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5.0 QUALITY ASSURANCE

The information in this chapter is a complete revision of the text in the Compliance Certification Application (CCA).

5.1 Introduction

This chapter was revised primarily to incorporate program changes, improve discussion of the characteristics and parameters of the Quality Assurance (QA) program, and clarify implementation of criteria from upper tier requirements documents. The following paragraphs provide an overview of the Carlsbad Field Office (CBFO) Quality Assurance Program Document (QAPD) development since submittal of the CCA.

In November 1999, Revision 3 of the QAPD incorporated transuranic (TRU) waste QA requirements contained in the Carlsbad Area Office (CAO) Quality Assurance Program Plan (QAPP), which was inactivated.

In August 2002, Revision 4 of the QAPD incorporated the Department of Energy (DOE) name change from the CAO to the CBFO, changes to the CBFO organization titles and associated responsibilities, and updated the Quality Improvement Section. It also provided an update of the source requirements documents for the QAPD, added specific QA functional responsibilities of the CBFO management, and eliminated divisions between "general requirements" and "additional requirements." Editorial, formatting, and paragraph number changes were also incorporated.

The latest revision, Revision 5, of the QAPD was issued in May 2003. This revision was issued to address an Environmental Protection Agency (EPA) finding that the QAPD did not adequately incorporate the Quality Assurance Program Requirements for Nuclear Facilities, ASME NQA-1, 1989 edition criteria regarding assignment of organizational responsibilities for achievement of quality and verification of quality. In addition, Revision 5 deleted the requirement for organizations receiving records to return a receipt acknowledgment to the sender, for TRU waste program participants to maintain a QAPD procedures matrix (neither is required by NQA-1, -2, -3, or other regulatory documents) and deleted references to compliance with the Federal Acquisition Regulations. It also deleted the requirements for maintaining records related to the characterization of mixed TRU waste form as lifetime records, maintaining audit and surveillance checklists as QA records. The revision also changed the requirement for calibration laboratories to comply specifically with ANSI/NCSL Z540-1 to the requirement for compliance to national standards. Finally, Revision 5 added the Safety Analysis Report (SAR) for the HalfPACT shipping package as a source document, deleted Section 5.5 (criteria addressed in Section 5.1G), and corrected typographical errors and section references.

5.1.1 Mission and Policy

In Title 40 of the Code of Federal Regulations (CFR) Part 194, the U.S. EPA establishes the QA requirements criteria for determining compliance with 40 CFR 191 Subparts B and C, which specifies environmental radiation protection standards for disposal of TRU waste. The mission of the U.S. DOE is to protect human health and the environment of the Waste Isolation Pilot Plant (WIPP) for safe disposal of TRU waste, and to manage TRU waste from its acceptance to

its disposal. It is the policy of the DOE to maintain an effective QA program consistent with the criteria in 40 CFR Part 194, and consistent with other applicable federal, state, and local laws and regulations, including applicable DOE Orders. This policy helps to direct the CBFO mission and to ensure that the risks, safety, and environmental impacts are identified and minimized, and that safety, reliability, and performance are optimized.

5.1.2 Quality Assurance Program History

Previous QA program history is given in the CCA. In 1996, the CAO (now CBFO) implemented the QA requirements of 40 CFR § 194.22(a)(1). In addition, both DOE Order 5700.6C, Quality Assurance, and 10 CFR § 830 Subpart A – Quality Assurance Requirements were implemented through the DOE, CBFO QAPD.

In 1999 WIPP began disposal operations by receiving waste. By that time, all applicable regulatory requirements had been incorporated into the QAPD. These include 40 CFR § 194.22(a)(1), 10 CFR Part 830 Subpart A, DOE Order 414.1A, Quality Assurance, and NUREG 1297, Peer Review for High-Level Nuclear Waste Repositories. These requirements continue to be specified and implemented in the QAPD.

5.2 Quality Assurance Program Requirements

5.2.1 Requirements in the Code of Federal Regulations

5.2.1.1 40 CFR Part 194

40 CFR Part 194 sets forth the QA criteria necessary for compliance with 40 CFR 191 Subparts B and C. 40 CFR § 194.8(a), Quality Assurance Programs at Waste Generator Sites, establishes a site-specific QA program plan that addresses the applicable nuclear quality assurance (NQA) criteria of 40 CFR § 194.22(a)(1) for items and activities identified in § 194.22(a)(2), § 194.24(c)(3), and § 194.24(c)(5). The QA Program applied to the National TRU Program was certified in March 1999, and is audited annually by the EPA using the criteria for audits or inspections, including publishing notices in the Federal Register as set forth in § 194.8(a)(2).

5.2.1.2 40 CFR § 194.22, Quality Assurance

The following documents and regulation establish the requirements for the WIPP QA program. Figure 5-1 is a flow-down chart of these requirements documents.

- ASME NQA-1-1989 edition, Quality Assurance Program Requirements for Nuclear Facilities;

- ASME NQA-2-1989 edition, Quality Assurance Requirements for Nuclear Facilities Applications. ASME NQA-2a-1990 addenda, part 2.7, Quality Assurance Requirements of Computer Software for Nuclear Facility Applications;

