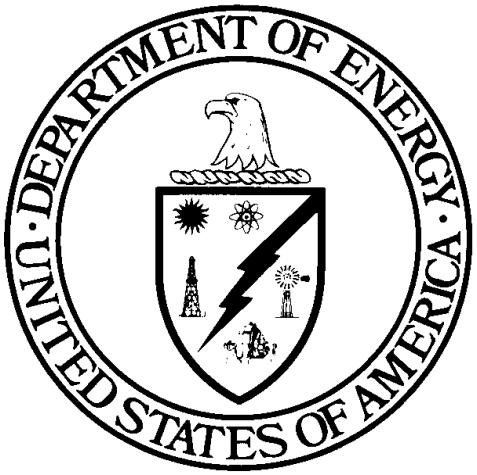
Title 40 CFR Part 191
Subparts B and C
Compliance Recertification
Application
for the
Waste Isolation Pilot Plant

Appendix QAPD-2009
Quality Assurance Program Document



United States Department of Energy
Waste Isolation Pilot Plant

Carlsbad Field Office
Carlsbad, New Mexico

Appendix QAPD-2009
Quality Assurance Program Document

U.S. DEPARTMENT OF ENERGY

CARLSBAD FIELD OFFICE

QUALITY ASSURANCE PROGRAM DOCUMENT

DOE/CBFO-94-1012

REVISION 9

Prepared by: *//signature on file//* **Date:** 11/20/2007

QA Manager, CBFO

Approved by: *//signature on file//* **Date:** 11/20/2007

Manager, CBFO

POLICY STATEMENT

The mission of the Carlsbad Field Office (CBFO) is to protect human health and the environment by operating the Waste Isolation Pilot Plant (WIPP) for safe disposal of transuranic (TRU) waste and by establishing an effective system for management of TRU waste from generation to disposal.

To help fulfill this mission and to ensure that the risks and environmental impacts are identified and minimized and that safety, reliability, and performance are optimized, it is the policy of the CBFO to establish, implement, and maintain an effective quality assurance (QA) program that supports compliance with applicable Federal, State, and local regulations and U.S. Department of Energy (DOE) orders and requirements.

Further, it is the intent of the CBFO to establish a culture and work environment that encourages setting and maintaining effective standards, identifying and resolving problems, emphasizing a continual pursuit of improvement, and fostering mutual respect and effective communication within the CBFO and among its participants, their suppliers, the public, and other stakeholders.

The *CBFO Quality Assurance Program Document* (QAPD) establishes QA program requirements for all quality-affecting programs, projects, and activities sponsored by the CBFO. The CBFO and organizations supporting the CBFO shall implement the applicable requirements of this QAPD within their systems for management and control of these activities.

It is the responsibility of all personnel assigned to CBFO-sponsored activities to achieve quality, identify problems, and recommend improvements. CBFO organizations define and achieve quality, recommend and promote improvements in the quality of items and processes, and identify, document, and resolve problems. CBFO quality assurance organizations verify the achievement of quality. CBFO management establishes and cultivates principles and practices that integrate QA program requirements and performance standards into their management approach and control systems. Additionally, CBFO management provides personnel who perform work with the proper qualifications, training, resources, oversight, and support to achieve the CBFO organizational and mission objectives.

The CBFO QA program requirements, as described in this QAPD, have my full endorsement and complete support. Implementation of the applicable QAPD requirements, responsibilities, and authorities is mandatory for all CBFO personnel.

In support of this policy statement, all CBFO personnel are expected to demonstrate their personal commitment to the achievement of quality through their active involvement in the implementation of the CBFO QA program.

David C. Moody
Manager, Carlsbad Field Office

Date

CHANGE HISTORY

Revision:	Changes to the QAPD
Rev 1	The QAPD has been substantially rewritten, the structure has been reorganized, and the content has been supplemented to broaden its scope from a CAO internal requirements and participant guidance document to a CAO program-wide requirements document. The document elements that defined the extent of applicability regarding specific QA program requirements have been clarified through the identification of "general" and "additional" requirements. Requirements for the grading of management controls have been clarified and more fully developed. The requirement for Sandia National Laboratories (SNL) and Westinghouse Waste Isolation Division (WID) QAPDs was deleted. A requirement was added for each organization to prepare, submit for review, and maintain a QA implementing procedures matrix. Revisions were made to incorporate all the requirements of 40 CFR Part 194, ANSI/NCSL Z540-1, and stakeholder comments. The use of the terms "will" and "shall" are interchangeable and denote requirements. Editorial changes were made throughout.
Rev 2	The section describing the organization and responsibilities for CAO personnel have been deleted from section QAPD-1.0 and incorporated into a policy statement (Attachment A and Attachment B). The QA program document hierarchy (Table QAPD-1), has been updated to reflect current regulatory requirements commitment and guidance documents. Requirements have been clarified in the areas of 1) grading, 2) the control of conditions adverse to quality, and 3) the preparation and maintenance of document review comments. Section QAPD-7.0, *Software,* has been rewritten to include both general and additional requirements. Definitions in the glossary have been added, deleted, and clarified. Editorial changes have been made throughout the document.
Rev 3	Changes in Revision 3 have been limited to those necessary to achieve full compliance with the Waste Analysis Plan (WAP) in the WIPP Hazardous Waste Facility Permit and to incorporate certain TRU waste QA requirements contained in the CAO QAPP, which is to be inactivated. Refer to the following list of pages affected by Revision 3.

List of Pages Affected by QAPD Revision 3

Change History	iv to v
Table of Contents	vi to xii
List of Acronyms	xiii to xiv
Introduction	I-1 to I-2
Section I - Management	1-1 to 1-23
Appendix A - Glossary	A-1 to A-10
Appendix B - References	B-1
Appendix C - CAO Organization	C-1 to C-2
Appendix D - CAO QA Manager Responsibilities	D-1 to D-2
Appendix E - TRU Sites Organization	E-1 to E-4

The pages in Revision 3 that are not listed above (Sections 2.0 through 6.0) remain effective.

Rev 4 The changes in Revision 4 were made to incorporate the DOE name change from the Carlsbad Area Office (CAO) to the Carlsbad Field Office (CBFO) and reflect current CBFO organization titles and responsibilities, rewrite the Quality Improvement section, update the source requirements documents listed in Table I-1, make changes to capture the wording used in the requirements documents, add more specific detail to the QA functional responsibilities of the CBFO management, and eliminate divisions between "general requirements" and "additional requirements." Editorial, formatting, and paragraph number changes have been made throughout the document. Change markings are present for those revisions that affect content. Changes related to editorial and formatting revisions are not marked. Technical revisions were made to the following specific sections:

	List of Acronyms and Abbreviations	ix - x
Table I-1	QA Program Source Documents	xii
1.1.1	Organization	1-1
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1.1.2.4	Grading Items and Activities and Applying Management Controls	1-6
1.2.1	Qualification Requirements	1-8
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1.3	Quality Improvement	1-9 to 1-15
1.4.B	Documents	1-15
1.5.2	Generating QA Records	1-17 to 1-18
1.5.4	Classifying QA Records	1-19 to 1-20
1.5.6.1	Records Classification and Disposition	1-22
2.1.3.A	Item Identification and Control	2-2
2.2	Design Control	2-5
2.2.9	Design Change	2-11

2.3.5.A	Procurement Document Review and Approval	2-14
2.3.7.1	Source Verification	2-16
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2.3.9	Commercial Grade Items	2-18
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3.2.A	Independent Assessment	3-1
3.2.2.8.B	Reporting Audit Results	3-8 to 3-9
5.4	Qualification of Existing Data	5-4 to 5-6
5.5	Quality Assurance Compliance Data (new section)	5-6
Appendix A	Glossary	A-1 to A-2, A-5 to A-7, A-9 to A-10
Appendix C	CBFO Organization, Responsibilities, and Interfaces	C-1
Appendix D	CBFO Quality Assurance Manager Responsibilities	D-1 to D-2
Appendix E	TRU Waste Characterization and Certification Organizational and Individual Responsibilities	E-1

Rev 5 The changes in revision 5 were made to address an EPA finding from the annual EPA QA audit conducted on January 7 – 9, 2003. This finding concerned the language in the QAPD regarding the responsibilities for achievement and verification of quality not matching the requirements from NQA-1. In addition to the change made to address the EPA finding, the following changes were made:

- The requirement for program participants to maintain a QAPD procedures matrix has been deleted; because this matrix is not required by NQA-1, 2, or 3, or other regulatory document.
- The requirement for organizations receiving records to return a receipt acknowledgment to the sender has been deleted, because this also is not required by NQA-1, 2, or 3, or other regulatory document.
- The requirement that CBFO and participant organization ensure that they comply with the Federal Acquisition Regulations was deleted because the QAPD is not the appropriate document to specify this requirement.
- The requirement to maintain records related to the characterization of the mixed transuranic waste form as lifetime QA records was deleted. Records classification of mixed waste characterization records is specified in the Hazardous Waste Facility Permit.
- The requirement to maintain audit and surveillance checklists as QA records was deleted, because this is not a requirement of NQA-1, 2, or 3, or other regulatory document.
- The requirement for calibration laboratories to comply with ANSI/NCSL Z540-1 was deleted because this is not a requirement of NQA-1, 2, or 3, or

other regulatory document.

- The safety analysis report for the HalfPACT shipping package was added as a regulatory source document to Table QAPD-1
- Section 5.5 was deleted. The requirements for data quality evaluation during scientific investigation planning are addressed in Section 5.1.G of the QAPD. Section 5.5 was redundant and specified requirements for the content of compliance applications, which was not appropriate for the QAPD.
- Changes were also made to correct typographical errors and incorrect section references.

Technical revisions were made to the following specific sections:

Section	Section Title
	Policy Statement
	Introduction
1.1.1	Organization
1.1.1.1.D	Management
1.1.1.3	Quality Assurance Management
1.1.2.2	Procedures Matrix (deleted)
1.2.1	Qualification Requirements
1.3.2.5	Disposition of Nonconforming Items or Data
1.5.4.B and E	Classifying QA Records
1.5.6.A	Storage, Preservation, Safekeeping, and Disposition of QA Records
2.1.B	Work Processes
2.3	Procurement
2.3.4	Procurement Document Requirements
2.4.6	Use and Control of M&TE
2.4.7	Calibration
3.2.2.10	Audit Records
Appendix C	CBFO Organization, Responsibilities, and Interfaces
Appendix D	CBFO Quality Assurance Manager Responsibilities

Rev. 6 The changes in Revision 6 were made to implement the new CBFO organization chart that was approved on May 15, 2004.

Revisions were made to the following specific sections

	List of Acronyms and Abbreviations
	Introduction
Appendix C	CBFO Organization, Responsibilities, and Interfaces
Appendix D	CBFO Quality Assurance Manager Responsibilities
Appendix E	TRU Waste Characterization and Certification Organizational and Individual Responsibilities

Rev. 7 The changes in Revision 7 were the direct result of DOE EM 3-2 comments relative to compliance with DOE O 414.1B.

Revisions were made to the following specific sections:

	Policy Statement
	List of Acronyms and Abbreviations
	Section 1.3
	Section 2.3
	Program Source Documents
	Appendices C and D

Rev. 8 The changes in Revision 8 were made to address thirteen minor findings and one concern from an EPA inspection of CBFO's QA program (Ref: Letter from Gitlin to Moody dated April 18, 2006). Document citations were added to include remote-handled waste packaging. The exemption of NEPA-related software from the requirements of the QAPD was deleted. The applicability of software QA to safety software was clarified. Editorial changes related to the June 26, 2006 reorganization of the CBFO were also incorporated.

Revisions were made to the following specific sections:

	List of Acronyms and Abbreviations
	Introduction
1.1.2.1	Quality Assurance Program Documents
1.2.2	Training Requirements
1.3.2.3	Reporting Nonconformances
1.5.3	Indexing QA Records
1.5.6	Storage, Preservation, Safekeeping, and Disposition of QA Records
1.5.6.1	Records Disposition
2.3.1	Procurement Planning Requirements
2.3.7	Acceptance of Items or Services
2.3.8	Control of Supplier Nonconformances
2.4.2	Qualification of Nondestructive Examination Personnel
2.4.7	Calibration
3.2.2.1	Scheduling Audits
6.1	Applicability
6.6.2.4	Testing Phase
6.7.3	Validation
Appendix A	Glossary
Appendix B	References
Appendix C	CBFO Organization, Responsibilities, and Interfaces
Appendix D	CBFO Quality Assurance Manager Responsibilities

Appendix E	TRU Waste Characterization and Certification Organizational and Individual Responsibilities

Rev. 9

The QAPD was revised to clarify that reliance on administrative controls alone is not sufficient for differentiating between waste that is acceptable for shipment to WIPP and waste that does not meet the WIPP waste acceptance criteria. The classification of conditions adverse to quality related to the Hazardous Waste Facility Permit was also clarified. The language regarding reporting nonconformances was revised to comport with the November 16, 2006 Permit Modification. The requirements for records disposition were revised to comport with the Class 1 Permit Modification that was approved by NMED on September 13, 2007.

