the NQA standards.

DOE's approach for meeting the requirements of NQA-1 Element 1, *Organization,* is addressed in Section 5.3.1 of the 2004 CRA. CBFO's organization is structured so that operational organizations performing the work are responsible for achieving quality. And, CBFO's QA organization has the authority and organizational freedom to properly verify the achievement of quality. CBFO's requirement for *Organization* is established in Section 1.1 of the QAPD. The organizational structure is defined in Section 1.1.1 of the CBFO QAPD. The responsibilities and authority of the CBFO QA Manager are described in Appendix D of the CBFO QAPD. The current organizational chart for CBFO is available through its QA records.

The QAPD requires personnel conducting assessments to be: technically qualified and knowledgeable about the items and activities being assessed, and be independent of any direct responsibility for the performance of the activities being assessed.

NQA-1 Element 2, *Quality Assurance Program*, requirements are addressed in Section 5.3.2 of the 2004 CRA. The CBFO QA program is documented and established in the QAPD. The QA organizational structures, primary interfaces, functional responsibilities, and levels of authority for activities affecting quality are described and documented in Section 1 of the QAPD. CBFO's program for the NQA-1, Element 2 supplemental requirements for training is established in Section 1.2 of the QAPD.

*QA Grading* is used to identify the levels of QA assessments to be applied to items and activities. Grading is 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*, requirements are addressed in Section 5.3.3 of the 2004 CRA. Design work, including changes, incorporates appropriate controls and

requirements such as general design criteria, design bases, and control of inputs. Design interfaces are identified and controlled. The adequacy of design products is verified by individuals or groups independent from those who performed the work. Verification is completed before approval and implementation of the design. The control of design activities also includes design reviews and qualification testing. CBFO's QAPD Section 2.2 properly establishes the *Design Control* requirements of the NQA standards.

NQA-1 Element 4, *Procurement Document Control,* requirements are addressed in the 2004 CRA Section 5.3.4. 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 are reviewed to verify that the documents include appropriate provisions for ensuring that items and services meet the prescribed requirements. CBFO requires that these procurement documents 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. CBFO's QA organization conducts audits and surveillances to verify that these requirements are being met. CBFO's QAPD, Sections 2.3.4 and 2.3.5, establish the requirements for *Procurement Document Control*.

NQA-1 Element 5, *Instructions, Procedures, and Drawings*, requirements are addressed in Section 5.3.5 of the 2004 CRA. Activities affecting quality are prescribed by and performed in accordance with the appropriate established, documented, and approved instructions, procedures, or drawings. Instructions, procedures, and drawings are developed, reviewed, and approved by technically competent personnel. Each of the program participants develops implementing documents that address the quality activities applicable to his or her QA program requirements and work scope. CBFO QAPD Sections 1.4 and 2.1.2 establish the requirements for *Instructions, Procedures, and Drawings*.

NQA-1 Element 6, *Document Control,* requirements are addressed in Section 5.3.6 of the 2004 CRA. 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 are reviewed by competent personnel, using specified criteria for adequacy, correctness, and completeness before approval and issuance. Review comment documentation is maintained by the originating organization. Responsibilities for document preparation are specified and the documents are controlled during the preparation, review, approval, issuance, use, and revision processes. CBFO's *Document Control* requirements are established in CBFO QAPD Section 1.4.

NQA-1 Element 7, *Control of Purchased Items and Services*, requirements are addressed in Section 5.3.7 of the 2004 CRA. Controls are established to ensure that procured items and services meet performance specifications. Prospective suppliers are evaluated and selected on the basis of documented criteria. Procurement controls are in place to ensure that approved suppliers continue to provide acceptable items and services. CBFO QAPD Section

2.3 establishes CBFO's program for *Control of Purchased Items and Services*.