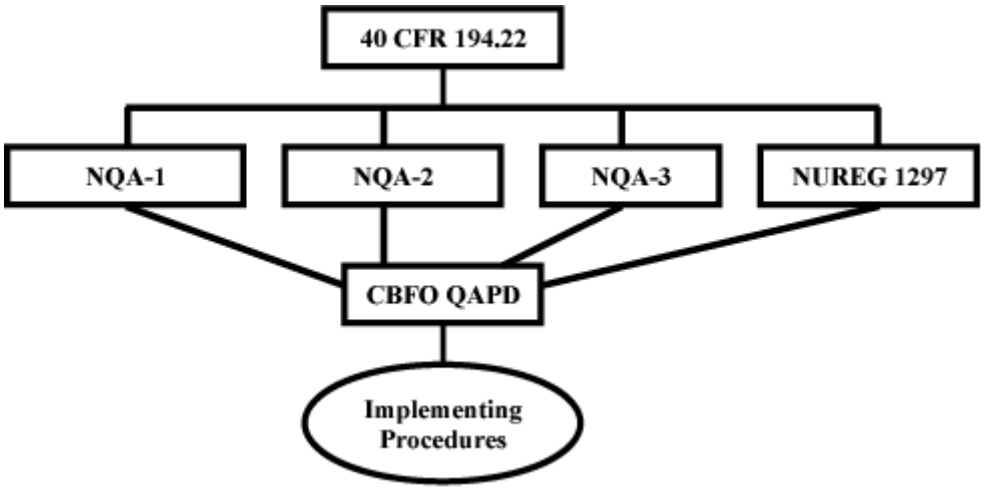

Figure 5-1. Requirements Flow-Down Chart

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

- NUREG 1297, Peer Review for High-Level Nuclear Waste Repositories (required by 40 CFR § 194.22(b) for "qualification of data and information," § 194.27 for compliance application documents associated with "conceptual models," § 194.24(b) for "waste characterization analyses," and § 194.44 for "engineered barrier evaluation").

5.2.2 Other Requirements and Standards

The WIPP QA program incorporates QA requirements in 10 CFR Part 71(H), Quality Assurance. The WIPP-related QA program applies to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modifications of components of packaging, transportation, and handling of TRU waste that are important to safety. The WIPP-related QA program also applies to the requirements and standards found in the WIPP Hazardous Waste Facility Permit (HWFP), 10 CFR 830 Subpart A, DOE Orders, and National Consensus Standards. Applicable requirements from these documents are incorporated into the QA program applied to the National TRU Program.

5.3 Incorporation of 40 CFR § 194.22 Criteria in the QAPD

The following section lists 22 criteria incorporated in the CBFO QAPD. These criteria were taken from the requirements documents and regulation described in Section 5.2.1.2. Criteria 1 through 18 were taken from NQA-1-1989; Criterion 19 from NQA-2-1990a, Part 2.7; Criterion 20, 21, and 22 from NQA-3-1989; 40 CFR § 194.22(b) and (c), and NUREG 1297.

5.3.1 Criterion 1 – Organization

The CBFO is structured so that the individual performing the work is responsible for achieving and maintaining quality. Management is responsible for defining quality, developing appropriate

plans to attain quality, supporting the workers in pursuit of quality, and evaluating quality achievement within their area of responsibility. Figure 5-2 illustrates the authority and reporting structures of the CBFO QA and its major program participants.

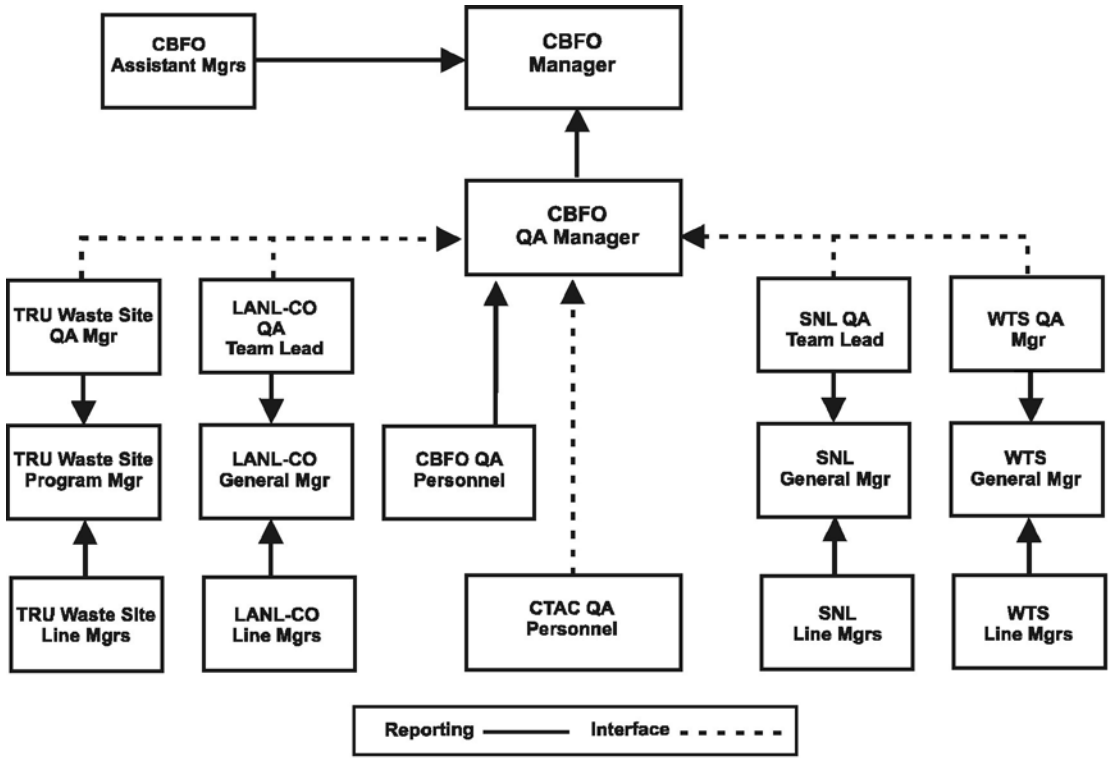

Figure 5-2. Reporting Interface Diagram

All program participants have the authority, organizational freedom, and the overall responsibility to independently assess the effective implementation of the QA program. Reporting is made to a management level so that the required authority and organizational freedom is provided, including sufficient independence from cost and schedule considerations. The QA organizations have sufficient authority, access to work areas, and organizational freedom to:

- verify, through checking, auditing, and inspecting, that quality-affecting activities have been performed correctly;
- identify quality problems;
- initiate, recommend, or provide solutions to quality problems through designated channels;
- verify implementation of solutions; and
- ensure that further processes, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or condition adverse to quality has occurred.

The CBFO QAPD requires personnel conducting assessments and other quality-affecting activities to be technically qualified and knowledgeable about the item(s) and processes being assessed, and be independent of any direct responsibility for the performance of the activities being assessed. To manage any perceptions of assessment bias, CBFO requires the Carlsbad Field Office Technical Assistance Contractor (CTAC) organization to ensure independence through the implementation of an organizational and individual conflict of interest avoidance and mitigation process.