Revisions were made to the following specific sections:

1.3.2.3	Reporting Nonconformances
1.3.2.4	Segregating Nonconforming Items
1.3.3.2	Classification of Conditions Adverse to Quality
1.3.3.5	Corrective Action Planning
1.5.6.1	Records Disposition

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Table QAPD-1. QA Program Source Documents QAPD-2

Acronyms and Abbreviations

ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
ASNT	American Society of Nondestructive Testing
ASTM	American Society for Testing and Materials
CAP	Corrective Action Plan
CAQ	Condition Adverse to Quality
CATS	Corrective Action Tracking System
CBFO	Carlsbad Field Office
CFR	Code of Federal Regulations
DQO	Data Quality Objective
DOE	U.S. Department of Energy
EPA	U.S. Environmental Protection Agency
HWFP	Hazardous Waste Facility Permit
M&DC	Monitoring and Data Collection Equipment
M&TE	Measuring and Test Equipment
M&O	Management and Operating Contractor
NARA	National Archives and Records Administration
NDE	Nondestructive Examination
NEPA	National Environmental Policy Act
NFPA	National Fire Protection Association
NIST	National Institute of Standards and Technology
NMED	New Mexico Environment Department
NQA	Nuclear Quality Assurance
NRC	Nuclear Regulatory Commission
NTP	National TRU Program
NUREG	Nuclear Regulatory Commission Report designation
OD	Office Director
QA	Quality Assurance
QAPD	Quality Assurance Program Document
QAPjP	Quality Assurance Project Plan
QAPP	Transuranic Waste Characterization Quality Assurance Program Plan (CAO-94-1010)

QC	Quality Control
RIDS	Records Inventory and Disposition Schedule
SCAQ	Significant Condition Adverse to Quality
SNL	Sandia National Laboratories
SQA	Software Quality Assurance
TRAMPAC	TRUPACT-II Authorization Methods for Payload Control
TRU	Transuranic
TRUPACT-II	Transuranic Package Transporter, Model II
UL	Underwriter's Laboratory
WAP	Waste Analysis Plan
WID	Westinghouse Waste Isolation Division
WIPP	Waste Isolation Pilot Plant
WTS	Washington TRU Solutions

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QAPD-1.0 Introduction

The Carlsbad Field Office (CBFO) Quality Assurance Program Document (QAPD) is the document that describes and establishes the CBFO Quality Assurance (QA) program. The provisions of this QAPD apply to all programs and projects managed by the CBFO which require a QA program, including activities related to compliance application, waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the Waste Isolation Pilot Plant (WIPP) facility. This document identifies the sources of all applicable QA program requirements. The subject requirements are based on criteria contained, or incorporated by reference, in source documents listed in Table QAPD-1. These documents have been placed into one of three categories:

1. Regulatory documents, including those incorporated by reference, that define the requirements necessary for the WIPP to be granted a certificate of compliance by the Federal Government and permit(s) by State governmental agencies to dispose of transuranic (TRU) and mixed TRU wastes in the WIPP repository, or that define requirements applicable to the management of the WIPP as a U.S. Department of Energy (DOE) non-reactor nuclear facility

2. Commitment documents that are imposed by DOE management

3. Guidance documents that provide additional information that is useful in developing and implementing the CBFO QA program

The purpose of the QAPD is to describe the applicability and requirements of the CBFO QA program as applied within the CBFO management infrastructure. In this context, the management infrastructure includes all CBFO program participants (e.g., Sandia National Laboratories [SNL] as Science Advisor; Washington TRU Solution [WTS] as the Management and Operating [M&O] contractor of the WIPP, and various DOE organizations and contractors performing work under the direction of the CBFO). This program is developed and maintained through an ongoing process that selectively applies the varied QA program criteria. This process provides due consideration to the extent of source requirement applicability, a graded-approach, available guidance, and the current foreseeable activities expected to be performed under the direction of CBFO.

The requirements in this QAPD are based on the principle that work shall be planned, documented, performed under controlled conditions, and periodically assessed to establish work item quality and process effectiveness and to promote improvement. Management, line personnel, and organizations are responsible for planning and achieving quality and for promoting continuous improvement. Quality assurance organizations and personnel are responsible for the verification of the achievement of quality. This QAPD further delineates the quality contributions expected of all personnel and encourages their active participation in implementing the CBFO QA program.

Table QAPD-1. QA Program Source Documents

MAJOR REGULATORY REQUIREMENTS DOCUMENTS	TITLE
40 CFR Part 191	Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes
40 CFR Part 194	Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations
10 CFR Part 830	Nuclear Safety Management
10 CFR Part 71	Packaging and Transportation of Radioactive Material
10 CFR Part 21	Reporting of Defects and Nonconformances
ASME NQA-1-1989 (incorporated by reference in 40 CFR Part 194)	Quality Assurance Requirements for Nuclear Facilities
ASME NQA-2a-1990 addenda, Part 2.7 (incorporated by reference in 40 CFR Part 194)	Quality Assurance Requirements of Computer Software for Nuclear Facility Applications
ASME NQA-3-1989 excluding Section 2.1(b) and (c) and Section 17.1 (incorporated by reference in 40 CFR Part 194)	Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories
NM 48901 39088 – TSDF/WIPP	WIPP Hazardous Waste Facility Permit
NRC Certificate Number 9212	RH-TRU 72-B Certificate of Compliance
NRC Certificate Number 9218	TRUPACT-II Certificate of Compliance
NRC Certificate Number 9279	HalfPACT Certificate of Compliance
NRC Certificate Number 9204	10-160B Certificate of Compliance
NUREG-1297 (1988) (incorporated by reference in 40 CFR Part 194)	Peer Review for High-Level Nuclear Waste Repositories
COMMITMENT DOCUMENTS	**TITLE**
DOE O 414.1C	Quality Assurance
DOE O 226.1	Implementation of Department of Energy Oversight Policy
SNT-TC-1A-1980	American Society of Nondestructive Testing (ASNT) "Recommended Practice No. l SNT-TC-1A, Personnel Qualification and Certification in Nondestructive Testing," August 1980
GUIDANCE DOCUMENTS	**TITLE**
DOE, G-414.1-2A	Quality Assurance Management System Guide for Use with 10 CFR Part 830.120 and DOE O 414.1
NUREG/BR-0167 (1993)	Software Quality Assurance Program and Guidelines

QAPD-2.0 Management Requirements

This section describes the fundamental elements related to the organization and management of the CBFO QA program, as well as the fundamentals to be applied in managing the work of the program.

QAPD-2.1 Organization and Quality Assurance Program

This section describes the requirement for the organizational structure, primary interfaces, functional responsibilities, and levels of authority required to implement the CBFO QA program. In addition, this section describes the basic elements of the QA program and their applicability.

QAPD-2.1.1 Organization

Effective implementation of the CBFO QA program is dependent on the efforts at all levels of the program participants. The organizational structures and the responsibility assignments of program participants shall be such that those organizations that have been assigned responsibility for performing the work are responsible for achieving and maintaining quality. Management is responsible for defining quality, developing appropriate plans to attain quality, and supporting the workers in pursuit of quality. QA organizations of the program participants are responsible for verifying the achievement of quality in the implementation of the CBFO QA program. CBFO organizational and individual responsibilities are addressed in Attachment A and B. Organizational and individual responsibilities for TRU waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP facility are addressed in Section QAPD-2.3.3.1.

QAPD-2.1.1.1 Management

1. Management has overall responsibility for successfully accomplishing activities subject to this QAPD. Management provides the necessary planning, organization, direction, control, resources, and support to achieve their defined objectives. Management is responsible for planning, performing, and improving the work.

2. Management is responsible for establishing and implementing policies, plans, and procedures that control the quality of work, consistent with the provisions of this QAPD.

3. Management quality responsibilities include:

   A. Ensuring that adequate technical and QA training is provided for personnel performing activities subject to this QAPD

   B. Ensuring compliance with all applicable regulations, DOE orders and requirements, and applicable Federal, State, and local laws

   C. Ensuring that personnel adhere to procedures for the generation, identification, control, and protection of QA records

D. Exercising the authority and responsibility to stop unsatisfactory work such that cost and schedule do not override environmental, safety, or health considerations

E. Developing, implementing, and maintaining plans, policies, and procedures that implement this QAPD

F. Identifying, investigating, reporting, and correcting quality problems

4. Quality achievement is the responsibility of those performing the work. Line organizations are responsible for achieving quality in their areas.

5. Management empowers employees by delegating authority and decision making to the lowest appropriate level in the organization.

QAPD-2.1.1.2 Employees

Each program participant employee is responsible for the quality of his or her work and for promptly reporting all existing, developing, or potential conditions adverse to quality to the responsible management for evaluation and action.

QAPD-2.1.1.3 QA Management

An organization's QA management has the authority and overall responsibility to independently assess the organization's effective implementation of the QA program to verify the achievement of quality.

1. QA management shall:

A. Schedule and conduct QA assessments

B. Maintain liaison with participant QA organizations and other affected organizations

C. Ensure preparation, review, and issuance of QA plans and procedures that implement the provisions of this QAPD

D. Review and approve supplier and subcontractor QA plans

E. Track or perform trend analysis of quality problems, and report quality problem areas

F. Provide for the administrative processing of documentation concerning conditions adverse to quality

G. Have direct access to responsible management at a level where appropriate action can be effected

H. Be sufficiently independent from cost and schedule considerations

I. Have the organizational freedom to communicate with management

J. Have no assigned responsibilities unrelated to the QA program that would prevent appropriate attention to QA matters

K. Develop, establish, and interpret QA policy and ensure effective implementation

L. Interface, as appropriate, with the CBFO staff, participants, and other stakeholders on QA matters

M. Assist subordinate organizations with quality planning, documentation, quality measurement, and problem identification and resolution

N. Provide guidance to all applicable subordinate organizations concerning identification, control, and protection of QA records

2. The QA organization shall have sufficient authority, access to work areas, and organizational freedom to:

A. Identify quality problems

B. Recommend solutions

C. Verify implementation of solutions

D. Ensure that unsatisfactory conditions are controlled until proper disposition has occurred

QAPD-2.1.1.4 Communication and Interface Responsibilities

1. Communication Responsibilities

Participating organizations at all management levels shall establish communication channels that provide timely and wide dissemination of information pertinent to quality performance, such as:

A. The status of development and implementation of the QA program

B. The status and resolution of significant quality problems

C. The lessons learned from significant quality problems and adverse conditions

D. Quality management practices and improvements

E. Trend analysis results

2. Interface Responsibilities

A. Where more than one organization is involved in the execution of activities covered by this QAPD, the responsibility and authority of each organization shall be clearly established, defined, and documented. The external interfaces between organizations, the internal interfaces between organizational units, and interface changes shall be

documented. Interface responsibilities shall be defined and documented and shall include the requirements for management, performance, and assessment.

B. CBFO-sponsored activities, performed by organizations external to the CBFO, include, but are not limited to, compliance application, waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP facility. Responsible CBFO organizations shall ensure the effective implementation of the CBFO QA program.

QAPD-2.1.1.5 Delegation of Work

Individuals or organizations responsible for establishing, planning, accomplishing, and assessing the work may delegate work to other individuals or organizations. However, the individuals or organizations making the delegation shall retain overall responsibility for the delegated work.

QAPD-2.1.1.6 Resolution of Disputes

Differences of opinion involving the definition and implementation of QA program requirements will be brought to the attention of the appropriate QA manager and the responsible manager. If not resolved, the issues will be elevated progressively to successively higher levels of management as necessary.

QAPD-2.1.2 Implementation of the CBFO QA Program

QAPD-2.1.2.1 Quality Assurance Program Documents

Program participants shall develop and follow plans and procedures that effectively implement the requirements described in this QAPD along with those requirements contained within the Resource Conservation and Recovery Act (RCRA) Permit Waste Analysis Plan (WAP), Quality Assurance Project Plans (QAPjPs), Certification QA Plans, Waste Acceptance Criteria (WAC), and Certificates of Compliance for NRC licensed nuclear packaging, as applicable.

QAPD-2.1.2.2 Applicability of QAPD Requirements

The terminology "items or activities important to compliance application, waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP facility" is used generically throughout this QAPD to refer to the following:

1. WIPP site activities or operations that process or store radioactive liquid or solid waste, perform waste management activities involving radioactive materials, or design, manufacture, or assemble items for use with radioactive materials in such a form and quantity that a nuclear hazard exists

2. Waste characterization activities

3. Environmental monitoring, monitoring the performance of the disposal system, and sampling and analysis activities

4. Field measurements of geological factors, ground water, meteorology, and topography

5. Computations, codes, models, and methods used to demonstrate compliance with disposal regulations

6. Expert judgment elicitation to support applications for recertification or determination of compliance

7. Design of the disposal system and actions taken to ensure compliance with design specifications

8. The collection of data and information used to support compliance application(s) and/or any modifications to the compliance application

9. Other systems, structures, components, and activities important to the isolation of waste in the disposal system

10. Those items and activities related to Nuclear Regulatory Commission (NRC) licensed packaging (e.g., Transuranic Package Transporter Model II [**TRUPACT-II**], **RH-72B**, CNS 10-160B), design, purchase, fabrication, handling, shipping, storage, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification or components of packaging that are important to safety

QAPD-2.1.2.3 Grading Items and Activities and Applying Management Controls

1. The graded approach is the process by which the level of analysis, documentation, verification, and other controls necessary to comply with QA program requirements are developed commensurate with the following factors:

   A. The importance of an item or activity with respect to safety, waste isolation, and regulatory compliance

   B. The importance of the data to be generated

   C. The need to demonstrate compliance with specific regulatory design and QA requirements

   D. The impact on the results of performance assessments and engineering analyses

   E. The magnitude of a hazard or the consequences of failure

   F. The life-cycle stage of a facility or item

   G. The programmatic mission of a facility

H. The particular characteristics of a facility, item, or activity (e.g., complexity, uniqueness, history, or the necessity for special controls or processes)

I. The relative importance of radiological and non-radiological hazards

2. The extent of management and QA controls applied to an item or activity will vary as a function of the degree of confidence needed to achieve the desired quality of the item or activity. The grading process provides the flexibility to design and implement controls that best suit the facility or activity. Each organization should develop their own method to determine that the defined grading process is effective. The use of the graded approach shall determine the appropriate level of controls necessary to manage the items, systems, and activities necessary to ship TRU waste to WIPP.

3. Grading methods for each organization shall provide for:

A. The assignment of management and QA control levels

B. The definitive criteria used in selecting those levels

C. Detailed descriptions of the management and QA control provisions corresponding to those levels, based on the above requirements

4. Program participant procedures that establish and implement a graded approach for items and activities under the cognizance of the CBFO shall be submitted to the CBFO QA Manager for approval for use in CBFO programs.

QAPD-2.1.2.4 Planning Work

Planning shall be performed and documented to ensure that work is accomplished under suitably controlled conditions. As appropriate, planning elements shall include:

1. Definition of work scope, objectives, and a listing of the primary tasks involved

2. Identification of scientific approaches or technical methods used to collect, analyze, or study results of applicable work

3. Identification of field and laboratory testing standards and quality criteria

4. Identification of applicable implementation documents (appropriate nationally recognized standards shall be used whenever possible)

5. Identification of field and laboratory testing equipment or other equipment

6. Identification of, or provisions for the identification of, required records and the recording of objective evidence of the results of the work performed

7. Identification of prerequisites, special controls, specific environmental conditions, processes, or skills

8. Identification of computer software

QAPD-2.1.2.5 Peer Reviews

Peer reviews performed in support of WIPP compliance activities shall be documented, as shall all peer review processes. Peer reviews of the following activities shall be conducted in a manner consistent with NUREG-1297, *Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories:*

1. Conceptual models selected and developed by the DOE

2. Waste characterization analysis as required in 40 CFR § 194.24(b)

3. Engineered barrier evaluation as required in 40 CFR § 194.44

QAPD-2.2 Personnel Qualification and Training

Personnel shall be trained and qualified to ensure they are capable of performing their assigned tasks and to ensure that job proficiency is maintained.