NQA-1 Element 8, *Identification and Control of Items*, requirements are addressed in Section 5.3.8 of the 2004 CRA. "Item" is an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, support system, or data. Processes have been established to identify, control, and maintain items from receipt through installation and end-use. Item identification ensures the appropriate traceability as specified in design documents, codes, standards, specifications, and implementing procedures. An identification marking is placed on the item or in documents traceable to the item. Acceptable methods and materials for characteristics and markings are prescribed, and the authority for applying and removing status indicators and markings is also specified. CBFO QAPD Section 2.1.3 establishes requirements for *Identification and Control of Items*.

NQA-1 Element 9, *Control of Processes*, requirements are addressed in Section 5.3.9 of the 2004 CRA. Work processes are performed in accordance with established, approved, and documented technical standards and administrative controls. Work is planned, authorized, and performed under controlled conditions using approved instructions, procedures, drawings, or other appropriate means. Implementing procedures are developed, reviewed, and approved by qualified and competent personnel. Personnel performing work are responsible for complying with appropriate instructions. CBFO QAPD Section 2.1 establishes requirements for *Control of Processes*.

NQA-1 Element 10, *Inspections*, requirements are addressed in 5.3.10 of the 2004 CRA Section. Inspections 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; and
- identification number and the calibration due date.

CBFO QAPD Section 2.4 establishes the requirements for *Inspections*.

NQA-1 Element 11, *Test Control*, requirements are addressed in Section 5.3.11 of the 2004 CRA. Tests determine the capability of an item to meet specified requirements by subjecting the item to a set of defined operating conditions. Tests included as part of scientific investigations are conducted in accordance with the methods described in Section 5.3.20 of the 2004 CRA. 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.

In addition, the documentation of test results identifies: (1) the test date, (2) the personnel performing the test, (3) the data collected and the results of the tests, (4) the actual measuring and test equipment used, (5) the actions taken when unexpected results are obtained, and (6) the personnel evaluating the test results. A qualified person evaluates the results to ensure that all test requirements have been met. CBFO QAPD Section 2.4.4 establishes the requirements for *Test Control*.

NQA-1 Element 12, *Control of Measuring and Test Equipment (M&TE)*, requirements are addressed in Section 5.3.1 of the 2004 CRA. The M&TE control system is established for monitoring, measuring, testing, and the proper use of data collection equipment to ensure that suspect and out-of-tolerance equipment that could affect quality are not used. If such equipment is inadvertently used, the control system provides for the segregation of the defective equipment and the evaluation of the data obtained while the out-of-tolerance or defective equipment was used. *Control of M&TE* requirements are established in CBFO QAPD Section 2.4.6.

NQA-1 Element 13, *Handling, Storage, and Shipping*, requirements are addressed in Section 5.3.13 of the 2004 CRA. Handling, storage, cleaning, packaging, shipping, and preservation of items are controlled to prevent damage or loss and to minimize deterioration. Items supporting compliance with 40 CFR Part 191 Subparts B and C and 40 CFR Part 194 are managed and controlled using approved implementing documents. *Handling, Storage and Shipping* requirements are established CBFO QAPD Section 2.1.5.

NQA-1 Element 14, *Inspection, Test, and Operating Status*, requirements are addressed in Section 5.3.14 of the 2004 CRA. Status indicators help prevent inadvertent installation, use, or operation of items that have not passed the required inspections or tests. Only authorized persons 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. QAPD Section 2.4 establishes the requirements for *Inspection, Test and Operating Status*.

NQA-1 Element 15, *Control of Nonconforming Items*, requirements are addressed in

Section 5.3.15 of the 2004 CRA. Items that do not conform to specified requirements are controlled to prevent their installation, use, or operation before correction. Nonconforming items may be identified at any time by anyone. QAPD Section 1.3.2 establishes the requirements for *Control of Nonconforming Items*.

NQA-1 Element 16, *Corrective Action*, requirements are addressed in Section 5.3.16 of the 2004 CRA. "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 are evaluated, the appropriate corrective actions are defined and implemented, and the completion and effectiveness of the corrective action are 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 is halted until the appropriate actions have been taken and verified. CBFO QAPD Section 1.3.3 establishes the requirements for *Corrective Action*.