5.3.2 Criterion 2 – Quality Assurance Program

5.3.2.1 Quality Assurance Program Overview

The CBFO QA program is described in the QAPD and includes QA requirements from multiple sources. The QA organizational structures, primary interfaces, functional responsibilities, and levels of authority for activities affecting quality are described and documented in the QAPD. The major QA organizational interfaces are illustrated in Figure 5-2.

The CBFO Manager directs activities to effectively and efficiently meet DOE and WIPP missions and safety expectations. The Manager reports directly to the DOE Assistant Secretary for Environmental Management for program policy and direction. The Manager is responsible for and maintains a QA program that ensures work activities meet customer requirements, including federal, state, and local laws and regulations, permit requirements, and DOE Orders and requirements. The Manager provides technical direction in interpreting QA requirements and in reviewing and concurring with QA plans and programs.

The CBFO QA Manager has been delegated the authority for executing the QA function by the CBFO Manager and reports directly to the CBFO Manager. The QA Manager has the authority and overall responsibility to independently assess the adequacy, implementation, and effectiveness of the TRU waste QA programs, within both the CBFO organization and program participant organizations. Participant QA managers have the authority and responsibility to independently assess the effective implementation of the applicable QAPD requirements within both their participant organization and any lower-tier organizations.

The following are program participant responsibilities:

- Program participants have the responsibility for TRU waste QA program development, implementation, and assessment within their own and lower-tier organizations. CBFO reviews and accepts the WIPP waste-related QA program documents of Sandia National Laboratories (SNL), Washington TRU Solutions (WTS), the TRU waste generator sites, and other TRU waste program participants, e.g., Los Alamos National Laboratory-Carlsbad (LANL-CO). CBFO performs QA audits and surveillances of these organizations to verify compliance with QA and technical program requirements.

- Washington TRU Solutions has the responsibility for implementing and maintaining the QA program for the operation and maintenance of the WIPP site, monitoring the site environment, and for the receipt of waste. WTS is also responsible for the Central Characterization Project (CCP), which is tasked with characterizing and certifying TRU

waste at specified waste generator sites for disposal at the WIPP. The CBFO Manager and Assistant Manager for the Office of National Transuranic Program provide overall policy direction for the CCP. Specific details of this organization are described in the CCP TRU Waste Certification Plan, CCP-PO-002.

- Sandia National Laboratories has the responsibility for implementing and maintaining a QA program for activities involved in the development, confirmation, and verification of models used to simulate long-term repository performance. SNL's QA program covers research, experiments, and tests performed to collect the data needed for input to the models.

  In January 1999, the SNL QA program converted from a system of QA procedures (QAPs) to an improved system of revised nuclear waste management QA procedures (NPs). The NPs were issued with two objectives. First, the NPs were written to be responsive to requirements contained in the latest CBFO QAPD. These NPs were also verified to be compliant with the CBFO QAPD by completing an extensive matrix to map the upper-tier requirements for each procedure. Second, the NPs were streamlined, and additional information was added to make them easier to use. For example, several QA plans that addressed the same subject area (analyses) have been combined into one NP (NP 9-1).

  These changes implement the same QA program requirements but improve the implementing processes. They do not represent significant changes in activities or conditions pertaining to the disposal system. The SNL QA program is routinely subject to CBFO audits and EPA inspections.

- Los Alamos National Laboratory – Carlsbad has the responsibility for implementing and maintaining a QA program for activities involved in actinide chemistry and for the Transuranic Waste Baseline Inventory Report (TWBIR) (see Appendix BIR). The TWBIR is the inventory source document that provides the waste data used in the performance assessment of the WIPP site.

- Sites intending to send TRU waste to the WIPP are responsible for implementing and maintaining a QA program that meets the applicable requirements of the QAPD, for characterizing TRU waste, for meeting the WAC, and for participating in the waste certification and recertification programs.

5.3.2.2 Grading

Quality assurance grading is used to identify the controls applied to activities that support the TRU waste QA program. Grading is based upon an evaluation of the complexity and importance of the activity to quality, safety, risk, and the environment. Based on the results of the evaluation, appropriate procedural controls are identified. The rigor of QA controls is commensurate with, but not limited to, the following criteria:

- the function or end-use of the item;

- the importance and end-user of the data generated;
- the probability of failure;
- the complexity or uniqueness of the design, fabrication, or implementation;
- the reproducibility of the results;
- the quality history of the item or service;
- the necessity for special controls or processes; and
- the ability to demonstrate functional compliance with applicable regulations.

The CBFO staff and program participants perform management assessments to ensure the QA program meets customer requirements and expectations.

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

5.3.2.3 Quality Assurance Program Documents

The CBFO and program participants implement the requirements of the CBFO QAPD in accordance with QA program documents and implementing procedures prepared and maintained by their organizations.

A table of QA program documents that implement the various TRU waste QA programs is presented in Section 5.4 along with a description of the CBFO QAPD and a listing of CBFO procedures.

When the CBFO QAPD is revised, lower-tier documents such as site Quality Assurance Project Plans (QAPjPs), certification documents, QA plans, and program participants implementing procedures are evaluated and appropriately revised to ensure that the QA program of each organization meets all the applicable requirements of the CBFO QAPD.

5.3.2.4 Qualification and Training

Personnel performing work are qualified and capable of performing their assigned tasks. Program participants have established formal methods for the evaluation, selection, indoctrination, training, and qualification of personnel performing work to ensure compliance with the CBFO QAPD requirements.

In the case of Lead Auditors, a comprehensive process, including training and an examination, is required, along with specific experience and education requirements that must be met in order to obtain Lead Auditor certification.

5.3.2.5 Management Assessments

Management assessments are performed by the CBFO and program participants to determine the effectiveness of the QA programs established and implemented to meet customer requirements and expectations.

Key elements of management assessments that help to determine effectiveness include:

- the conduct of regular assessments of the QA program with reports at least annually to senior managers who have sufficient authority to effect corrective measures; and

- the use of management assessment results as a means for determining and taking the necessary actions to correct quality problems, achieve quality, and ensure the proper application of resources to achieve and verify quality.

5.3.3 Criterion 3 – Design Control

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.