QAPD-2.2.1 Qualification Requirements

Qualification requirements for CBFO and participant positions or job functions shall be established for activities important to compliance application, waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP facility. The evaluation shall be documented. At a minimum, these positions include managers, designers, scientists, independent assessment personnel, operators, maintenance personnel, technicians, and inspectors.

The responsible organization shall:

1. Analyze each job position to determine the task responsibilities of the position subject to the QAPD. The analysis shall identify minimum education, experience, and training prerequisites for each position involved in the planning, performance, or verification of activities subject to the QAPD, commensurate with the scope, complexity, and nature of the work.

2. Ensure that personnel selected to perform or verify activities subject to the QAPD have education, experience, and training commensurate with the minimum requirements specified. The qualification of an individual shall be based upon evaluation of education and experience, which is compared to the established requirements for the position.

QAPD-2.2.2 Training Requirements

CBFO and participant personnel performing activities important to compliance application, waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP facility shall receive related training in accordance with the following requirements. Training shall

emphasize the correct performance of work, describe why the applicable quality and nuclear safety requirements exist, and describe the fundamentals of the work and the context. Training shall be subject to ongoing review to determine instruction and training program effectiveness and shall be upgraded whenever needed improvements or enhancements are identified. Management shall:

1. Ensure that personnel receive indoctrination and training, including on-the-job and hands-on training, as needed, to achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, job responsibilities and authority, and quality assurance implementing procedures, prior to performing any tasks subject to the QAPD.

2. Ensure that personnel receive indoctrination in the following:

   A. General criteria, including applicable QA plans, codes, regulations, and standards

   B. Specific criteria, including applicable QAPjPs and implementing procedures

3. Ensure that records generated during qualification, general indoctrination and training, or specific skill training activities are collected and maintained as QA records.

QAPD-2.3 Quality Improvement

Quality improvement is a management process carried out to improve items, services, products, or processes. All aspects of work that affect quality and the management system are subject to continuous improvement through assessment and feedback processes.

For findings identified by the organizations listed in DOE O 414.1C, Attachment 4, Paragraph 1, the implementation process described in DOE G 450.4-1B, Appendix G will be invoked. The CBFO Office Director, Office of Disposal, is responsible for the management of the identified issues as required by the DOE Corrective Action Tracking System (CATS) User's Guide. This function is applicable only to safety issues identified at the CBFO. The waste generator sites are required to implement the process of the Corrective Action Management Program as directed by the appropriate site office.

Quality-related program deficiencies are addressed as indicated in Section QAPD-2.3.3.3.

QAPD-2.3.1 Quality-Affecting Problems

Quality-affecting problems and items, services, and processes that do not meet established requirements shall be identified, documented, reported, controlled, and corrected. Quality problems may be identified by the organization or by an external source.

QAPD-2.3.1.1 Problem Identification

All personnel shall be responsible for identifying quality problems and shall be encouraged by management to suggest improvements. CBFO and participant organizations foster a "no-fault" attitude for quality problems and prioritize and focus resources on preventive actions and on those quality problems that have the greatest potential for:

1. Posing adverse risks to the environment and human health
2. Adversely impacting the quality, safety, and reliability of waste operations
3. Affecting the ability to meet quality requirements

QAPD-2.3.1.2 Problem Types

Quality-affecting problems may involve:

1. Noncompliance with a QA program requirement. A noncompliance is classified as a Condition Adverse to Quality (CAQ) or Significant Condition Adverse to Quality (SCAQ)
2. Nonconforming items, including suspect/counterfeit items or data, that do not conform to specified requirements.

QAPD-2.3.2 Nonconformances

Items or data that do not conform to established requirements shall be controlled to prevent inadvertent installation or use.

QAPD-2.3.2.1 Documenting and Evaluating Nonconforming Items

The documentation and evaluation of nonconforming items shall be accomplished by:

1. Clearly identifying and describing the characteristics that do not conform to specified criteria
2. Reviewing nonconformance documentation and proposed recommended disposition of the nonconforming item or data. The review shall include a determination of the need for corrective action in accordance with the requirements of Section QAPD-2.3.3, *Corrective Action*. In addition, organizations affected by the nonconformance shall be notified.
3. Evaluating and approving of recommended dispositions
4. Ensuring that personnel performing evaluation or recommending disposition have demonstrated competence in the specific area they are evaluating or dispositioning, and have an adequate understanding of the requirements
5. Implementing procedures that specify the responsibility and authority for reviewing, evaluating, approving the disposition, and closure of the nonconformance

QAPD-2.3.2.2 Identifying Nonconforming Items or Data

1. Nonconforming items shall be physically identified by marking, tagging, segregation, or other methods that do not adversely affect the end use. The identification shall be legible and easily recognizable, and shall be traceable to the reporting documentation.

2. If physical identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be physically identified as in A above.

QAPD-2.3.2.3 Reporting Nonconformances

Organizations affected by a nonconformance shall be notified. The CBFO shall be notified in writing within 5 calendar days of identification of any non-administrative nonconformance related to applicable requirements specified in the WIPP Hazardous Waste Facility Permit (HWFP) Waste Analysis Plan (WAP), which is first identified at the site project manager's signature release level (i.e., a failure to meet a data quality objective [DQO]). Notification is also required if the results sampling and analysis specified in Permit Attachment B are inconsistent with acceptable knowledge documentation. The nonconformance report shall be submitted to CBFO within 30 calendar days of identification of the deficiency.

Nonconformances related to defects or failure to comply with requirements applicable to NRC licensed packaging (e.g., TRUPACT II, RH 72-B) shall be reported to the CBFO Office of the National TRU Program. The WIPP M&O contractor will evaluate issues and nonconformances for reporting to the NRC under 10CFR Part 21 or Part 71 and provide the results of this evaluation to CBFO.

QAPD-2.3.2.4 Segregating Nonconforming Items

1. Further processing, delivery, installation, or use of nonconforming items shall be controlled pending the evaluation and approval of the disposition.

2. Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned.

3. If segregation is impractical or impossible due to physical condition, other precautions shall be employed to preclude inadvertent use.

4. Reliance solely on other precautions (i.e., administrative controls) to differentiate waste containers that are acceptable for shipment to WIPP from those containers that do not meet the WIPP acceptance criteria is not allowed.

QAPD-2.3.2.5 Disposition of Nonconforming Items or Data

The disposition of nonconforming characteristics shall be accomplished as follows:

1. The nonconformance characteristics shall be reviewed, and recommended dispositions of nonconforming items or data shall be proposed and approved in accordance with documented procedures. Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area they are evaluating, have adequate understanding of the requirements, and have access to pertinent background information.

2. The dispositions "use-as-is," "reject," "repair," or "rework" for nonconforming items or data shall be identified and documented.

3. The technical justification for the acceptability of a nonconforming item or data that has been dispositioned "use-as-is" or "repair" shall be documented.

4. Items that do not meet original design requirements that are dispositioned "use-as-is" or "repair" shall be subject to design control measures commensurate with those applied to the original design, and

   A. If changes to the specifying document are required to reflect the as-built condition, then the disposition shall require action to change the specifying document to reflect the accepted nonconformance.

   B. Any document or QA record change required by the disposition of the nonconformance shall be identified in the nonconformance documentation and, when a document or record is changed, the justification for the change shall reference the nonconformance documentation.

5. The disposition of an item to be reworked or repaired shall contain a requirement to re-examine (inspect, test, or examine by nondestructive examination) the item to verify acceptability. Repaired or reworked items shall be re-examined using the original process and acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.

QAPD-2.3.2.6 Quality Trending of Nonconformances

Nonconformance documentation shall be periodically analyzed by the QA organization to identify quality trends in accordance with Section QAPD-2.3.3, *Corrective Action*.

QAPD-2.3.3 Corrective Action

QAPD-2.3.3.1 Identifying Conditions Adverse to Quality (CAQ)

A CAQ occurs when a QA requirement has not been met.

QAPD-2.3.3.2 Classification of Conditions Adverse to Quality

Classification of CAQs is based on the effect the CAQ has on compliance to regulatory requirements for safety, operability, TRU waste characterization, TRU waste site certification, TRU waste containment, and the effective implementation of the QAPD. Any CAQs that are determined to be noncompliant with an HWFP condition or requirement require corrective action plans (CAPs) that meet the requirements of Section QAPD-2.3.3.5.

QAPD-2.3.3.3 Conditions Adverse to Quality

1. CAQs shall be documented and reported to the appropriate levels of management responsible for the condition and to the QA organization for tracking.

2. Responsible management shall determine the extent and impact of the adverse condition and, at a minimum, complete remedial action as soon as practical.

QAPD-2.3.3.4 Significant Conditions Adverse to Quality

1. Implementing documents shall include criteria for determining if a condition adverse to quality is significant. These criteria shall be based on the criteria in the definition of conditions adverse to quality included in Section QAPD-8.0.

2. SCAQs shall be investigated, documented (including the extent of the condition and the impact on completed work), and reported to the management responsible for the condition, their senior management, and the QA organization for tracking.

3. Responsible management shall determine when an SCAQ related to the WIPP HWFP (i.e., a waste characterization process currently certified by the CBFO at a TRU waste site) requires accelerated corrective action. The required time interval for accelerated corrective action shall be established by the CBFO QA Manager.

QAPD-2.3.3.5 Corrective Action Planning

CAPs are required for all SCAQs. SCAQ CAPs shall address:

1. Remedial Action: actions necessary to resolve the initial problem

2. Investigative Actions: assessment of the extent and impact of the SCAQ

3. Root Cause Determination: identification of the root cause of the SCAQ

4. Actions to Preclude Recurrence: actions necessary to prevent recurrence of the SCAQ

5. Schedule: milestones for completion of the CAP, including expected completion dates and identification of responsible individuals

QAPD-2.3.3.6 Work Suspension

If a work suspension condition has been identified, responsible management shall take appropriate action to lift and close the work suspension, based on the resolution of the related SCAQ. The QA organization shall verify and document the completion of applicable corrective actions prior to any management action releasing the work suspension.

QAPD-2.3.3.7 Corrective Action Follow-up

A system shall be established to verify the effective implementation of scheduled corrective actions and to complete corrective actions in a timely manner. The QA organization shall evaluate the adequacy of corrective actions planned, assign responsibility for follow-up verification, and perform and document verification results. If results of verification are unsatisfactory, the CAP shall be revised appropriately, and corrective actions and verification performed.

QAPD-2.3.3.8 Recurring Conditions Adverse to Quality

For recurring CAQs, management shall:

1. Determine the events leading up to the occurrences
2. Develop an understanding of the technical and work activities associated with the CAQ
3. Ascertain and identify any generic implications and impacts on completed work
4. Determine the extent to which similar quality problems, or precursors to the problem, have been identified
5. Determine the effectiveness of corrective actions that have been taken
6. Consider suspending work associated with the applicable activity, as appropriate
7. Suggest actions that can be taken by the responsible organization to preclude recurrence, as appropriate

QAPD-2.3.3.9 Quality Trending

The need for quality improvement is accomplished through quality analysis and trending. To provide reliable trending information, the following activities shall be performed:

1. Quality performance data shall be identified, collected, and routinely analyzed to identify opportunities to improve items, services, activities, and processes. This analysis shall consider information from external sources and not be limited to one type of work or to one organization.
2. The analyses shall be performed semi-annually to provide for prompt identification of trends adverse to quality. Reports of CAQs, including those identified during quality assurance audits as Corrected During the Audit/Surveillance (CDAs/CDSs), shall be evaluated to identify adverse quality trends and root causes, with results reported to the organization responsible for corrective actions.
3. Program participants will report trending information to responsible management and to the applicable organization.

QAPD-2.4 Documents

1. Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design.
2. Documents that specify requirements, prescribe processes, or establish design important to the compliance application, waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP facility, such as instructions, procedures, drawings,

test plans, management plans, technical reports, performance reports, and test reports, shall be controlled according to the requirements listed below to ensure that the correct documents are being used.

QAPD-2.4.1 Document Preparation, Review, Approval, and Issuance

1. Documents shall be reviewed for adequacy, correctness, and completeness prior to approval and issuance. Program participants shall identify the individuals or organizations responsible for the preparation, review, approval, and issuance of controlled documents.

2. Documents shall be controlled during the review and approval phase in accordance with approved procedures.

3. The requesting organization shall identify the applicable criteria for the review. These criteria shall consider technical adequacy, accuracy, completeness, and compliance with established requirements.

4. Pertinent background information or data shall be made available by the organization requesting the review if the information is not readily available to the reviewer.

5. The review will be performed by individuals other than the originator.

6. Reviewers will be technically competent in the subject area being reviewed.

7. The organization or technical discipline affected by the document shall review the document according to the established review criteria.

8. The appropriate quality assurance organization shall review documents that translate CBFO QAPD or other CBFO requirements.

9. Review comment documentation shall be resolved in accordance with approved procedures. Evidence of review comment resolution shall be maintained by the originating organization.

10. Documents shall be approved for release by authorities designated in accordance with approved procedures.

11. Documents shall be issued by designated individuals or organizations in accordance with approved procedures.

QAPD-2.4.2 Document Distribution and Use

The distribution and use of controlled documents and forms that document or prescribe work, including changes and editorial corrections to documents, shall be controlled to meet the following requirements:

1. Documents shall be distributed to affected personnel and used at the work location.

2. Effective dates shall be established and identified on the approved documents.

3. The disposition of obsolete or superseded documents and forms shall be controlled to avoid their inadvertent use.

4. Controls shall be established and maintained to identify the current status or revision of controlled documents and forms.

5. Controls shall provide for identification of documents to be controlled and their distribution.

QAPD-2.4.3 Document Changes

1. Changes to documents, other than those defined below as editorial changes, shall be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated in accordance with approved procedures.

2. Document changes shall be:

   A. Reviewed by the organizations or technical disciplines affected

   B. Clearly indicated in the changed document

3. Editorial or minor changes may be made without the same level of review and approval as the original or otherwise changed document. The following items are considered editorial or minor changes:

   A. Correcting grammar or spelling (the meaning has not changed)

   B. Renumbering sections or attachments

   C. Updating organizational titles

   D. Changes to non-quality affecting schedules

   E. Revising or reformatting forms, providing the original intent of the form has not been altered

   F. Attachments marked “Example,” or “Sample,” or exhibits that are clearly intended to be representative only

   G. Clarification changes that do not affect the purpose of the document

4. A change in an organizational title accompanied by a change in responsibilities is not considered an editorial change.