NQA-1 Element 17, *Quality Assurance Records*, requirements are addressed in Section 5.3.17 of the 2004 CRA. Records generated under the QA program are 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. *QA Records* requirements are established in QAPD Section 1.5.

NQA-1 Element 18, *Audits*, requirements are addressed in Section 5.3.19 of the 2004 CRA. 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. QAPD Section 3.2.2 establishes the *Audit* requirements. Audits conducted since the CCA 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 demonstrates that CBFO 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*, requirements are addressed in Section 5.3.20 of the 2004 CRA. Software QA controls are in place 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 or waste characterization processes. The application of these requirements is prescribed in written plans, policies, procedures, or

instructions. *Software QA* requirements are established in CBFO QAPD Section 6.

The NQA-3 requirements for *Scientific Investigation* are addressed in Section 5.3.21 of the 2004 CRA. 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. *Scientific Investigation* requirements are established in QAPD Section 5.

The NQA-3 requirements for *Data and Sample Management* are addressed in Section 5.3.22 of the 2004 CRA. 40 CFR § 194.22(c) stipulates that to the extent practicable, data used to support compliance will be assessed to ensure data accuracy, precision, representativeness, completeness, and comparability. DOE applies these data characteristics to tasks involving the quantification of specific constituents in an environmental medium through sampling and analysis. DOE applies these requirements to activities such as the determination of the presence or absence of constituents within TRU waste streams. Waste characterization and environmental monitoring are examples of the types of activities in which data quality characteristics are applied. In these cases, the performance measurement is the concentration of the constituent of interest. Data quality measures include:

- data accuracy - a measure of the bias in a system, which is the degree of agreement of a measurement with an accepted reference or true value;
- data precision - a measure of mutual agreement among individual measurements of the same property, usually expressed in terms of standard deviation;
- data representativeness - the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, or an environmental condition;
- data completeness - a measure of the amount of valid data obtained from a measurement system compared to the amount that was planned; and
- data comparability - a measure of the confidence with which one data set can be compared to another.

CBFO's program for *Data and Sample Management* is established in CBFO QAPD

Section 4.

CBFO's program for the NQA-3 requirement for *Qualification of Data* is established in Section 5.4 of the CBFO QAPD. Data can be qualified by using one or more of the following methods:

- data used in performance assessment have been obtained under an approved QA program that implements the QA requirements referenced in Section 5.2.1.2;
- existing data collected before the implementation of a qualified QA program have been qualified by showing that the data were obtained under a QA program that is equivalent to one satisfying the NQA requirements referenced in 40CFR 194.22(a)(1);
- existing data have been qualified by peer review conducted in a manner compatible with NUREG 1297, Peer Review for High-Level Nuclear Waste Repositories;
- corroborating data processes may also be used to qualify the data; or
- confirmatory testing may be performed.

*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.

EPA finds that CBFO's QA Plan (appendix QAPD of the CRA) properly establishes the applicable elements of the Nuclear Quality Assurance standards invoked under 40 CFR 194.22 for items and activities that are important to the long-term isolation of transuranic waste.

Information on Audits of QA Plan Implementation

The 2004 CRA provides information on internal and external auditing of the implementation of the CBFO QA Plan (QAPD) in Sections 5.3.19 and 5.7. Section 5.7 of the 2004 CRA describes the CBFO audit process that covers internal and external audits, audit schedules and audit team leader requirements. Table 10 of Appendix AUD provides a summary of audits conducted on the CBFO QA Plan. These include:

Audit Number A-00-04
Conducted 4/24-28/00
Internal QA audit by DOE/Headquarters of CBFO
The QA program was adequate, satisfactorily implemented, and effective.
Audit Number A-01-15
Conducted 4/30-5/4/01
Internal QA audit of CBFO by DOE/Headquarters
The CBFO implementation of DOE 414.1A into the QA program was adequate, satisfactorily implemented, and effective.
Audit Number S-01-20

Conducted 7/24-25/01
The CBFO observation process
The observation process was effective, but marginally implemented and marginally adequate. Corrective action reports have all been completed and closed.