5.3.4 Criterion 4 – Procurement Document Control

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.

Quality-affecting 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 technical and 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 conducts audits and surveillances to verify that these requirements are being met.

5.3.5 Criterion 5 – Instructions, Procedures, and Drawings

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

- responsibilities;

- program requirements;

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

The CBFO implementing procedures are listed in Section 5.4.9. Each of the program participants develops implementing documents that address the quality activities applicable to his or her QA program requirements and work scope.

5.3.6 Criterion 6 – Document Control

Documents affecting quality that specify quality requirements, prescribe processes, or establish designs important to compliance with 40 CFR 191 Subparts B and C and 40 CFR Part 194, such as instructions, procedures, drawings, test plans, and management plans, which are controlled to ensure 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.

5.3.7 Criterion 7 – Control of Purchased Items and Services

Controls are established to ensure that procured items and services meet applicable technical and QA requirements and performance specifications. Prospective suppliers are evaluated and selected on the basis of documented criteria. Procurement controls are in place to ensure that approved suppliers continue to provide acceptable items and services. Procurement controls include, as appropriate:

- procurement planning,
- supplier selection and performance evaluation,
- proposal and bid evaluation,
- procurement documents,
- source verification and supplier certification of conformance,
- receipt inspections and post-installation testing,

- control of supplier nonconformances, and
- commercial-grade items.

5.3.8 Criterion 8 – Identification and Control of Items

"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.

Items used in support of 40 CFR Part 191 Subparts B and C and 40 CFR Part 194 are identified and controlled. Processes have been established to identify, control, and maintain items from receipt through installation and end-use. Item identification ensures the appropriate traceability as specified in design documents, codes, standards, specifications, and implementing procedures. 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.

5.3.9 Criterion 9 – Control of Processes

Work processes that support compliance with 40 CFR Part 191 Subparts B and C and 40 CFR Part 194 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. The procedures contain information, including the following elements, appropriate to the work being performed:

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

Personnel performing work are responsible for complying with appropriate instructions, which include or reference procedure, personnel, and equipment qualification requirements. Handling, storage, cleaning, shipping, and other processes that are implemented to preserve, transport, and package items are conducted in accordance with established work and inspection procedures, shipping instructions, or other specified documents.

Processes that are highly dependent on the control of the process and on the skill of the operator where quality results cannot be readily determined by inspection or test of the product are considered "special processes." Implementing procedures for special processes are required to include the conditions necessary for completion of the special process, including equipment, statistical process control, controlled parameters of the process, and calibration requirements.

5.3.10 Criterion 10 – Inspection

Inspections determine acceptance or rejection of a process, product (item), or service. 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; and
- identification of any measuring and test equipment used, including the equipment identification number and the calibration due date.

5.3.11 Criterion 11 – Test Control

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. 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.

5.3.12 Criterion 12 – Control of Measuring, Monitoring, Data Collection and Test Equipment

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. In addition, the calibration system includes provisions for:

- using documented procedures that describe the calibration system and the detailed calibration methods;
- using qualified calibration services that meet the requirements of the CBFO QAPD;
- developing a schedule for the initial calibration of M&TE and for periodic recalibration to ensure acceptable reliability;
- documenting the results of the calibration;
- labeling and identifying all M&TE to provide the information needed for recalibration and to ensure that adequate standards are traceable to the M&TE;
- identifying any needed precautions for handling, storing, and transporting equipment to prevent damage or out-of-tolerance conditions;
- providing the environment needed to calibrate the M&TE and to take measurements; and
- using calibration standards traceable to nationally recognized standards or physical constants. When such standards do not exist, the bases for calibration are documented.

5.3.13 Criterion 13 – Handling, Storage, and Shipping

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. Precautions taken include the following:

- preparing procedures that describe the methods to be applied, the proper controls, and the records to be generated;
- using and documenting special equipment and environments when required; and
- creating and maintaining markings and labeling that identify the item, any special environments required, and the need for any other special controls as necessary.

5.3.14 Criterion 14 – Inspection, Test, and Operating Status

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

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

5.3.15 Criterion 15 – Control of Nonconforming Items

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.

When appropriate, further work on the item is halted until the appropriate actions have been taken and verified. The nonconformance control process is documented in applicable QA plans. The process identifies implementing procedures for identifying nonconforming items, methods that do not adversely affect the end-use of the item, and methods designed to prevent damage or loss and to minimize deterioration. Precautions taken include:

- preparing procedures that describe the methods to be applied, the proper controls, and the records to be generated;
- using and documenting special equipment and environments when necessary;
- creating and maintaining markings and labeling that identify the item, any special environments required, and the need for any other special controls;
- segregating nonconforming items, when practical;
- assigning the responsibility to halt or control further work on the item;
- evaluating and dispositioning nonconforming items by authorized persons; and
- reexamining the item to verify acceptability after rework or repair.

In addition, suppliers are required to identify items that do not meet the requirements of the procurement documents, to document the nonconforming condition and the proposed disposition, and to provide technical justification for the disposition.

5.3.16 Criterion 16 – Corrective Action

"Corrective actions" are measures that are taken to rectify a condition that is adverse to quality and, where necessary, to preclude recurrence.

All personnel are responsible for identifying conditions adverse to quality. 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 is defined as a condition, which, if uncorrected, could have a serious effect on safety, operability, waste confinement, TRU waste site certification, compliance demonstration, or the effective implementation of the QA program.

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

- identifying and documenting conditions adverse to quality;
- assigning the responsibility to halt or control further work on the item, activity, or process;
- evaluating and dispositioning conditions adverse to quality by authorized persons;
- notifying management of the results of evaluations of significant conditions adverse to quality;
- preparing corrective action plans that include remedial actions, investigative actions, root cause determinations, expected completion dates, and responsible persons, as appropriate;
- evaluating the corrective action plans and verifying the completion and effectiveness of the corrective actions taken; and
- assigning unique numbers to each corrective action request generated, maintaining a log of the specific status of each request until it is closed, and regularly reporting and reviewing the status of all open corrective action requests.