5. The organization responsible for preparing the document shall identify and approve editorial changes.

QAPD-2.5 Records

1. Records shall be specified, prepared, reviewed, approved, and maintained.

2. A "QA record" is an authenticated record that provides objective evidence of the quality of items or activities. QA records shall be controlled in accordance with the following requirements.

QAPD-2.5.1 Records System

1. A QA records system shall be established by the responsible organization at the earliest practical time, consistent with the schedule for accomplishing work activities. The QA records system shall be defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation.

2. This does not prohibit the management of QA records within a general records system, nor does this require a separate records system for QA records, as long as the applicable provisions of this section are satisfied for the control of QA records.

QAPD-2.5.2 Generating QA Records

1. Prior to conducting a work activity, the responsible organization shall:

   A. Identify those documents that shall become QA records

   B. Identify the organization responsible for submitting the QA records to the records system

2. QA records shall be legible, accurate, and completed appropriate to the work accomplished.

3. Individuals handling documents intended to become QA records shall provide reasonable protection for the records from damage or loss until the records are submitted to the records system (this includes documents generated during field operations).

4. Documents shall be considered valid QA records only if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated. If the nature of the record (such as magnetic or optical media) precludes stamping or signing, then other means of authentication by authorized personnel are required. This authentication represents a certification as to the content of the record by those individuals with knowledge of the related facts, whether by direct personal knowledge or through the direct reports of others. The authentication should not be confused with any subsequent reviews of the content.

5. Once authenticated, QA records shall be submitted to the records system as prescribed by approved procedures. Upon completion of a project or other discrete task or activity, responsible management shall verify that the contents of the applicable QA records package are stored in the records system.

6. QA records may be originals or reproducible copies unless otherwise required.

7. Documents referenced by final reports, except readily available references such as encyclopedias, dictionaries, engineering handbooks, and national codes and standards, shall be retrievable from records files. Preparers of such records shall ensure that the documents are entered into the records system.

QAPD-2.5.3 Indexing QA Records

The records system shall provide for the indexing of QA records according to the following requirements:

1. An individual or organization shall be assigned the responsibility of indexing and maintaining QA records.

2. The indexing system shall include, at a minimum, record retention times and the location of the record within the records system. These and other features of the records system shall facilitate the disposition of scheduled QA records and ensure the retrievability of any QA records entered in accordance with planned retrieval times based upon the record type.

3. Records and/or indexing system(s) shall provide sufficient information to permit identification between the record and the item(s) to which it applies.

QAPD-2.5.4 Classifying QA Records

1. QA records shall be classified as either "post-closure," "lifetime," or "nonpermanent." Post-closure QA records may be required to be maintained for periods of several hundred years and in a manner that will permit future generations to maintain them longer, if desired, using reasonably available technology. Records that fall into one or more of the following categories shall be classified as "post-closure" QA records:

   A. Records assisting prevention of actions that could impair the long-term isolation of the waste

   B. Records preserving information that would prevent inadvertent human intrusion, such as the nature and hazard of the waste and the locations of the geologic repository operations area, the underground facility, boreholes and shafts, and boundaries of the controlled area

   C. Records providing information relevant to post-closure monitoring and assessment of performance of the repository system

   D. Records preserving for future generations information regarding the geologic setting relevant to mitigation of releases of radioactive materials

   E. Records of significant value in exercising the retrieval option for waste packages after decommissioning and closure of the repository

2. Records not falling into the categories listed above, but falling into one or more of the following categories, shall be classified as "lifetime" QA records:

A. Records used for repository permitting or certification

B. Records used to identify and assess the performance capabilities of those engineered and natural barriers important to waste isolation

C. Records of computer programs and mathematical models needed to perform ongoing correlations between performance assessment predictions and actual tests and data analyses

D. Records of significant value in demonstrating the capability for safe operation of the WIPP repository or in determining the cause of an accident or a malfunction of an item in the WIPP repository

E. Records of significant value in maintaining, reworking, repairing, replacing, or modifying WIPP repository systems, components, or structures

F. Records needed during decommissioning and closure of the repository

G. Records relating to site characterization samples and data

H. Records relating to data used in performance assessment of the WIPP facility

I. Records documenting regulatory compliance

J. Records providing required baseline data for in-service inspections

3. Lifetime QA records are required to be retained and preserved in an acceptable condition for the operating life of the repository (i.e., until termination of the repository permit). Prior to destruction of any lifetime record, it shall be evaluated for upgrade to a post-closure record

4. Records that provide objective evidence that the QA program has been properly implemented, but that do not meet the above criteria for post-closure or lifetime records shall be classified as "nonpermanent" QA records. The retention period for nonpermanent records shall be established in writing.

5. Records shall be classified in accordance with the requirements of the major regulatory requirements documents listed in Table QAPD-1. In the case of conflicts between the records requirements contained in these documents, the most stringent requirements shall be used in determining the records classification.

QAPD-2.5.5 Receiving QA Records

Each organization responsible for the receipt of QA records shall designate the person or organization responsible for receiving the records. The designee shall be responsible for organizing and implementing a system of controls for the receipt of QA records for permanent and temporary storage. At a minimum, the receipt control system shall include:

1. Provisions to permit a current and accurate assessment of the status of QA records

2. A method for identifying the records required to be included in the records system

3. A method for identifying the records that have been received

4. Procedures for the receipt and inspection of incoming records, including verification that the QA records received are in agreement with the transmittal document and that the records are legible

5. Provisions to control and protect the records from damage or loss during the receiving processes

6. A method for submittal of completed records to the storage facility without unnecessary delay

QAPD-2.5.6 Storage, Preservation, Safekeeping, and Disposition of QA Records

1. QA records shall be stored and preserved in predetermined storage facilities in accordance with approved QA implementing procedures that provide :

   A. A description of the storage facility

   B. A description of the filing and indexing systems used

   C. For records submitted to the WIPP Records Center for final storage, provisions for providing a receipt acknowledgement to the sender.

   D. A description of controls governing QA records access, retrieval, and removal

   E. A method for filing supplemental information and documenting the authorization for corrections

2. The records storage arrangements shall provide adequate protection of records, including special processed records (such as radiographs, photographs, negatives, microfilm, and magnetic media) to preclude damage from:

   A. Natural disasters such as winds, floods, or fires

   B. Environmental conditions such as high and low temperatures and humidity

   C. Infestation of insects, mold, or rodents

3. Records shall be firmly attached in binders or placed in folders or envelopes in steel file cabinets or on shelving in containers.

4. Records that require special processing and control, such as software and related documentation or information on high density media or optical disks, or hardware and

software required to maintain and access records, shall be controlled to ensure that the records are useable.

QAPD-2.5.6.1 Records Disposition

1. Lifetime QA records shall be retained and preserved in an acceptable condition for the operating life of the WIPP repository (i.e., until termination of the operating permits), or for the particular item while it is installed in the repository or is being stored for future use. Lifetime records shall be evaluated for the need to be upgraded to post-closure records prior to their destruction.

2. Waste characterization data and related QA/Quality Control (QC) records in the generator/storage site project files for TRU waste to be shipped to the WIPP facility are designated as either lifetime records or non-permanent records as specified in Attachment B of the WIPP Hazardous Waste Facility Permit. Records that are designated as lifetime records shall be maintained for the life of the waste characterization program at a participating generator/storage site plus six years, or transferred for permanent archival storage to the WIPP Records Archive facility. Waste characterization records designated as non-permanent records shall be maintained for ten years from the date of (record) generation at the participating generator/storage site, or at the WIPP Records Archive facility and then dispositioned according to their approved records inventory and disposition schedule (RIDS). If a generator/storage site ceases to operate, records shall be transferred before closeout for management at the WIPP Records Archive facility.

3. Records relevant to an enforcement action under the WIPP Hazardous Waste Permit, regardless of assigned dispositions, shall be maintained at the TRU waste site until the NMED determines that they are no longer needed for enforcement actions, and then dispositioned as required.

4. Waste characterization data for each TRU mixed waste container transmitted to WIPP shall be maintained by CBFO for the active life of the WIPP facility plus two years. The active life of the WIPP facility is defined as the period from the initial receipt of TRU mixed waste at the facility until NMED receives certification of final closure of the facility. After their active life, records shall be retired to the WIPP Records Archive facility and maintained for 30 years.

5. Design and construction of a single records storage facility shall meet the applicable requirements of NQA-1-1989, NQA-3-1989, 10 CFR 71, and current requirements of the National Archives and Records Administration (NARA).

6. The construction details shall be reviewed by a person who is competent in the technical field of fire protection and fire extinguishing to determine the adequacy of protection of contents. If the facility is located within a building or structure, the environments and construction of that building can provide a portion or all of these criteria.

7. The following criteria are acceptable alternatives to the current NARA requirements and NQA-1-1989 criteria for a single storage facility:

A. Two-hour fire-rated vault meeting the National Fire Protection Association (NFPA) 232-1986, *Standards for the Protection of Records,* or NFPA 232AM-1986, or both

B. Two-hour fire-rated Class B file containers meeting the requirements of NFPA 232-1986, or NFPA 232AM-1986, or both

C. Two-hour fire-rated file room meeting the requirements of NFPA 232-1986, or NFPA 232AM-1986, or both, with the following additional provisions:

i. Early warning fire detection and automatic fire suppression capability with electronic supervision at a constantly attended central station

ii. Records storage in fully enclosed metal cabinets

iii. Adequate access and aisle ways

iv. Prohibition in the room of work not directly associated with record storage or retrieval

v. Prohibition of smoking, eating, or drinking

vi. Two-hour fire-rated dampers or doors in all boundary penetrations

8. If storage at dual facilities for each record is provided, the facilities shall be at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard. Each facility is not required to satisfy the requirements of paragraphs 5, 6, or 7 above, but shall meet all other records storage requirements prescribed in this QAPD.

9. When temporary storage of records (such as for processing, review, or use) is required by an organization's procedures, the records shall be stored in a 1-hour fire-rated container. The procedures shall specify the maximum allowable time limit for temporary storage. The container shall bear a UL label (or equivalent) certifying one-hour fire protection, or be certified by a person competent in fire protection.

10. Access to storage facilities shall be controlled. A list designating personnel who are permitted access to the QA records shall be maintained and posted. Measures shall be established to preclude the entry of unauthorized personnel into the storage area. These measures shall guard against theft and vandalism.

11. Measures shall be taken to provide for replacement, restoration, or substitution of lost or damaged records.

12. QA records shall not be destroyed until the following conditions are met:

A. The appropriately assigned NARA authorized disposition specifies destruction

B. Regulatory requirements are satisfied

C. Operational status permits the disposal of such records

D. The related contractual requirements have been satisfied

E. In cases of conflicting requirements concerning records retention requirements, the most stringent requirements shall be used in determining the final disposition.

QAPD-2.5.7 Correcting Information in QA Records

1. Corrections to records will include the initials or signature of the authorized person making the correction and the date the correction was made.

2. Corrections to QA records shall be authorized by the originating organization.

3. Corrections to QA records should be made using a single line through and shall not obliterate the prior entry. QA records shall not be corrected with correction fluids or tapes.

QAPD-3.0 Performance Requirements

QAPD-3.1 Work Processes

1. Work shall be performed in accordance with established technical standards and administrative controls. Work shall be performed under controlled conditions using approved instructions, procedures, or other appropriate means. Items shall be identified and controlled to ensure their proper use. Items shall be maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection shall be calibrated and maintained.

2. The intent of this section is to establish the policy that those who have been assigned responsibility for performing work are responsible for achieving and maintaining quality. Those performing work have the goal of doing work correctly the first time. To ensure that those doing the work achieve that goal, management is responsible for establishing processes and procedures to ensure that all work is planned and performed under controlled conditions by personnel who are knowledgeable of the work requirements, and that these individuals are capable of accomplishing the work in accordance with the requirements of this QAPD.

3. This section further establishes management involvement in the work processes through their interactions with personnel performing the work and through their review and assessment of ongoing and completed work. This helps to ensure that the definition of "acceptable work performance" is clearly communicated and that personnel are provided the necessary training, resources, and administrative controls to properly accomplish their tasks.

QAPD-3.1.1 Work

1. Personnel performing work are responsible for the quality of their work. Because the individual worker is the first line in ensuring quality, personnel will be knowledgeable of requirements for work they perform and the capability of the tools and processes they use.

2. Line managers will ensure that personnel working under their supervision are qualified and are provided the necessary training, resources, and administrative controls to accomplish assigned tasks. Criteria describing acceptable work performance shall be defined for the worker.

3. Line managers will review work and related information to ensure that the desired quality is achieved and to identify areas needing improvement.

4. Work shall be planned, authorized, and accomplished under controlled conditions using technical standards, QA requirements, and implementing procedures commensurate with applicable control levels.

QAPD-3.1.2 Implementing Procedures

1. Implementing procedures shall be developed, reviewed, and approved by technically competent personnel.

2. Implementing procedures shall include the following information, as appropriate to the work to be performed:

   A. Responsibilities of the organizations affected by the document

   B. Technical, regulatory, quality assurance, or other program requirements

   C. Sequential description of the work to be performed, including any allowance for out-of-sequence processing

   D. Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished

   E. Prerequisites, limits, precautions, process parameters, and environmental conditions

   F. Special qualification and training requirements

   G. Verification points and hold points

   H. Methods for demonstrating that the work was performed as required (such as provisions for recording inspection and test results, check-off lists, or sign-off blocks)

   I. Identification and classification of QA records to be generated by the implementing procedure

3. Individuals performing work shall comply with implementing procedures; however, when work cannot be accomplished as described in the implementing procedure or accomplishment of such work would result in an undesirable situation, a condition adverse to quality, or an unacceptable safety risk, the work shall be suspended until the appropriate procedure change provisions are implemented.

QAPD-3.1.3 Item Identification and Control

1. Processes shall be established and maintained to identify, control, and maintain items to prevent their damage, loss, or deterioration. The identification of items shall be maintained to ensure appropriate traceability. Traceability requirements shall be specified in design documents or implementing procedures. Processes shall be established and implemented to control consumables and items with limited operating or shelf life and to prevent the use of incorrect or defective items.

2. The following controls shall be established to ensure that only correct and accepted items are used or installed:

   A. Items shall be identified and traced from the time of receipt, up to and including installation or end use. Records shall be maintained to ensure that the item can be traced at all times, from its source through installation or end use.