Audit Number S-03-08
Conducted 2/10-13/03
Activities within the Office of Program Support
The QA program was adequate but it was not being satisfactorily implemented and was not effective. Corrective action is being taken through the CAR system.

The Agency has determined that the 2004 CRA provides references to general and auditable information regarding internal and external audits to verify proper implementation of the CBFO QA Plan. Further, the Agency has conducted periodic audits since the CCA to verify the proper implementation of the CBFO QA Plan.

Information on Audits of QA Programs at Lower-Tier Organizations

The 2004 CRA addresses internal and external auditing of the CBFO QA Plan in Section 5.3.19 as a requirement of NQA-1-1989 and again in Section 5.7. Section 5.7 of the 2004 CRA describes the CBFO audit process that covers internal and external audits, audit schedules and audit team leader requirements. Audit history can be located in Tables AUD-1 through AUD-11 of Appendix AUD 2004 for assessments performed of TRU waste generator sites and suppliers performing quality affecting work during the time span of 1999 to 2003. All audits are assigned an audit number, which allows traceability. A summary of the tables is as follows:

- Table 1 - Los Alamos National Laboratory (LANL) Audits consists of 11 audits.
- Table 2 - Los Alamos National Laboratory - Carlsbad Operations (LANL-CO) Audits consists of 2 audits.
- Table 3 - Nevada Test Site (NTS) Audits consists of 5 audits.
- Table 4 - Hanford Site Audits consists of 9 audits.
- Table 5 - Rocky Flats Environmental Technology Site (RFETS) Audits consists of 20 audits.
- Table 6 - Idaho National Engineering and Environmental Laboratory (INEEL) Audits consist of 13 audits.
- Table 7 - Washington TRU Solutions (WTS) Audits consists of 19 audits.
- Table 8 - Sandia National Laboratories (SNL) Audits consists of 7 audits.
- Table 9 - Savannah River Site (SRS) Audits consists of 6 audits.
- Table 11 - Carlsbad Field Office (CBFO) Supplier Audits consists of 8 audits. Audited suppliers include Carlsbad Field Office Technical Assistance Contractors (CTAC),

Argonne National Laboratory – East (ANL-E), Battelle Columbus Lab (BCL), Mobile Characterization Services, LLC (MCS) and Carlsbad Environmental Monitoring and Research Center (CEMRC).

EPA finds that the 2004 CRA contains general and auditable information describing an active auditing program by CBFO of lower-tier and supplier organizations. Further, the Agency has conducted periodic audits since the CCA to verify the proper execution of QA programs at the lower-tier organizations.

Information on Establishment of NUREG-1297 for Peer Reviews.

NUREG-1297 provides guidance on the definitions of peer reviews, the area for which peer review is appropriate, the acceptability of peers, and the conduct and documentation of peer reviews. The CBFO Peer Review Process is outlined in the 2004 CRA, Chapter 9, Section 9.2. Section 9.2 is broken into sub-sections 9.2.1 through 9.2.8 that generally mirror the topics in NUREG-1297. The remainder of Chapter 9 discusses the results of peer reviews conducted prior to 2004.

CBFO's Management Procedure (MP) 10.5 establishes the requirements of NUREG-1297. The Agency evaluated MP 10.5 and its description in 2004 CRA, Chapter 9, Sections 9.2.1 through 9.2.8. The 2004 CRA, Chapter 9 sections for Peer Review are as follows:

9.2.1 Peer Review Plan – CBFO Management Procedure MP 10.5, Attachment 1, Section 6.1 requires that the Peer Review Manager ensure that a peer review plan is prepared and approved prior to the performance of each peer review. Specific plans are approved by the cognizant CBFO Assistant Manager. The plan documents the expectations for the peer review. It provides the scope of the peer review, a description of the work to be reviewed, the intended use of the work, and methods for conducting peer reviews.