5.3.17 Criterion 17 – QA Records

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 work quality and evidence that the QA program has been properly implemented during work performance. The records management system is documented in appropriate QA plans and implementing procedures and includes:

- identifying those documents that will become QA records and identifying the organizations responsible for submitting the QA records to the records system;
- generating records that are legible, accurate, and complete;
- protecting documents that will become QA records during generation and use;

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

The generation, classification, indexing, and retention of QA records are controlled in accordance with appropriate plans and records-related procedures.

5.3.18 Auditor and Technical Specialist Skills and Background

Auditors and Technical Specialists that conduct CBFO audits are qualified and certified in accordance with the CBFO Team Procedure (TP) 10.1, Qualification of Audit Personnel and Certification of Lead Auditors.

The Auditors possess a comprehensive knowledge of ASME NQA-1, DOE Orders, and Codes of Federal Regulations applicable to hazardous waste facilities. These individuals possess knowledge of CBFO program documents including the QAPD, Waste Analysis Plan (WAP), Contact-Handled Transuranic Waste Acceptance Criteria (WAC) For The Waste Isolation Pilot Plant, TRUPAC-II Authorized Methods for Payload Control (TRAMPAC) sufficient to successfully assess assigned activities during an audit. In addition, the audit team possesses experience with and a working knowledge of the corrective action process to properly identify problems, assess corrective action plans, and verify the closure and effectiveness of corrective actions.

Technical Specialists are trained in the audit process. They possess a comprehensive knowledge of the WIPP HWFP and the Program Documents. They have experience in either hazardous or nuclear waste generation or waste management, the Compliance Certification Application, or in a technical discipline associated with the operation of a nuclear facility or laboratory. Technical Specialists have a working knowledge of industry standards, operational methods, and regulations associated with the discipline in which the individual has expertise. In addition, they have a working knowledge of visual examination (VE), nondestructive examination (NDE), acceptable knowledge (AK), data verification and validation (V&V), and nondestructive assay (NDA).

Technical Specialists, Auditors, and Lead Auditors complete training commensurate with the activities they perform during audits. Auditors and Lead Auditors must successfully complete the CBFO Auditor/Lead Auditor Course for qualification. In addition, Lead Auditors must meet educational and experience requirements and pass a comprehensive written examination before

certification. Lead Auditors are required to maintain their proficiency through audit participation, training, or reading assignments. Failure of Lead Auditors to maintain proficiency requires recertification.

Qualification of Technical Specialists and Auditors and the certification of Lead Auditors are documented and maintained as QA records. Lead Auditor maintenance of proficiency is also documented and maintained as a QA record.

With the current audit staff, Lead Auditors, on the average, have over 20 years of experience and expertise in performing audits. Auditors typically average over 15 years of experience in auditing, and Technical Specialists average over 20 years of experience in their technical disciplines

5.3.19 Criterion 18 – Audits and Surveillances

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

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

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

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

Audits and surveillances conducted since the CCA have been rolled up into summary tables in Appendix AUD 2004. These tables reflect the extensive and comprehensive auditing and surveillance efforts that CBFO has implemented in order to ensure adequacy, implementation, and effectiveness of the TRU waste program.

5.3.20 Criterion 19 – Software Quality Assurance

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

The sponsoring organization for software acquisition and related services verifies the capability of the software 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 and users, if applicable.

Software not developed under a QA program meeting the requirements of the CBFO QAPD, including preexisting software, is evaluated, uniquely identified, and controlled in accordance with the requirements of the CBFO QAPD, Section 6.0. When accepted, the software is placed under configuration control before use. QA records (for software) are controlled and stored as described in Section 5.3.17.

Software is controlled using an iterative or sequential approach during the various life cycle phases, which include:

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

Verification and validation of the software, including a review of the completed 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 CBFO QAPD. Software verification is performed during the software development phases to verify that the requirements of the previous phase have been fulfilled. Software validation is performed to ensure that the software satisfies all requirements.

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

Software documentation generated and retained during software development includes:

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

For released versions, software problems are documented, evaluated, and if appropriate, corrected. The evaluation of software problems includes the identification of any impact on previous use and any appropriate corrective action. Problems that significantly impact decisions based upon prior use or that require significant modification to the software are identified. Errors that qualify as a condition adverse to quality are controlled as described in Section 5.3.16.

5.3.21 Criterion 20 – Scientific Investigation

Technical investigations and design-development data collection activities 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. Planning for scientific investigations includes provisions for:

- identifying and appropriately controlling variables that affect interrelated scientific investigations;
- documenting the intended use of the data before collection;
- verifying the compatibility of data processing with any conceptual or mathematical models used at each applicable stage;
- reviewing and approving the technical acceptability of procedures;
- reviewing and approving the documented development activities used to establish new methods or procedures;

- establishing acceptance criteria for the data quality evaluation;
- identifying known sources of error and uncertainty; and
- identifying input data that are suspect or whose quality is beyond the control of the performing organizations.

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

Methods used in the investigations are reviewed to ensure that they are technically sound and have been properly selected. Data collection and 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. Data are controlled to:

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

Data used for compliance with 40 CFR Part 191 Subparts B and C and 40 CFR Part 194 that were not collected under a QA program meeting the CBFO QAPD requirements are qualified through one or a combination of five methods detailed in Section 5.3.22. If peer reviews are necessary, the CBFO uses an approved procedure and process that is consistent with NUREG 1297 (1988), Peer Review for High-Level Nuclear Waste Repositories.

5.3.22 Criterion 21 – Data Quality Characteristics

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. The DOE applies these data characteristics to tasks involving the quantification of specific constituents in an environmental medium through sampling and analysis. The 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.

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

Data are used to develop conceptual models and support distributions for parameter values. Between the point of data collection and the final computational model, uncertainty is introduced (for example, experimental design, extrapolation of the experimental results to spatial or temporal scales, etc.). These parameter distributions may span several orders of magnitude, and many parameters derived from data measurements need to be known only within orders of magnitude of their true value.

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

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

Instead of quality characteristics, other steps are used to ensure that data are of adequate quality. Upper-tier quality requirement documents specifically define QA requirements for the collection of scientific and technical information. Section 5 of the CBFO QAPD, Scientific Investigation

Requirements, identifies the current requirements and processes used for data collection. For inclusion in compliance calculations, the data must be collected under an approved QA plan or otherwise be qualified as existing data.