B. Item identification methods shall include physical markings. If physical markings are either impractical or insufficient, other appropriate means shall be employed (such as physical separation, labels or tags attached to containers, or procedural controls). When used, physical markings shall:

i. Be applied using materials and methods that provide clear, permanent, and legible identification

ii. Not be detrimental to the function or service life of the item

iii. Be transferred to each part of an identified item when the item is subdivided

iv. Not be obliterated or hidden by surface treatments, coatings, or installation unless other means of identification are substituted

C. If codes, standards, or specifications include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification or grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other record(s)), then identification and traceability methods shall be implemented to ensure the special requirements are met.

D. Item identification control system records shall provide the inspection, test, and operating status of items. Items that have satisfactorily passed the required inspections and tests shall be identified. The identification methods shall preclude the inadvertent installation, use, or operation of items that have not passed required inspections and tests.

E. The status of inspections and tests shall be identified either on the items or in documents traceable to the items. Status shall be maintained through the use of status indicators (such as tags, markings, labels, or stamps) or other means (such as inspection or test records), and the authority for applying and removing status indicators shall be specified.

QAPD-3.1.4 Special Processes

1. Processes shall be considered as special processes if they meet any one or a combination of the following criteria:

A. The results are highly dependent on the control of the process

B. The results are highly dependent on the skill of the operator

C. The quality of the results cannot be readily determined by inspection or test of the product

2. Implementing procedures shall be developed and implemented to ensure that special process parameters are controlled and specified environmental conditions are maintained. In addition to the requirements provided in Section QAPD-3.1.2, special process implementing procedures shall include or reference:

A. The requirements for training/qualification of personnel and quality processes/equipment

B. The conditions necessary for completion of the special process, including equipment, statistical process control, controlled parameters of the process, and calibration requirements

QAPD-3.1.5 Handling, Storage, and Shipping

1. Handling, storage, cleaning, shipping, and other means of preserving, transporting, and packaging of items shall be conducted in accordance with established work and inspection procedures, shipping instructions, or other specified documents.

2. If required for critical, sensitive, perishable, or high-value articles, specific implementing procedures for handling, storage, cleaning, packaging, shipping, and other preservation shall be prepared and used.

3. Measures shall be established and implemented for the marking and labeling of items for packaging, shipping, handling, and storage as necessary to adequately identify, maintain, and preserve the item. Markings and labels shall indicate the presence of special environments or the need for special controls, as necessary, and shall be applied and removed by authorized personnel.

4. If required for protection or maintenance of particular items, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas and specific moisture and temperature levels) shall be specified, planned for, and provided.

   A. If special protective equipment and environments are used, provisions shall be made for verifying their adequacy.

   B. Special handling tools and equipment shall be used and controlled, as necessary, to ensure safe and adequate handling.

   C. Special handling tools and equipment shall be inspected and tested at specified intervals and in accordance with implementing procedures to verify that the tools and equipment are adequately maintained.

   D. Operators of special handling and lifting equipment shall be sufficiently experienced and trained to use the equipment.

5. If storage of items is required, methods shall be established for the control of item identification records that are commensurate with the planned duration and conditions of storage. These methods shall provide for, as applicable:

   A. Maintenance or replacement of markings and identification tags damaged during handling or aging

B. Protection of identification markings that are subject to excessive deterioration due to environmental exposure

C. Update of related identification records and documentation

6. Status indicators, such as tagging valves and switches to prevent inadvertent operation, shall be used to indicate the operating status of items. Status indicators, such as lockout tags, shall also be used where appropriate and shall be applied and removed by authorized personnel.

QAPD-3.2 Design Control

1. Items and processes shall be designed using sound engineering and scientific principles and appropriate standards. Design work, including changes, shall incorporate appropriate requirements, such as general design criteria and design bases. Design interfaces shall be identified and controlled.

2. The adequacy of design products shall be verified by individuals or groups other than those who performed the design work. Required verification and validation shall be completed before approval and implementation of the design.

3. Designs (from conceptual through final) shall be defined, controlled, and verified. In establishing design controls, management is responsible for ensuring that design inputs are technically correct; that design interfaces are identified; that authorities, responsibilities, and lines of communication are clearly defined; and that the design processes clearly define the acceptance criteria for the product.

QAPD-3.2.1 Design Input

Applicable design inputs such as design bases, conceptual design reports, performance requirements, regulatory requirements, codes, and standards shall be controlled by those responsible for the design in accordance with the following requirements:

1. Design inputs shall be identified and documented and their selection reviewed and approved by those responsible for the design.

2. Design inputs shall be specified and approved on a timely basis to the level of detail necessary to permit the design work to be carried out correctly in a manner that provides a consistent basis for making design decisions, accomplishing design verification, and evaluating design changes.

3. Changes from approved design inputs and reasons for the changes shall be identified, approved, documented, and controlled.

4. Design inputs based on assumptions that require reverification shall be identified and controlled.

QAPD-3.2.2 Design Process

The design process shall be controlled according to the following requirements:

1. Appropriate standards shall be identified and documented and their selection reviewed and approved. Changes from specified standards, including the reasons for the change, shall be identified, approved, documented, and controlled.

2. Design work shall be prescribed and documented on a timely basis and to the level of detail necessary to permit the design process to be carried out correctly.

3. Design documents shall be adequate to support design, fabrication, construction, and operation.

4. Design documents shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can understand the documents and verify their adequacy without recourse to the originator.

5. Controls for identifying assemblies or components that are part of the item being designed shall be established. If a commercial grade assembly or component is modified or selected by special inspection or testing to meet requirements that are more restrictive than the supplier's published product description, then the assembly or component shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

6. Controls for selecting and reviewing design methods, materials, parts, equipment, and processes essential to the function of an item shall be established.

7. Drawings, specifications, and other design output documents shall contain appropriate inspection and testing acceptance criteria.

QAPD-3.2.3 Design Analyses

1. Design analyses shall be planned, controlled, and documented.

2. Documentation of design analyses shall include

   A. Definition of the objective of the analyses

   B. Definition of design inputs and their sources

   C. Results of literature searches or other applicable background data

   D. Identification of assumptions and designation of those assumptions that shall be verified as the design proceeds

E. Identification of any computer calculations, including computer type, computer software name, revision identification, inputs, outputs, and the bases (or reference thereto) supporting application of the software to the specific physical problem.

F. Identification of the reviewer and the approver

3. Calculations shall be identifiable by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date, or by other designator such that the calculations are traceable.

4. Computer software used to perform design analyses shall be developed, qualified, and used according to the requirements of QAPD-7.0.

QAPD-3.2.4 Design Interface

1. Design interfaces shall be identified, documented, and controlled so that efforts are coordinated among participating organizations.

2. Design interface controls shall including the assignment of responsibility and the establishment of implementing procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces

3. Design information transmitted across interfaces shall be documented and controlled.

4. The status of the design information or issued design documents shall be identified in transmittals. Where necessary, incomplete designs that require further evaluation, review, or approval shall be identified.

QAPD-3.2.5 Design Verification

The acceptability of design work and documents, including design inputs, processes, outputs, and changes, shall be verified. The following design control requirements shall be applied to verify the adequacy of design:

1. Design verification shall be performed using one or a combination of the following methods:

A. Design review

B. Alternate calculations

C. Qualification testing

2. The particular design verification method shall be identified and its use justified.

3. The results of design verification shall be clearly documented, including the identification of the verifier.

4. Design verification shall be performed by competent individuals or groups other than those who performed the original design (but they may be from the same organization). If necessary, this design verification may be performed by the originator's supervisor, provided that:

   A. The supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design.

   B. The supervisor is the only individual in the organization competent to perform the verification.

   C. The determination to use the supervisor is documented and approved in advance.

5. Design verification shall be performed at appropriate times during the design process.

   A. Verification shall be performed before release for procurement, manufacture, construction, or release to another organization for use in other design work.

   B. Design verification shall be completed before relying on an item to perform its function.

6. The extent of the design verification required shall be based on the complexity, risk, uniqueness of design, complexity of design, degree of standardization, state of the art, and similarity to previously proven designs. When the design has been subjected to a verification process in accordance with this QAPD, the verification process need not be duplicated for identical designs.

7. Use of previously proven designs shall be controlled according to the following requirements:

   A. The applicability of standardized or previously proven designs shall be verified with respect to meeting pertinent design inputs for each application.

   B. Known problems affecting standard or previously proven designs and their effects on other features shall be considered.

   C. The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design.

   D. Changes in previously verified designs shall require reverification. Such reverifications shall include the evaluation of the effects of those changes on the overall previously verified design and on any design analyses upon which the design is based.

QAPD-3.2.6 Design Reviews

1. Design reviews shall be controlled, documented, and performed, and shall consider the following:

   A. Design inputs were correctly selected and incorporated.

B. Assumptions necessary to perform the design work were adequately described, reasonable, and reverified as necessary.

C. Appropriate design methods were used.

D. Design output is reasonable compared to design inputs.

E. The necessary design input and verification requirements for interfacing organizations were specified in the design documents or in supporting implementing procedures.

2. Disposition of design review comments shall be documented.

QAPD-3.2.7 Alternative Calculations

Alternative calculations are calculations or analyses that are made using alternate methods to verify correctness of the original calculations or analyses. The appropriateness of any assumptions, the input data used, any computer programs, or other calculation methods used, shall be evaluated.

QAPD-3.2.8 Qualification Testing

If design adequacy is to be verified by qualification tests, the tests shall be pre-identified. When qualification testing is used, the following requirements shall apply:

1. The test configuration shall be defined and documented.

2. Testing shall demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions.

3. If the tests verify only specific design features, the other features of the design shall be verified by other means.

4. Test results shall be documented and evaluated by the responsible design organization to ensure that test requirements have been met.

5. If qualification testing indicates that a modification to an item is necessary to obtain acceptable performance, the modification shall be documented and the modified item retested or otherwise verified to ensure satisfactory performance.

6. Scaling laws shall be established and verified when tests are being performed on models or mockups.

7. The results of model test work shall be subject to error analysis, where applicable, before the results are used in final design work.

QAPD-3.2.9 Design Change

Design changes shall be controlled in accordance with the following requirements:

1. Changes to final designs, field changes, and nonconforming items dispositioned "use as is" or "repair" shall be justified and shall be subject to design control measures commensurate with those applied to the original design.

2. Design control measures for changes shall include provisions to ensure that the design analyses for the item are still valid.

3. Changes shall be approved by the same groups or organizations that reviewed and approved the original design documents, with the following considerations:

   A. If an organization that originally was responsible for approving a particular design document is no longer responsible, the new responsible organization shall be designated.

   B. The cognizant design organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.

4. When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into these documents, where such incorporation is appropriate.

5. If a significant design change becomes necessary because of an incorrect original design, the design process and design verification methods and implementing procedures shall be reviewed and modified as appropriate. These design deficiencies shall be documented according to the requirements provided in Section QAPD-2.3.2.

6. Field changes shall be incorporated into the applicable design documents.

7. Design changes that affect related implementing procedures or training programs shall be communicated to the appropriate organizations.

QAPD-3.3 Procurement

CBFO and participant organizations shall ensure that procured items and services meet established technical and QA requirements, and that they perform as specified. Prospective suppliers shall be evaluated and selected on the basis of documented criteria. The responsible organization shall verify that approved suppliers continue to provide acceptable items and services.

QAPD-3.3.1 Procurement Planning Requirements

The processes for procurement and design control described in this QAPD are sufficient to implement the requirements associated with Suspect/Counterfeit Items (S/CI) Prevention described in DOE O 414.1C, Attachment 3. The process of this section is consistent with the

CBFO activity hazards and mission impact. The CBFO Program Participant in Procurement and Engineering Managers are responsible for compliance with the applicable requirements.

The waste generator sites are responsible for developing a S/CI Prevention program/process in accordance with DOE O 414.1C, Attachment 3, as directed by the appropriate site office.

Procurement activities shall be planned as early as possible. At a minimum, the activities shall be planned no later than the start of those procurement activities that are required to be controlled. Procurement planning shall be documented to ensure a systematic approach to the procurement process. Procurement planning shall:

1. Identify procurement methods and organizational responsibilities, including the appropriate QA organization

2. Identify and document the sequence of actions and milestones needed to effectively complete the procurement

3. Provide for the integration of the following activities:

    A. Procurement document preparation, review, and change control

    B. Selection of procurement sources

    C. Proposal or bid evaluation and award

    D. Purchaser evaluation of supplier performance

    E. Purchaser verifications including any hold-point and witness-point notifications

    F. Control of nonconformances

    G. Corrective action

    H. Acceptance of the item or service

    I. Identification of QA records

QAPD-3.3.2 Supplier Selection

1. Supplier selection shall be based on evaluation of the supplier's capability to provide items or services in accordance with procurement document requirements

2. Organizations responsible for supplier source selection shall be identified and shall include the appropriate QA organization.

3. Measures for selecting procurement sources shall include one or more of the following elements:

A. An evaluation of the supplier's history for providing an identical or similar product that performs satisfactorily in actual use

B. An evaluation of the supplier's current QA documentation, supported by any documented qualitative and quantitative information

C. An evaluation of the supplier's technical and QA capability, based on an evaluation of the supplier's facilities, personnel, and quality program implementation

4. D. The results of procurement source selection shall be documented.

QAPD-3.3.3 Proposal/Bid Evaluation

1. The proposal or bid evaluation process shall include a determination of the extent of conformance to the procurement document requirements. This evaluation shall be performed by designated, technically qualified personnel, including the quality assurance organization, and shall include, at a minimum, the following:

A. Technical considerations

B. QA program requirements

C. Supplier personnel skills

D. Supplier production capabilities

E. Supplier past performance

F. Alternatives proposed by the supplier

G. Exceptions taken by the supplier

2. Before the contract is awarded, the purchaser shall resolve, or obtain commitments to resolve, deficiencies identified during the proposal or bid evaluation.

3. Supplier QA provisions shall be accepted by the purchaser QA management before the supplier is authorized to start work.

QAPD-3.3.4 Procurement Document Requirements

Procurement documents shall include the following, as applicable to the item or service being procured:

1. The scope of work

2. Technical requirements, including the following:

A. Design bases shall be identified or referenced.

B. Specific documents (such as drawings, codes, standards, regulations, DOE orders, procedures, or instructions) that describe the technical requirements of the items or services to be furnished shall be identified. The revision level or change status of these documents shall also be identified.

C. Tests, inspections, hold points, or acceptance criteria that the purchaser shall use to monitor and evaluate the performance of the supplier shall be specified.