9.2.2 Size and Composition of Peer Review Panels - The size and composition of peer review panels established after the promulgation of 40 CFR Part 194 are determined by a selection committee consisting of the Peer Review Manager and two members selected by the Peer Review Manager. This process is described in MP 10.5, Attachment 1, Section 2.1.

Technical requirements for each peer review panel are established by the Peer Review Manager and provided to the selection committee, which then develops a list of potentially qualified personnel. Once a panel member is officially selected and agrees to serve, the selection committee members document the rationale for the selection of that peer review panel member on a "Peer Review Panel Selection, Size and Composition Justification/Decision Form," which is maintained as a QA record.

The number of members selected for a particular panel depends on the amount and complexity of the work to be reviewed, its importance for waste isolation, the number of technical disciplines involved, the degree to which uncertainties in the data or technical

approach exist, and the extent to which differing viewpoints were strongly held within the applicable technical and scientific community concerning the issues under review. The panel members are selected based on their collective technical expertise and qualifications such that they span the technical issues and areas involved in the work to be reviewed, including differing bodies of scientific thought. The technical areas more central to the work under review receive proportionally more representation on the peer review panel. To the extent practical, the panels represent the major schools of scientific thought pertinent to the subject being reviewed. The selection committee strives to eliminate the potential for technical or organizational partiality by selecting peer reviewers that provided a balanced panel.

9.2.3 Technical Qualifications of Panel Members - MP 10.5, Attachment 1, Section 2.2 specifies that the acceptability of any peer review panel member be based on the NUREG-1297 requirements. The Peer Review Manager is required to ensure that education and pertinent experience information is verified and documented prior to the start of the peer review process. This documentation is also maintained as QA records.

9.2.4 Independence of Panel Members - MP 10.5, Attachment 1 provides in Section 2.2.3 that the NUREG-1297 requirements be used in selecting panel members. Each peer review panel member is required to document his or her independence. These documents are reviewed and approved by the Peer Review Manager and maintained as QA records.

9.2.5 Training of Peer Review Panel Members - MP 10.5, Attachment 1, Section 3 requires that the Peer Review Manager ensure all peer review panel members receive adequate training prior to beginning a peer review. Training consists of reading assignments and, if deemed necessary by the Peer Review Manager or the Peer Review Panel Coordinator, briefings and classroom training. Assigned reading includes 40 CFR Parts 191 (EPA 1993) and 194, NUREG-1297, the CBFO QAPD, MP 10.5, and the applicable Peer Review Plans. MP 10.5 further requires that all panel members receive an orientation prior to the start of the peer review process. The orientation includes information on the peer review process, administrative requirements, the applicable Peer Review Plan, a summary of the technical subject matter, and an overview of MP 10.5. Panel member training and orientation are documented and this documentation is maintained as a QA record.

9.2.6 Peer Review Panel Report - MP 10.5, Attachment 1, Section 6.4 requires that a peer review report be prepared for each peer review. Each panel member is required to sign and date the report. The report describes the work or issue that was reviewed and the conclusions reached by the panel, and also provides individual statements by the members reflecting dissenting views or additional comments, as appropriate. Finally, the report lists the peer review panel members and provides technical qualifications and independence information for each member.

9.2.7 Quality Assurance Records Management – MP 10.5, Section 6 requires that "written minutes, including graphic or calculated materials used in panel meetings, be prepared

for meetings, deliberations, daily caucuses, and other activities. These written minutes are maintained as QA records. MP 10.5 also requires that a QA records management system be developed and implemented to ensure that peer review documents are identified, assembled, and transferred on a timely basis and in an orderly manner to the appropriate records center.