In summary, it is not practicable to apply data quality characteristics to most scientific investigations that are 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 ensure the necessary quality.

5.3.23 Criterion 22 – Qualification of Data

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 Section 5.2;
- 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.

For data qualified by the implementation of a QA program meeting the criteria of 40 CFR 194 (first method above), the supporting documents and controls include the QA plan, audits and surveillances of the work that produced the data, and other objective evidence of QA implementation. If the audits show the program to be adequate and effectively implemented, then the data may be qualified. If audits identify significant deficiencies, then data whose quality is affected by those deficiencies are not qualified until impact assessments are completed and corrective actions have been implemented and verified.

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 Chapter 9.0, Peer Review.

Corroborating data are existing data used to support or substantiate other existing data. Existing data may be qualified through the use of corroborating data. Inference drawn to corroborate the existing data needs to be clearly identified, justified, and documented. The level of confidence associated with corroborating data is related to the quality of the program under which it was developed and the number of independent data sets. The amount of corroborating data needed is determined on a case-by-case basis in the documented qualification reviews.

Confirmatory testing is testing conducted under a QA program that investigates the properties of interest (e.g., physical, chemical, geologic, mechanical) of an existing database. Existing data

may be qualified through confirmatory testing. One example of confirmatory testing is testing that is conducted under the same environmental conditions and with the same or similar procedures, test material, and equipment as the original test that generated the existing data. Another type of confirmatory testing is testing conducted by different test methods and equipment but which still investigates the same properties of interest. The amount of confirmatory testing required is determined on a case-by-case basis in the documented qualification reviews.

40 CFR §194.27, Peer Review, requires CBFO to conduct peer reviews on the following:

- conceptual models selected and developed by the Department;
- waste characterization analyses as required in §194.24(b); and
- engineered barrier evaluation as required in §194.44.

5.4 The Carlsbad Field Office Quality Assurance Program Document

5.4.1 Purpose of the Quality Assurance Program Document

The CBFO QAPD describes the QA program requirements that apply to programs and projects managed by the CBFO. This program-wide requirements document describes the TRU waste QA controls applicable to all program participants within the TRU waste management structure.

5.4.2 U.S. Environmental Protection Agency Requirements in the Quality Assurance Program Document

The QAPD meets all EPA criteria for those items important to the containment of TRU waste, including the following items and activities:

- waste characterization activities and assumptions;
- environmental monitoring, monitoring of disposal system performance, and sampling and analysis activities;
- field measurements of geological, groundwater, meteorologic, and topographic characteristics;
- computations, computer codes, models, and methods to demonstrate compliance with 40 CFR Part 194;
- procedures for implementation of expert judgment elicitation to support the applications for certification and recertification of compliance with 40 CFR Part 194;
- design of the disposal system and actions taken to ensure compliance with design specifications;
- collection of data and information to support compliance application(s); and

- other systems, structures, components, and activities important to the containment of waste in the disposal system.

5.4.3 Use of the Graded Approach

The use of a graded approach supports the proper implementation of QA program requirements for items and activities important to compliance with 40 CFR Part 191 Subparts B and C and 40 CFR Part 194. The grading process is described in Section 5.3.2.3.

5.4.4 Quality Assurance Program Document Implementation

Based upon requirements from the QAPD, program participants have developed, implemented, and assessed their management systems and controls to ensure that items, processes, and services meet or exceed applicable requirements.

The adequacy and the effectiveness of implementation of these management systems and controls are verified through audits and surveillances conducted by the DOE and the program participants. The audits and surveillances are used to assess the adequacy, implementation, and effectiveness of the individual QA programs. The adequacy, implementation, and effectiveness of the various TRU waste QA programs are discussed in Section 5.6.

5.4.5 Quality Assurance Program Document Changes

Limited changes to the QAPD have been made since submittal of the CCA. The changes have been made to clarify application of requirements because new source requirement documents have been added to the TRU waste program.

Additional changes incorporated into the QAPD include CBFO organization and responsibility changes. Clarifications have been made in the areas of grading, control of conditions adverse to quality, and the preparation and maintenance of commitment and guidance documents.

5.4.6 Quality Assurance Program Participant Support

The CBFO identifies the QA program requirements applicable to all WIPP participants through the QAPD. The QAPD requirements are further supported and amplified by CBFO and program participant implementing procedures.

In addition to identifying applicable QA requirements through program documents, the participating organizations conduct the following activities in support of the QA program:

- audits and surveillances (external and internal) to evaluate the adequacy, implementation, and effectiveness of the applicable QA programs; and

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

5.4.7 Structure of the QAPD

The QA requirements for quality-affecting activities for all program participants (as applicable to the scope of work) are described in the six sections of the QAPD. The QAPD is presented in Appendix QAPD.

5.4.8 Quality Assurance Program Document Crosswalk to NQA-1, -2, and -3 Requirements

Table 5-1 presents a crosswalk of QAPD and NQA requirements.

Table 5-1. QAPD vs. NQA-1, -2, and -3 Requirements

Criteria	Title	QAPD Reference
NQA-1, Criterion 1	Organization	Section 1
NQA-1, Criterion 2	Quality Assurance Program	Section 1
NQA-1, Criterion 3	Design Control	Section 2.2
NQA-1, Criterion 4	Procurement Document Control	Sections 2.3.4 and 2.3.5
NQA-1, Criterion 5	Instructions, Procedures, and Drawings	Sections 1.4 and 2.1.2
NQA-1, Criterion 6	Document Control	Section 1.4
NQA-1, Criterion 7	Control of Purchased Items and Services	Section 2.3
NQA-1, Criterion 8	Identification and Control of Items	Section 2.1.3
NQA-1, Criterion 9	Control of Processes	Section 2.1
NQA-1, Criterion 10	Inspection	Section 2.4
NQA-1, Criterion 11	Test Control	Section 2.4.4
NQA-1, Criterion 12	Control of Measuring and Test Equipment	Section 2.4.6
NQA-1, Criterion 13	Handling, Storage, and Shipping	Section 2.1.5
NQA-1, Criterion 14	Inspection, Test, and Operating Status	Section 2.4
NQA-1, Criterion 15	Control of Nonconforming Items	Section 1.3.2
NQA-1, Criterion 16	Corrective Action	Section 1.3.3
NQA-1, Criterion 17	Quality Assurance Records	Section 1.5
NQA-1, Criterion 18	Audits	Section 3.2.2
NQA-2, Part 2.7, Criterion 19	Software Quality Assurance	Section 6
NQA-3, Criterion 20	Scientific Investigation	Section 5
NQA-3, Criterion 21	Data and Sample Management	Section 4
NQA-3, Criterion 22	Qualification of Data	Section 5