3. QA provisions specified by the purchaser QA organization shall include:

A. The requisite QA and documentation requirements, depending on the control level of the item or service being procured

B. The pass-down requirements that the supplier shall incorporate into any sub-tier procurement document

C. When deemed appropriate, the purchaser may permit some or all supplier work to be performed under the purchaser QA program, provided that the requirements are adequately implemented. In these cases, procurement documents shall specify that the purchaser's QA implementing procedures are applicable to the supplier and that the purchaser shall provide these applicable documents to the supplier.

D. Right of access to supplier facilities and records for inspection and audit by the purchaser, CBFO, or other designee authorized by the purchaser

E. The requirements of Section QAPD-2.5 and provisions for disposition, if the supplier is required to maintain QA records

F. Requirements for the supplier to report nonconformances and obtain purchaser approval of supplier-recommended dispositions

G. Spare and replacement parts or assemblies and the appropriate technical and QA requirements for ordering

QAPD-3.3.5 Procurement Document Review and Approval

1. A review of the procurement documents and any changes thereto shall be made to verify that documents include appropriate provisions to ensure that items or services meet the prescribed requirements. Procurement document changes shall be subject to the same degree of control as the original documents.

2. Procurement document reviews shall be performed and documented prior to the document being issued to the supplier.

3. Reviews shall be performed by personnel who have access to pertinent information and who have adequate understanding of the requirements and scope of the procurement.

4. Procurement document reviews shall include representatives from the technical and QA organizations and shall be approved by responsible management.

QAPD-3.3.6 Supplier Performance Evaluation

The purchaser of items and services shall establish measures to interface with the supplier and to verify supplier performance, as deemed necessary by the purchaser. The measures shall include:

1. Establishing an understanding between the purchaser and supplier of the requirements and specifications identified in the procurement documents

2. Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements

3. Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement requirements

4. Identifying and processing necessary change information

5. Establishing the method to be used to document information exchanges between purchaser and supplier

6. Establishing the extent of assessment activities and inspection

QAPD-3.3.7 Acceptance of Items or Services

1. Methods shall be established for the acceptance of an item or service being furnished by a supplier.

2. Prior to offering an item or service for acceptance, the supplier shall verify that the item or service complies with the procurement requirements.

QAPD-3.3.7.1 Source Verification

1. The purchaser may accept an item or service by monitoring, auditing, surveilling, witnessing, or observing activities performed by the supplier. This method of acceptance is called source verification.

2. The extent of source verification shall be a function of the relative importance, complexity, and quantity of items or services being procured, as well as the supplier's quality of performance. Source verifications shall be accomplished as early as possible, but prior to the start of those activities that are required to be controlled, and shall include the active involvement of the purchaser's QA organization. In addition:

    A. Source verification shall be accomplished consistent with the supplier's planned inspections, examinations, or tests and performed at intervals consistent with the importance and complexity of the item.

B. Documented evidence of acceptance of source-verified items or services shall be furnished to the party receiving the item, to the purchaser, and to the supplier.

C. Source verification shall be performed by qualified personnel.

3. For procurement of services only (such as third party inspection, engineering and consulting services), and installation, repair, overhaul, or maintenance work, the purchaser shall accept the service by any or all of the following methods:

A. Technical verification of data produced

B. Surveillance and/or audit of the activity

C. Review of objective evidence for conformance to the procurement document requirements such as certifications or test reports

QAPD-3.3.7.2 Receiving Inspection

When a receiving inspection is used to accept an item:

1. The inspection shall include consideration of source assessments, verifications and audits and the demonstrated quality performance of the supplier.

2. The inspection shall be performed in accordance with established inspection procedures or instructions.

3. The inspection shall verify, as applicable, proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness.

4. The inspection shall be planned and executed in accordance with the applicable requirements of Section QAPD-3.4.

5. Receiving inspection shall include a review of the adequacy and completeness of any required supplier documentation.

QAPD-3.3.7.3 Post-Installation Testing

When post-installation testing is used as a method of acceptance, post-installation test requirements and acceptance documentation shall be mutually established and agreed upon by the purchaser and supplier.

QAPD-3.3.7.4 Supplier Certificate of Conformance

When a certificate of conformance is used, the following, at a minimum, shall be met:

1. The certificate shall identify the purchased material or equipment, including the purchase order and item number or other identification that is traceable to the requirements of the procurement document.

2. The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.

3. The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformances.

4. The certificate shall be signed or otherwise authenticated by an official of the supplier organization, whose function and position are described in the supplier's QA program.

5. The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificate, shall be described in the purchaser or supplier QA program.

6. Means shall be provided to verify the validity of supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the supplier or independent inspection or test of the items. Such verification shall be conducted by the purchaser at intervals commensurate with the supplier's past quality performance.

QAPD-3.3.8 Control of Supplier Nonconformances

The purchaser and supplier shall establish and document the process for dispositioning items and services that do not meet procurement document requirements in accordance with the following:

1. The supplier shall submit a report of nonconformance to the purchaser that includes supplier-recommended disposition (for example, "use as is" or "repair") and provide technical justification for such disposition.

2. Reports of nonconformances to procurement document requirements or documents approved by the purchaser shall be submitted to the purchaser for approval. Examples of conditions requiring a report of nonconformance include:

    A. Failure to meet technical or material requirements

    B. Failure to meet a requirement in supplier documents that have been approved by the purchaser

    C. The nonconformance cannot be corrected by continuation of the original manufacturing process or by rework

    D. The item does not conform to the original requirement even though the item can be restored to a condition such that its capability to function is unimpaired (i.e., a waiver is requested)

3. The purchaser shall evaluate the supplier-recommended disposition.

4. The purchaser shall verify implementation of the disposition.

QAPD-3.3.8.1 Commercial Grade Items

Where the design specifies the use of commercial grade items, the following requirements are an acceptable alternative to other requirements of this section.

1. The commercial grade item shall be identified in an approved design output document, such as a drawing, specification, or other document translated from a design input document. An alternative commercial grade item may be applied as long as the responsible design organization provides verification that the alternative commercial grade item performs the intended function and meets design requirements that are applicable to both the replaced item and its application.

2. Source evaluation and selection, where determined necessary by the purchaser based on complexity and importance to compliance application, waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP facility, shall be in accordance with Section QAPD-3.3.2.

3. Commercial grade items shall be identified in the procurement document by the manufacturer's published product description.

4. After receipt of a commercial grade item, the purchaser shall ensure that:

   A. Damage was not sustained during shipment

   B. The item received was the item ordered

   C. Inspection or testing is accomplished, to the extent determined by the purchaser, to ensure conformance with the manufacturer's published requirements

   D. Documentation, as applicable to the item, was received and is acceptable

QAPD-3.4 Inspection and Testing

1. Inspections and testing shall be performed in accordance with approved implementing procedures. An essential part of the work planning process is to identify the items and processes to be inspected or tested, the parameters or characteristics to be evaluated, the techniques to be used, the acceptance criteria, any hold points, and the organizations responsible for performing the tests and inspections. Inspection for acceptance shall be performed by personnel other than those who performed or directly supervised the work being inspected. Inspection and testing of specified items and processes shall be conducted using established acceptance and performance criteria. The acceptance of items and processes shall be made by and documented by qualified and authorized personnel. Equipment used for inspections and tests shall be calibrated and maintained.

2. Inspection and testing activities shall be conducted in accordance with the following requirements, as applicable.

QAPD-3.4.1 Qualification of Inspection and Test Personnel

This section provides amplified requirements for the qualification of personnel who perform inspection and testing to verify conformance to specified requirements for the purpose of acceptability. The requirements of this section do not apply to the qualification of personnel for performance of nondestructive examination. Qualification of personnel for nondestructive examination is addressed in Section QAPD-3.4.2.

1. The responsible organization shall designate those activities that require qualified inspection and test personnel and the minimum requirements for such personnel. Further, the responsible organization shall establish written procedures for the qualification of inspection and test personnel and for the assurance that only those personnel who meet the requirements of this section are permitted to perform applicable inspection and test activities.

2. When a single inspection or test requires implementation by a team or a group, personnel not meeting the requirements of this section may be used in data-taking assignments or in plant or equipment operation, provided they are supervised or overseen by a qualified individual.

3. Personnel selected for performing inspection and test activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities.

4. Provisions shall be made for the indoctrination of personnel to the technical objectives and requirements of the applicable codes and standards and the QA program controls that are to be employed.

5. The need for a formal training program shall be determined, and such training activities shall be conducted as required to qualify personnel that perform such inspections and tests. On-the-job training shall also be included in the program, as appropriate, with emphasis on first-hand experience gained through actual performance of inspections and tests.

6. The capabilities of a candidate for certification shall be initially determined by a suitable evaluation of the candidate's previous education, experience, training, and either test results or capability demonstration.

7. The job performance of inspection and test personnel shall be reevaluated for capability at periodic intervals, not to exceed three years. Reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability in accordance with the above requirements. If, during this evaluation or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated. Any person who has not performed inspection or testing activities in their qualified area for a period of one year shall be reevaluated for the required capability in accordance with the above requirements.

8. The qualification of personnel shall be certified in writing in an appropriate form and shall include the following information:

A. Employer's name

B. Identification of person being certified

C. Activities certified to perform

D. Basis used for certification, including such factors as: (1) education, experience, indoctrination, and training; (2) test results, where applicable; and (3) results of capability demonstration

E. Results of periodic evaluation

F. Results of physical examinations, when required

G. Signature of the employer's designated representative responsible for such certification

H. The date of certification and date of certification expiration

9. The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination.

10. Records of personnel qualification shall be established and maintained by the employer. These records shall include the information required above for certification.

QAPD-3.4.2 Qualification of Nondestructive Examination Personnel

This section identifies the requirements for the qualification of personnel who perform nondestructive examination (NDE) (radiographic, magnetic particle, ultrasonic, liquid penetrant, eddy current, neutron radiographic, leak testing, and visual testing) to verify conformance to specified requirements, for nondestructive examination activities.

1. The American Society of Nondestructive Testing (ASNT) Recommended Practice No. SNT-TC-1A, June 1980 Edition, and its applicable supplements, shall apply as requirements for personnel performing the above methods of NDE. Later editions of SNT-TC-1A may be used as the basis for the qualification of NDE personnel, as long as the minimum requirements of the June 1980 edition are met.

2. The responsible organization shall establish written procedures for the control and administration of the training, examination, and certification of NDE personnel.

3. Records of personnel qualification shall be established and maintained by the employer.

QAPD-3.4.3 Inspection

QAPD-3.4.3.1 Inspection Planning

1. Inspection planning shall be performed and documented and shall include:

A. Identification of work operations where inspections are necessary

B. Identification of the characteristics to be inspected and when during the work process inspections are to be performed

C. Identification of inspection or process monitoring methods to be employed

D. Identification of acceptance criteria

E. Identification of sampling requirements

F. Methods to record inspection results

G. Selection and identification of the measuring and test equipment (M&TE) to be used to perform the inspection

H. Process used to ensure that the equipment being utilized for inspection or testing is calibrated and is of the proper type, range, accuracy, and tolerance to accomplish the intended function

2. When statistical sampling is to be used to verify the acceptability of a group of items, the sampling method shall be based on recognized standard practices.

QAPD-3.4.3.2 Inspection Hold Points

Hold points are used to control work that is not to proceed without the specific consent of the organization placing the hold point. The specific hold points shall be indicated in appropriate documents. Only the organization responsible for the hold point may waive the hold point. Approval to waive specified hold points shall be documented before continuing work beyond the designated hold point.

QAPD-3.4.3.3 In-Process Inspections and Monitoring

1. Items in process shall be inspected as necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be conducted when control is deemed inadequate, using only one of these methods.

2. When a combination of inspection and process monitoring methods is used, monitoring shall be performed systematically to ensure that the specified requirements for control of the process and the quality of the item are met throughout the duration of the process.

3. Controls shall be established and documented for the coordination and sequencing of the work at established inspection points during successive stages of the process.

QAPD-3.4.3.4 Final Inspections

1. Final inspections shall include a review of the results and the verification of the resolution of all nonconformances identified by earlier inspections.

2. Finished items shall be inspected for completeness, markings, calibration, protection from damage, or other characteristics, as required to verify the quality and conformance of the item to the applicable requirements.

3. Records review shall be performed to ensure adequacy and completeness.

4. Item modifications, repairs, or replacements that are performed subsequent to final inspection shall require reinspection or retest, as appropriate, to verify acceptability.

QAPD-3.4.3.5 In-service Inspections

1. Required in-service inspection or surveillance of structures, systems, or components shall be planned and executed by or for the organization responsible for their operation.

2. Inspection methods shall be established and executed to verify that the characteristics of an item continue to remain within specified limits.

3. Inspection methods shall include evaluations of performance capability of essential emergency and safety systems and equipment, verification of calibration and integrity of instruments and instrument systems, and verification of maintenance, as appropriate.

QAPD-3.4.3.6 Inspection Documentation

Inspection documentation shall identify:

1. The item inspected and the date of the inspection

2. The name or unique identifier of the inspector who documented, evaluated, and determined acceptability

3. The method of inspection

4. The inspection criteria, sampling plan, or reference documents (including revision designation) used to determine acceptance

5. The results

6. The M&TE used during the inspection, including the identification number and the calibration due date

7. Reference to any information on actions taken in connection with nonconformances, as applicable

QAPD-3.4.4 Test Requirements

Testing shall be used to determine the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions. Examples of such tests include prototype qualification tests, production tests, proof tests prior to installation, construction tests, and pre-operational tests.

QAPD-3.4.4.1 Test Planning

Test planning shall include:

1. The identification of the implementing procedures to be developed to control and perform the test. In lieu of specially prepared written test procedures, appropriate sections of related documents such as American Society for Testing and Materials (ASTM) methods may be used. If used, they shall incorporate the information directly into the approved test implementing procedure, or shall be incorporated by reference.

2. The identification of the item to be tested and the test requirements and acceptance limit, including the required levels of precision and accuracy

3. The identification of the M&TE to be used to perform the test to ensure that the equipment being utilized is calibrated and is of the proper type, range, accuracy, and tolerance to accomplish the intended function

4. Any test prerequisites, including test equipment, instrumentation and software needs, personnel training and qualification, and suitably controlled environmental conditions

5. Any mandatory hold points

6. The methods to be used to record data and results

7. The provisions for ensuring that prerequisites for the given test have been met

QAPD-3.4.4.2 Test Documentation

Test documentation shall identify:

1. The applicable test requirements, plans, and procedures, including revisions

2. The item or work product tested

3. The date of the test

4. The name of the tester and data recorders

5. The type of observation and method of testing

6. The identification of test criteria or reference documents used to determine acceptance

7. The results and acceptability of the test

8. The actions taken in connection with any noted nonconformances

9. The name of the person evaluating the test results

10. The identification of the M&TE used during the test (including the identification number and calibration due date)

QAPD-3.4.4.3 Test Results

Test results shall be documented and their conformance with acceptance criteria shall be evaluated by a qualified individual within the responsible organization to ensure that all test requirements have been satisfied.