9.2.8 Quality Assurance Oversight – the CBFO QA organization is responsible for the surveillance of the peer review process, ensuring that all aspects of peer review conform to NUREG-1297. These requirements are flowed down by CBFO QAPD Chapter 5.0 and implemented in CBFO Procedure MP 10.5, Section 5.4.

The WIPP peer review process consists of an in-depth analysis and evaluation of documented assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of conclusions drawn in the original work. MP 10.5 was developed to specifically incorporate NUREG-1297 requirements into the WIPP peer review process.

The Agency has determined that although MP 10.5 does establish most of the NUREG-1297 requirements, it does not fully address Section IV.1, *Applicability of Peer Review*. Section IV.1(a) states that "Peer Review should be used when the adequacy of information...cannot otherwise be established through testing, alternative calculations, or through reference to previously established standards and practices." The fact that MP 10.5 does not address this section of NUREG-1297 has not hindered the use of MP 10.5 for the previous Peer Reviews (such as the Spallings Conceptual Model Peer Review), as these peer reviews were mandated by 40 CFR 194.

Information on Audits to Verify Implementation of NUREG-1297

The Agency has audited WIPP's peer reviews and found that peer reviews were conducted in accordance with the requirements of NUREG-1297. The Agency has also witnessed surveillance of peer reviews by QA organizations to verify compliance. Section V of NUREG-1297 states that "… the QA Organization should provide surveillance of the peer review..." The QAPD requires that surveillances be conducted to ensure that the peer reviews conform to NUREG-1297. MP 10.5, section 7.1 states "The CBFO QA Manager shall conduct assessments of the peer-review process to ensure that all aspects of the peer review process conform to this procedure."

EPA examined the 2004 CRA, Chapters 5 and 9, and Appendices PEER and AUD, to identify QA surveillances performed to verify proper implementation of NUREG-1297 requirements. Upon EPA request, DOE provided a list of surveillances of peer reviews (Docket A-98-49, Item II-A1-80).

Information on Assessments of Data Quality Characteristics

The 2004 CRA provides information which describes how all data used to support the compliance application have been assessed for accuracy, precision, representativeness, completeness, and comparability. This information is found in the following sections:

Chapter 5.0, Section 5.3.2.1
Chapter 5.0, Section 5.3.22
Chapter 5.0, Section 5.3.23
Chapter 9.0
Appendix PAR, Section PAR 3.0
Appendix QAPD
Appendix PEER

DOE applies these data characteristics to tasks involving the quantification of specific constituents in an environmental medium through sampling and analysis. DOE applies these requirements to activities such as the determination of the presence or absence of constituents within TRU waste streams. Waste characterization and environmental monitoring are examples of the types of activities in which data quality characteristics are applied. In these cases, the performance measurement is the concentration of the constituent of interest. Data quality measures include:

- data accuracy - a measure of the bias in a system, which is the degree of agreement of a measurement with an accepted reference or true value;
- data precision - a measure of mutual agreement among individual measurements of the same property, usually expressed in terms of standard deviation;
- data representativeness - the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, or an environmental condition;
- data completeness - a measure of the amount of valid data obtained from a measurement system compared to the amount that was planned; and
- data comparability - a measure of the confidence with which one data set can be compared to another.

EPA finds that the 2004 CRA provides information which describes how all data used to support the compliance application have been assessed for their quality characteristics.

Information on Data Qualifications

The 2004 CRA provides information on how all data are qualified for use in the demonstration of compliance. This information is found in section 5.3.23 which provides information on how all data used are qualified by using one or more of five methods. Audits were conducted to verify that data that were not qualified by one of these methods were not used for demonstrating compliance. EPA finds that the 2004 CRA provides information which describes how all data used to support the compliance application have been qualified.

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

**RECERTIFICATION DECISION**

Based on a review and evaluation of the 2004 CRA and supplemental information provided by DOE (FDMS Docket ID No. EPA-HQ-OAR-2004-0025, Air Docket A-98-49), EPA determines that DOE continues to comply with the requirements for Section 194.22.