5.4.9 CBFO Implementing Procedures

The CBFO implements Sections 1.4 and 2.1.2 of the QAPD through the use of Management Procedures (MPs) and Team Procedures (TPs):

- MP – An implementing document that specifies the process (methods and controls) for performing activities.
- TP – An implementing document that specifies the process (methods and controls) for performing functional activities within a specific, singular organizational area.

CBFO procedures include:

- MP 1.2, Selection of Quality Levels;
- MP 2.1, Personnel Qualification and Training;
- MP 3.1, Corrective Action Reporting;
- TP 3.2, Trend Identification and Reporting;
- MP 4.1, Preparation and Maintenance of CBFO Procedures;
- MP 4.2, Document Review;
- MP 4.4, Document Preparation and Control;
- MP 4.5, Generating, Receiving, Storing, and Controlling Active CBFO Project Records;
- MP 4.6, Records Filing, Inventorying, Scheduling, and Dispositioning;
- MP 4.7, Disposal of Nonpermanent Records;
- MP 4.8, Records Transfer and Retrieval;
- MP 4.9, Quality Assurance Records;
- MP 4.10, Processing of TRU Waste Site Documents;
- MP 5.2, TRU Waste Site Certification/Recertification;
- MP 5.3, Correspondence Standards;
- MP 7.1, QA Requirements for Procurement of Services;
- MP 9.1, Management Assessment;
- TP 10.1, Qualification of Audit Personnel and Certification of Lead Auditors;
- MP 10.2, Surveillances;
- MP 10.3, Audits;

- MP 10.5, Peer Review; and
- MP 10.7, Operational Assessments.

5.5 Applicability of the QA Program

The CBFO QAPD establishes and describes the QA program requirements. The QA program applies to all CBFO and participant activities affecting quality for the containment of TRU waste in support of the WIPP, including the eight programmatic areas addressed for compliance application (40 CFR § 194.22(a)(2)) demonstration. The QA program has been established as described in this chapter. The following program participants have quality assurance programs approved by the CBFO:

- CBFO Technical Assistance Contractor (CTAC)
- Sandia National Laboratories (SNL) – Carlsbad
- Los Alamos National Laboratory (LANL)
- Los Alamos National Laboratory Carlsbad (LANL-CO)
- Hanford site
- Idaho National Engineering and Environmental Laboratory (INEEL)
- Rocky Flats Environmental Technology Sites (RFETS)
- Savannah River Site (SRS)
- Washington TRU Solutions (WTS)
- Central Characterization Project (CCP)
- Advanced Mixed Waste Treatment Project (AMWTP)
- Argonne National Laboratory – East (ANL-E)

5.5.1 Waste Characterization Activities and Assumptions

The transuranic waste is inventoried and updated to provide an inventory source of waste data used in the performance assessment.

The WAC serves as the primary directive for ensuring that only waste that meets the legal definition of defense TRU waste and can be safety transported, handled, and disposed of is received at the WIPP. The WAC also identifies criteria to ensure generator and storage sites properly certify waste. Revised waste acceptance criteria have been provided to the EPA. In addition, information pertaining to the radiological properties of the waste and other disposal information from the obsolete QAPP has been added to the WAC (See Appendix TRU WASTE).

The Performance Demonstration Program (PDP) is used to evaluate the capability of the generator and storage sites to perform NDA for TRU waste characterization within acceptable limits. Initially, participating laboratories were required to participate in the PDP twice per year. The DOE has reduced the required frequency from twice per year to once per year and described this change to the EPA in correspondence dated November 10, 1998, and April 22, 1999 (Docket A-98-49). Based on this information, the EPA determined that the changes reported did not require modification, suspension, or revocation of the initial certification (refer to Chapter 4, Section 4.3.3.1).

Following is a list of waste generator sites certified to ship waste to the WIPP.

- Nevada Test Site (using CCP) – as of August 2002,
- LANL – as of December 2002,
- Rocky Flats Environmental Technology Site – as of March 2003,
- INEEL – as of May 2003,
- Hanford Site – as of June 2003,
- SRS (using CCP) – as of October 2002,
- Argonne National Lab (East) (using CCP) – as of September 2002, and
- Advanced Mixed Waste Treatment Project – as of August 2003.

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

All environmental and performance monitoring activities related to compliance with the requirements of 40 CFR Part 191 Subparts B and C and 40 CFR Part 194 are described in Appendix MON 2004.

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

A change to elevate the horizon at which Panels 3, 4, 5, 6, and 9 are mined was approved by the EPA on August 11, 2000. The change went through the design verification process to ensure compliance with identified requirements. Design controls specified in the WTS QAPD are in place to track and verify the design process. These controls ensure that new designs and design changes are subject to specifications commensurate with the original design and verify that the design analyses remain valid.

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

SNL collects information and data from experimental programs that serve multiple purposes in the WIPP project:

- Data relevant to the chemical or physical characteristics of the WIPP site;
- Data that allow estimation of the behavior of the wastes and the system during the 10,000-year regulatory period;
- To develop data to be used in testing alternative conceptual models and selecting the most appropriate model(s) of engineered system behavior for use in the performance assessment modeling process; and
- Scientific data collected in the areas of rock mechanics, actinide source term, chemical transport, disposal room, gas generation, non-Salado flow and transport, Salado Formation hydrology and transport.

5.6 Quality Assurance Program Adequacy, Implementation, and Effectiveness

Audits and other assessments are scheduled and conducted to verify the adequacy, implementation, and effectiveness of the QA program. The DOE, SNL, LANL-CO, and WTS QA programs have been determined to be adequate and effectively implemented in accordance with adequate procedures that meet the CBFO QAPD.