QAPD-3.4.5 Monitoring, Measuring, Testing, and Data Collection Equipment

The following sections establish requirements to ensure that equipment used for inspection and testing is properly controlled, calibrated, and maintained. Equipment discussed in the following sections includes inspection and test equipment, measuring and data collection equipment, equipment (either hand-held or installed) used for data indication, and other equipment used for data indication, collection, or evaluation. These are called M&TE.

Calibration and control measures may not be required for rulers, tape measures, levels, and other such devices, if normal commercial equipment provides adequate accuracy.

QAPD-3.4.6 Use and Control of M&TE

Each organization using M&TE shall:

1. Establish and document a system to control the use and calibration of M&TE

2. Have a program to recall for calibration, or remove from service, M&TE that has exceeded its calibration interval; has broken calibration seals; has been modified, repaired, or has had components replaced; or is suspected to be malfunctioning because of mishandling, misuse, or unusual results

3. Establish and maintain documented procedures to evaluate the adequacy of the calibration system and to ensure compliance with the requirements of this QAPD

4. Maintain records documenting that established M&TE schedules and procedures have been followed. These records shall include an individual record of calibration, or other means of control, providing:

    A. A description or identification of the item

    B. Calibration interval

C. Date calibrated

D. Identification of the calibration source

E. Calibration results (data and status)

F. Calibration action taken (e.g., adjusted, repaired, new value assigned, derated)

G. Evaluation and corrective action taken in response to out-of-calibration conditions

5. Label all M&TE to indicate the calibration status, the date calibrated, the calibration due date or usage equivalent, and the identification of any limitations. (When it is impractical to apply a label directly to an item, the label may be affixed to the instrument container or some other suitable means may be used to reflect calibration status.)

6. Evaluate the validity of previous inspection and test results and the acceptability of related items, data collected, and processes monitored, when M&TE is found to be out-of-calibration

7. Handle, store, and transport M&TE in a manner that does not adversely affect the accuracy of the equipment

8. Give due consideration to temperature, humidity, lighting, vibration, dust control, cleanliness, electromagnetic interference, and any other factors affecting the results of measurements. Where pertinent, these factors shall be monitored and recorded and, when appropriate, correcting compensations shall be applied to measurement results.

QAPD-3.4.7 Calibration

1. M&TE requiring calibration shall be calibrated at periodic intervals established and maintained to ensure acceptable reliability, where reliability is described as the probability that M&TE will remain in tolerance throughout the interval.

2. M&TE shall be calibrated to provide traceability of the calibration against certified equipment having known valid relationships to nationally recognized standards. If nationally recognized standards do not exist, the bases for calibration shall be documented.

3. Intervals shall be established for all M&TE requiring calibration unless the equipment is regularly monitored through the use of check standards in a documented measurement assurance process. Check standards must closely represent the item parameters normally tested in the process, and the check standard must be verified periodically.

4. Where intervals are used to ensure reliability, the interval setting system must be systematically applied and shall have stated reliability goals and a method of verifying that the goals are being attained.

5. Intervals may be based on usage or time since last calibration.

6. All exemptions from periodic calibration shall be approved and documented.

7. The recall system may provide for the temporary extension of the calibration due date for limited periods of time under specified conditions that do not unreasonably impair the satisfaction of task objectives.

8. If any M&TE is found to be significantly out-of-tolerance during the calibration process, the cognizant organization shall provide for the notification to the user and cognizant QA management of the out-of-tolerance condition, with the associated measurement data, so that appropriate action can be taken.

QAPD-4.0 Assessment Requirements

QAPD-4.1 Management Assessment

Managers at every level shall periodically assess the performance of their organization to determine the effectiveness of QA program provisions that enable the organization to meet customer requirements and expectations. This assessment shall emphasize the use of human and material resources to achieve organizational goals and objectives.

1. The management assessment should include an introspective evaluation to determine if the entire integrated management system effectively focuses on meeting strategic goals.

2. Managers shall retain overall responsibility for management assessments. Direct participation by senior management is essential to the success of the process because management is in the position to view the organization as a total system.

3. Management assessments should focus on the identification and resolution of both systemic and management issues and problems. Strengths and weaknesses affecting the achievement of organizational objectives should be identified so that meaningful action can be taken to improve quality.

4. Processes being assessed should also include strategic planning, organizational interfaces, cost control, use of performance indicators, staff training and qualifications, and supervisory oversight and support. Effective management assessments should evaluate such conditions as the state of employee knowledge, motivation, and morale; the amount of mutual trust and communication among workers and organizations; the existence of an atmosphere of creativity and improvement; and the adequacy of human and material resources.

5. Management assessments of the QA program shall be conducted regularly and reported at least annually to an identified senior management level with sufficient authority to effect corrective measures, as necessary.

6. Management assessment results should be used as input to the organizational continuous improvement process.

QAPD-4.2 Independent Assessment

1. Planned and periodic independent assessments shall be conducted to measure item and service quality, process effectiveness, and promote improvement. The organization performing assessments shall have sufficient authority and freedom from the activities being assessed to carry out its responsibilities. Persons conducting independent assessments shall be technically qualified and knowledgeable of the items and activities being assessed.

2. The types and frequencies of independent assessments shall be based upon the relevant control levels assigned to the items and activities under the cognizance of the organization.

3. The CBFO and participant organizations responsible for the performance of activities important to compliance application, waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP site shall implement a program of surveillance and audits. The program shall be planned and documented and shall include both routine surveillance of those activities and audits to verify compliance with all aspects of the quality assurance program and to determine its adequacy and effectiveness.

QAPD-4.2.1 Surveillances

1. A program of surveillance of the activities referenced above shall be planned, performed, documented, and reported to appropriate management personnel. The surveillance process consists of monitoring or observing to verify whether an item, activity, system, or process conforms to specified requirements.

2. Surveillances shall accomplish the following:

   A. Monitor work in progress

   B. Document compliance or noncompliance with established requirements and procedures

   C. Identify actual and potential conditions adverse to quality

   D. Obtain timely corrective action commitment from cognizant managers for identified conditions adverse to quality

   E. Provide notification to responsible managers of the status and performance of work under surveillance

   F. Verify timely implementation of corrective actions

3. Audits or other independent assessments of the subject activities, conducted by the responsible organization, may be counted as satisfying the requirement to do surveillances of related activities in the corresponding surveillance schedule period.

QAPD-4.2.2 Audits

The following sections describe the audit process requirements.

QAPD-4.2.2.1 Scheduling Audits

1. Audits shall be 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 assigned control level. The audit schedule shall be reviewed periodically and revised as necessary to assure that coverage is maintained current.

2. Periodically scheduled QA program audits shall be supplemented by, or integrated with, either audits or surveillances of a technical nature (e.g., performance-based audits) which assess the quality of selected work products and work processes.

QAPD-4.2.2.2 Planning and Preparation for Audits

The organization performing the audit shall develop and document a plan for each audit.

1. The plan shall include the scope, requirements, purpose, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists to be used.

2. Audit planning shall include a review of past assessment results to determine the nature of problems that have occurred. When recurring problems are found, the audit team shall review corrective actions that have been taken and attempt to determine whether the corrective actions were effective in preventing recurrence.

3. Audit preparation shall include review of pertinent background information, procedures, and technical documents so that audit team members are familiar with the work being audited.

4. Audits shall include technical evaluations of the applicable procedures, instructions, activities, and items, as appropriate.

5. The scope shall include related corrective actions taken since the previous assessment.

QAPD-4.2.2.3 Audit Team Selection

1. Audit team members shall be identified prior to the start of the audit activity. The team members shall be selected on the basis of technical qualifications and knowledge of the item or process being audited and shall be independent from the items or processes being audited. Audit team members shall have sufficient authority and organizational freedom to carry out their assigned responsibilities. In the case of internal audits, personnel having direct responsibility for performing the activities being audited shall not be involved in the selection of the audit team.

2. An audit team leader shall be appointed to provide indoctrination and supervision of the team, organize and direct the audit, and coordinate the preparation and issuance of the audit report.

3. Before starting the audit, the audit team leader shall ensure that the assigned personnel collectively have experience and training commensurate with the scope, complexity, or special nature of the work to be audited.

4. Technical specialists, with appropriate technical expertise or experience in the work being audited, shall be used when auditing the adequacy of technical processes.

QAPD-4.2.2.4 Auditor Qualification

Auditors shall be technically qualified in their assigned roles. In addition, they shall have appropriate training or orientation to develop their competence for performing audits. Competence of personnel performing various audit functions shall be developed by one or more of the following methods:

1. Orientation to provide a working knowledge and understanding of the QA program requirements and the auditing organization's implementing procedures used to perform audits and report audit results

2. Training programs that provide general and specialized training in audit performance, including fundamentals, objectives, characteristics, organization, performance, and results of quality auditing. Training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of evaluating the effectiveness of corrective actions for conditions adverse to quality.

3. On-the-job training, guidance, and counseling under the direct supervision of a lead auditor. Such training shall include audit planning, performing, reporting, and follow-up actions.

QAPD-4.2.2.5 Technical Specialist Qualification

Technical specialists selected for audit assignments shall receive indoctrination commensurate with the scope, complexity, or special nature of the work being audited. In addition, they shall be trained to the requirements of the audit process associated with their duties.

QAPD-4.2.2.6 Lead Auditor Qualification

A lead auditor shall be capable of organizing and directing audits, reporting audit results, and evaluating planned and implemented corrective action. A lead auditor also shall be certified as meeting the requirements provided in this section for education and experience, communication skills, training, audit participation, and the successful completion of a lead auditor examination.

1. Lead Auditor Education and Experience:

The prospective lead auditor shall have verifiable evidence that a minimum of 10 credits have been accumulated under the following scoring system:

A. Education (four credits maximum)

i. An associate's degree from an accredited institution scores one credit. If the degree is in engineering, physical sciences, mathematics, or QA, it scores two credits.

ii. A bachelor's degree from an accredited institution scores two credits. If the degree is in engineering, physical sciences, mathematics, or QA, it scores three credits. In addition, score one more credit for a master's degree (or higher) in engineering, physical sciences, business management, or QA from an accredited institution.

B. Experience (nine credits maximum)

i. The prospective lead auditor shall have participated in a minimum of five QA audits or equivalent verifications (such as management assessments, pre-award surveys, or comprehensive surveillance, as long as the parameters of the audit process are met) within three years prior to the date of certification, one of which shall be a nuclear QA audit within the year prior to qualification. In addition, for technical experience in such areas as scientific investigation, site characterization, nuclear waste management, production, transportation, engineering, manufacturing, construction, operation, or maintenance, or experience applicable to the auditing organization's area of responsibility, score one credit for each full year, with a maximum of five credits.

ii. If two years of this experience have been in a nuclear field, score one additional credit; or

iii. If two years of this experience have been in QA, score two additional credits; or

iv. If two years of this experience have been in auditing or assessment, score three additional credits; or

v. If two years of this experience have been in nuclear-related QA, score three additional credits; or

vi. If two years of this experience have been in nuclear-related QA auditing or assessment, score four additional credits.

C. Professional Competence (two credits maximum)

For certification of competency in engineering, science, or QA specialties, issued and approved by a state agency or national professional or technical society, score two credits.

D. Rights of Management (two credits maximum)

When determined appropriate, the organization performing the qualification may grant up to two credits for other performance factors applicable to auditing that are not explicitly called out in this section (such as leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and completed QA training courses).

2. Lead Auditor Communication Skills

The prospective lead auditor shall have the capability to communicate effectively both in writing and orally. These skills shall be attested to in writing by the candidate's supervisor.

3. Lead Auditor Training

Prospective lead auditors shall be trained to the extent necessary to ensure their competence in skills as established by the organization responsible for performing audits. Training in the

following areas shall be accomplished and its completion verified based upon a management evaluation of the particular needs of each prospective lead auditor:

A. Knowledge and understanding of the participant organization's QA program and other program-related procedures, codes, standards, regulations, DOE orders, and regulatory guides, as applicable

B. General structure of QA plans and implementation procedures as a whole

C. Auditing techniques of examining, questioning, evaluating, reporting, and methods of identifying, following up, and closing corrective actions

D. Audit planning in functional areas of nuclear QA

4. Lead Auditor Examination

The prospective lead auditor shall pass an examination that evaluates his or her comprehension of, and ability to apply, the audit knowledge described in this section. The examination may be oral, written, practical, or any combination thereof.

The development and administration of the examination for a lead auditor is the responsibility of the organization responsible for the auditing program. This organization shall:

A. Maintain the integrity of the examination through confidentiality of files and, where applicable, proctor examinations

B. Develop and maintain objective evidence regarding the type and content of the examination

5. Lead Auditor Certification

Lead auditors shall be certified by the organization responsible for the auditing program as being qualified to lead audits. This certification will document the:

A. Name of the organization performing the certification

B. Name of the lead auditor

C. Date of certification or recertification

D. Basis of certification (such as education, experience, communication skills, and training)

E. Signature of the designated representative of the organization responsible for the certification

6. Lead Auditor Proficiency Maintenance

A. Lead auditors shall maintain their proficiency through one or a combination of the following:

i. Regular and active participation in the audit process

ii. Review and study of codes, standards, QA implementation procedures, instructions, and other documents related to QA program auditing

iii. Participation in training programs

iv. Management of the auditing organization shall evaluate the proficiency of lead auditors annually. Based on the evaluation, management shall choose to extend the qualification, require retraining, or require requalification. Management evaluations shall be documented.

B. Lead auditors who fail to maintain their proficiency for a two-year period shall require requalification to the requirements of this section of the QAPD. However, participation in only one nuclear audit is required.

QAPD-4.2.2.7 Performing Audits

1. Audits shall be performed using the written procedures or checklists related to the activity being audited.

2. Elements that have been selected for audit shall be evaluated against specified requirements. Objective evidence shall be examined to the depth necessary to determine if those elements are being implemented effectively.