The CBFO maintains and implements an assessment schedule to assess initial and continuing CBFO, SNL, LANL-CO, WTS, and TRU waste generator site QA program adequacy, implementation, and effectiveness. Assessment scheduling is a dynamic process that requires frequent changes to respond to DOE and participant needs. The CBFO assessment schedule is updated monthly and is distributed to WIPP participants and other stakeholders. The assessment schedule accommodates the routine, recurring, and any focused or special purpose assessments that are determined to be appropriate by management.

5.6.1 Adequacy of the Quality Assurance Program

The adequacy of the QA program refers to an approved and documented QA program that meets the applicable requirements addressed in the CBFO QAPD. Adequacy is determined by the review of participant QA programs to ensure that upper-tier requirements have been incorporated into the appropriate documents.

The flow-down of requirements in the established QA program is presented in Figure 5-1. Organizations establishing a QA program or making changes to an established program must evaluate all the requirements addressed in the CBFO QAPD for applicability to their activities and document these criteria in new or revised implementing documents in order to meet the applicable requirements.

The adequacy of the documented QA program and any changes to an established QA program are verified before performing independent reviews for implementation and effectiveness (e.g., determining whether the documentation addresses the proper migration of requirements from the QAPD into the implementing documents).

5.6.2 Implementation of the Quality Assurance Program

Implementation of a QA program is determined by the extent to which the organization complies with its QA and technical procedures. QA program implementation is verified during audits and assessments of the program. Audits are scheduled to begin as early in the life of a project or activity as practicable and continue at intervals consistent with the schedule for accomplishing the work and commensurate with the assigned control levels. Audits, surveillances, management assessments, and other reviews are conducted to determine the acceptability of the procedural implementation.

5.6.3 Effectiveness of the Quality Assurance Program

Effectiveness refers to a process that produces the desired (specified) end-product or end-service. Effectiveness can be determined by:

- Technical Specialists being used to determine the effectiveness of technical processes and documents,
- management assessments being used to determine continued effectiveness, and
- trend analysis data and other information being used to assure process effectiveness.

5.7 The Carlsbad Field Office Audit Process

5.7.1 Overview of the Carlsbad Field Office Assessment Processes

Audits are conducted of CBFO activities (internal audits) and activities performed by organizations outside the CBFO (external audits). External organizations include the WTS, SNL, LANL, TRU waste sites, and other program participants conducting work for the CBFO. The audits are conducted to assess QA and technical activities that relate to regulatory compliance, safety, certification, transportation, and waste isolation.

The CBFO QA Manager coordinates with the CBFO assistant managers to identify appropriate assessments. These assessments are included in the CBFO assessment schedule. The following factors are considered when scheduling audits:

- work activities, level of effort, risk, and importance to regulatory compliance, safety, TRU waste site certification, or waste isolation issues;
- reviews of documentation furnished by, or regarding the work of, the organization or supplier (e.g., certificates of conformance, nonconforming notices, and corrective actions);
- consideration of previous assessment results, trends, corrective actions, effectiveness, and ancillary information (e.g., information from other sources such as industry or other DOE organizations, and regulatory agencies);

- reviews of previous assessments from identical or similar products or services furnished by the same organization or supplier; and

- results of surveillance activities.

Scheduled audits are supplemented, as necessary, to provide continuing coverage of work activities for any of the following reasons:

- to determine the adequacy, implementation, and effectiveness of contractor activities after contract award;

- to assess the impact of any significant changes made to a program or organizational structure;

- to evaluate the cause and impact of any declining trends in quality performance; and

- to verify implementation of extensive, large-scale corrective action activities.

Audit Team Leaders are selected from a list of certified Lead Auditors. The Audit Team Leader selects qualified Auditors and Technical Specialists, as required to meet the scope of the audit. The members of the audit team are selected based on independence from the organization or activities being audited. They have sufficient authority and organizational freedom to objectively conduct the audit.

The Audit Team Leader develops the audit plan and obtains the approval of the CBFO QA Manager. An audit notification letter addressed to the key auditee individual is transmitted to the organization to be audited. The Audit Team Leader provides audit team orientation and notifies any observers. Audit team members prepare the audit checklists, which are approved by the Audit Team Leader. The Audit Team Leader forwards the approved checklists to the audited organization before the audit.

The Audit Team Leader conducts the preaudit meeting and manages the conduct of the audit. The audit team meets daily to discuss audit concerns, status, and exemplary practices. Results are summarized and discussed. A daily meeting is held with the management of the audited organization(s) to inform them of any audit results and the audit status. Deficiencies are documented on Corrective Action Reports (CARs). Isolated deficiencies corrected during the audit are documented as “corrected during the audit” (CDAs). CDAs are documented in the audit report for trending purposes.

The audit report is prepared by the Audit Team Leader and submitted to the CBFO QA Manager for review and approval. The CBFO QA Manager distributes the report to the CBFO Manager, the appropriate management of the audited organization, the responsible CBFO assistant managers, the EPA, the State of New Mexico, and other interested parties in a timely manner.

5.7.2 Auditor and Technical Specialist Independence

Independent assessments of program participants are performed by Lead Auditors, Auditors, and Technical Specialists who are independent of the work and organization being assessed.

Whenever audit team independence may be an issue, a mitigation procedure is utilized to provide alternatives and controls to ensure that audit team independence is achieved and maintained. Examples of mitigation controls include the reassignment of personnel, Audit Team Leader discussions relative to independence with audit team members, and an Audit Team Leader review of the activities and results of those performing the audits. In the event that an audit team member has performed program development activities for a program participant, the individual is not permitted to perform audit activities in those areas until a subsequent independent audit has been performed of those activities (usually one year).

5.7.3 Audit History

The assessment summaries in Tables AUD-1 through AUD-11 of Appendix AUD 2004 reflect assessments that have been performed from 1999 to 2003 of TRU waste generator sites, SNL, LANL-CO, WTS, suppliers performing quality-affecting work, and the CBFO.

REFERENCE

U.S. Department of Energy (DOE). 2003. CBFO Quality Assurance Program Document, DOE/CBFO-94-1012. Carlsbad, NM.

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