3. Audit results shall be documented by audit personnel and reported to and reviewed by management having responsibility for the area audited. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

4. Conditions adverse to quality shall be documented and corrected according to the requirements of Section QAPD-2.3.3.

QAPD-4.2.2.8 Reporting Audit Results

1. The audit report shall be prepared and signed by the audit team leader and issued to the management of the audited organization and any affected organizations. The audit report shall include the following, as appropriate:

A. A description of the audit scope

B. Identification of the auditors

C. Identification of persons contacted during the audit

D. A summary of the documents reviewed, persons interviewed, and the specific results of the reviews and interviews (i.e., a summary of the checklist contents)

E. A summary of audit results, including a statement of the QA program adequacy, implementation, and effectiveness, as appropriate to the scope

F. A description of each reported condition adverse to quality in sufficient detail to enable corrective action to be taken by the audited organization

G. A description of commendable quality practices

2. Additionally, common audit findings shall be grouped in the report whenever possible so that related or systematic breakdowns in the QA program are identified. Findings or deficiencies shall be categorized based on their relative importance to indicate their degree of impact on compliance application, waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, or management and operation of the WIPP facility.

QAPD-4.2.2.9 Audit Response and Follow Up

Management of the audited organization will investigate conditions adverse to quality; determine and schedule corrective actions, including measures to preclude recurrence; and notify the auditing organization in writing of the actions planned or taken. The adequacy of audit responses shall be evaluated by or for the auditing organization. Follow-up action shall be taken to verify that corrective action is accomplished as scheduled.

QAPD-4.2.2.10 Audit Records

The following documents, when developed in fulfillment of the audit requirements of this QAPD, shall be controlled as QA records in accordance with Section QAPD-2.5 of this QAPD: audit plans, audit reports, audit responses, and documentation of corrective action completion and follow-up.

QAPD-5.0 Sample Control Requirements

This section identifies the requirements for controlling samples of waste and environmental media. The control measures shall include provisions for the identification, handling, storage, shipping, archiving, and disposition of the samples, including those identified as nonconforming.

QAPD-5.1 Sample Control

1. Samples shall be controlled and identified in a manner consistent with their intended use.

2. Implementing procedures shall define responsibilities, including organizational interfaces, related to documenting and tracking sample possession from sample collection and identification through handling, preservation, shipment, transfer, analysis, storage, and final disposition.

3. Sample control measures shall include provisions for the identification of the in situ orientation of samples, where appropriate.

4. A chain-of-custody record form shall be maintained. The chain-of-custody record shall provide a document trail of all persons who have custody of a given sample, including the date and time of its transfer.

5. Sample control measures, including identification and documentation, shall ensure that samples can be traced at all times, from collection through final disposition.

6. Where samples have a maximum life expectancy or expiration date, methods shall be employed that preclude the use of the sample beyond its specified life.

7. Representative archival samples from difficult-to-repeat sample collection activities, such as principal bore holes, shall be maintained.

8. Implementing procedures shall specify the representative samples to be archived if the need to archive samples is identified.

QAPD-5.2 Sample Identification

1. Each sample shall be uniquely identified from its initial collection through the final disposition of the sample.

2. Sample identification shall be verified and documented before each transfer or release for testing, analysis, or disposition.

3. Identification shall be maintained by placing the identification directly on the samples wherever possible or in a manner that ensures identification is maintained. If direct physical markings are either impractical or insufficient, other appropriate means shall be employed (e.g., physical separation, labels or tags attached to containers, or procedural control). When used, physical markings shall:

A. Be applied using materials and methods that provide clear and legible identification

B. Not effect the sample content or form

C. Be transferable to each identified sample part when the sample is subdivided

D. Not be obliterated or hidden by surface treatments or sample preparation unless other means of identification are substituted

4. If sample storage is required, methods shall be established for the control of sample identification that are commensurate with the planned duration and storage conditions. As applicable, these methods shall provide for:

A. The maintenance or replacement of markings and identification tags that have been damaged because of age or during handling

B. The protection of identification markings from excessive deterioration due to environmental exposure

QAPD-5.3 Handling, Storing, and Shipping Samples

1. Handling, storing, cleaning, packaging, shipping, and preserving samples shall be conducted in accordance with established work and inspection implementing procedures. Controls shall provide for the maintenance of sample characteristics, sample integrity, and sample identification during storage.

2. The controls shall be consistent with planned duration and storage conditions and shall describe actions to be taken where maximum sample life expectancy limits are identified.

3. Storage methodology shall be developed and implemented to ensure that samples are maintained in predetermined environmental conditions commensurate with their intended use and purpose.

4. Samples shall be controlled to preclude the mixing of like samples.

5. Samples on which analysis or tests have been performed shall be identified and maintained in a separate part of the storage area.

6. If required for critical, sensitive, perishable, or high-value samples, specific measures for the handling, storage, cleaning, packaging, shipping, and sample preservation shall be identified and used.

7. Measures shall be established for sample marking and labeling for packaging, shipping, handling, and storage as necessary to adequately identify, maintain, and preserve the sample. Markings and labels shall indicate the need for and the presence of special environments or the need for other special controls, if necessary.

8. Samples requiring special protective equipment (such as containers) and special protective environments (such as inert gas or limits on moisture and temperature) shall be specified, employed, verified, and documented.

QAPD-5.4 Disposition of Nonconforming Samples

1. Samples that do not conform to requirements specified in work controlling documents (such as job packages, travelers, or work requests) shall be identified, documented, evaluated, and segregated in accordance with Section QAPD-2.3.

2. The disposition for nonconforming samples shall be identified and documented and shall be limited to "use-as-is," "limited use," or "discard."

3. Samples that have lost their identity shall be documented as nonconforming and shall not be used.

QAPD-6.0 Scientific Investigation Requirements

Scientific investigations shall be defined, controlled, verified, and documented. Process variables affecting scientific investigations shall be measured and controlled. Test processes conducted in support of such investigations shall be controlled in accordance with the requirements of Sections QAPD-3.4, *Inspection and Testing*, QAPD-3.4.4, *Test Requirements*, and QAPD-3.4.5, *Monitoring, Measuring, Testing, and Data Collection Equipment*, as applicable, and as supplemented by the requirements of this section.

QAPD-6.1 Planning Scientific Investigations

1. Variables that affect interrelated scientific investigations shall be identified and controlled appropriately in each related investigation.

2. The intended use of the data shall be documented before collection as part of the planning for data processing. Any alternate use of the data shall be evaluated for appropriateness and the justification for use shall be documented.

3. Planning shall consider the compatibility of data processing with any conceptual or mathematical models used at each applicable stage.

4. The technical adequacy of procedures for conducting scientific investigations and their implementation shall be reviewed and approved by qualified persons other than those who prepared the procedures. Changes to procedures for conducting scientific investigations shall be reviewed and approved in a manner commensurate with the original procedure.

5. Development activities used to establish new methods or procedures for conducting scientific investigations shall be documented. The results of developmental testing shall be reviewed for adequacy and approved by qualified persons prior to implementation of the procedures for data collection.

6. Planning shall be coordinated with organizations providing input to or using the results of the investigation.

7. Planning shall include the establishment of acceptance criteria for data quality evaluation to ensure that the data generated are valid and satisfy documented requirements for the following characteristics, as appropriate: data precision, data accuracy, data representativeness, data comparability, and data completeness.

8. Planning shall include the identification of known sources of error and uncertainty, as well as any input data that are suspect or whose quality is beyond the control of the performing organizations.

QAPD-6.2 Performing Scientific Investigations

1. Scientific investigations shall be performed in accordance with requirements documented in test plans, procedures, and scientific notebooks.

2. If deviation from test standards or the establishment of specially prepared test procedures is deemed appropriate (e.g., no nationally recognized test standards exist), the modified or new test procedures shall be documented in sufficient detail to be repeatable and shall be justified, evaluated, and approved by the cognizant technical organization.

3. Scientific notebooks shall contain, at a minimum:

   A. A statement of the objectives and description of work to be performed or reference to an approved plan that describes the work

   B. The methods used

   C. Identification of the samples

   D. The M&TE used

   E. A description of the work performed and the results obtained, the names of individuals performing the work, and dated initials or signature, as appropriate, of individuals making the entries

   F. A description of changes made to methods used, as appropriate

   G. The potential sources of uncertainty and error in test plans, procedures, and parameters that must be controlled and measured to ensure that tests are valid

4. Scientific results shall be periodically reviewed by an independent qualified individual to verify that there is sufficient detail to retrace the investigation and confirm the results, if feasible, or repeat the investigation and achieve comparable results without recourse to the original investigator.

5. Practices, techniques, equipment, and manual or computerized methods used to obtain and analyze data shall be verified to ensure that they are technically sound and have been properly selected. Controls shall be established for these processes to ensure that they are properly implemented, including controls to prevent tampering.

6. Data collection and analysis shall be controlled by procedures of sufficient detail to allow the processes to be repeated. Where appropriate, quality control checks shall be performed using recognized methods such as replicate, spike, and split samples;

7. control charts; blanks; reagent checks; replication of the methods used to obtain the results; or alternate analysis methods.

8. Test media (e.g., fluids), when used, shall be characterized and controlled in accordance with test procedures.

9. Scientific notebooks and technical implementation documents shall be maintained as QA records.

QAPD-6.3 Data Documentation, Control, and Validation

QAPD-6.3.1 Data Identification and Usage

A. All data shall be recorded so that they are clearly identifiable and traceable to the test, experiment, study, or other source from which they were generated. Identification and traceability of the data shall be maintained for the lifetime of the WIPP.

B. The method of data recording (e.g., scientific notebooks, log books, data sheets, or computerized instrumentation systems) shall be controlled to avoid data loss and permit data retrievability. Controls shall be established to ensure that data integrity and security are maintained wherever data are stored. Controls shall prescribe how specific types of data will be stored with respect to media, conditions, location, retention time, security, and access. Data shall be suitably protected from damage and destruction during their prescribed lifetime and shall be readily retrievable.

C. Data transfer and reduction controls shall be established to ensure that data transfer is error free (or within a prescribed permissible error rate), that no information is lost in transfer, and that the input is completely recoverable. Data transfer and reduction will be controlled to permit independent reproducibility by another qualified individual. Examples of data transfer include copying raw data from a notebook into computerized data form, or copying from computer tape to disk.

D. Data that are determined to be erroneous, rejected, superseded, or otherwise unsuited for their intended use shall be controlled to prevent their inadvertent use.

Controls shall include the identification, segregation, and disposition of inadequate data. The basis for the disposition of erroneous data shall be justified and documented.

E. All processes which change either the form of expression or quantity of data, values, or number of data items (data reduction) shall be controlled by prescribed methods that allow for the validation of the conversion process.

F. Data collection and analysis shall be critically reviewed and questions resolved before the results are either used or reported. Uncertainty limits shall be assigned to the data prior to their use.

QAPD-6.3.2 Data Validation

Data validation is a systematic process used to review data to ensure that the required data quality characteristics have been obtained. Results of the review may require that qualifiers be placed on the use of the data.

1. Validation methods shall be planned and documented. The documentation shall include the acceptance criteria used to determine if the data are valid.

2. All applicable data collected shall be validated. Validation shall include the following:

A. The relevant documentation is reviewed to evaluate the technical adequacy, the suitability for the intended use, and the adequacy of the QA record.

B. The results of the data review shall be documented.

C. The reviewer shall be independent of the collection activities.

3. Data validation shall be controlled to permit independent reproducibility by another qualified individual.

4. Data considered as established fact by the scientific and engineering community, such as engineering handbook data or critical tables, do not require validation.

QAPD-6.4 Qualification of Existing Data

1. This section contains requirements unique to the post-qualification of data and information that are relied upon to support the WIPP compliance application and were collected prior to the implementation of this QAPD. While the qualification process shall be conducted in accordance with the program control requirements of the CBFO QAPD, it is not intended that the QAPD identify the data that are subject to this process or the technical requirements of the qualification process. The qualification process shall be conducted in accordance with approved procedures that provide for documentation of the decision process, the factors used in arriving at the choice of the qualification method, and the decision that the data are qualified for their intended use.

2. Existing data shall be qualified using one or a combination of the following methods:

A. Determination that the data were collected under a QA 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 NQA-3-1989. Factors to be considered include:

i. Qualifications of personnel or organizations generating the data

ii. Technical adequacy of the equipment and procedures used to collect and analyze the data

iii. Environmental conditions under which the data were obtained (if germane)

iv. Quality and reliability of the measurement control program under which the data were generated

v. Extent to which data demonstrate properties of interest (e.g., physical, chemical, geologic, or mechanical)

vi. Extent to which conditions generating the data may partially meet requirements of this QAPD

vii. Prior uses of the data and the associated verification processes

viii. Prior peer or other professional reviews of data and their results

ix. Extent and reliability of the documentation associated with the data

x. Extent and quality of corroborating data or confirmatory testing results

xi. Degree to which data generating processes were independently audited

xii. The importance of the data in showing that the repository design meets the performance objectives

B. The use of corroborating data, with the data relationships and inferences clearly identified and justified

C. Confirmatory testing that is performed and documented

D. Peer review conducted in a manner that is compatible with NUREG-1297, *Peer Review for High-Level Nuclear Waste Repositories*

i. Peer reviews shall be performed when the adequacy of information or the suitability of procedures and methods essential to showing that a repository system meets its performance requirements with respect to safety and calculations, or reference to previously established standards and practices.

ii. Peer reviews performed in support of WIPP compliance activities shall be documented, as shall all peer review processes.

E. Peer reviews are used for the following activities:

i. Conceptual models selected and developed by DOE

ii. Waste characterization analysis as required in 40 CFR 194.24(b)

iii. Engineered barrier evaluation as required in 40 CFR 194.44

QAPD-7.0 Software Requirements

This section of the QAPD establishes software quality assurance (SQA) requirements for CBFO participants who develop, acquire, maintain, or use computer software that is important to compliance application and waste characterization.

QAPD-7.1 Applicability

1. The requirements in this section apply to computer software used in the manipulation or production of data that are, in turn, used in the processing, gathering, or generation of information whose output is relied upon to make design, analytical, operational, or compliance-related decisions with respect to the performance of the waste confinement, waste characterization, waste transportation, or waste acceptance processes. The requirements also apply to safety software used by CBFO and its contractors. The application of these requirements shall be prescribed in written plan(s), policies, procedures, or instructions.

2. The **basic requirements** defined in this section apply to those activities involved in the processing, control, or measurement of the hazardous, radioactive, and waste matrix materials of the TRU or TRU mixed waste. Waste matrix materials include but are not limited to metals, cellulosics, chelating agents, water, and other liquids, plastics, and rubber. The requirements also apply to safety software used by CBFO and its contractors.

3. The **NQA-2 Part 2.7 requirements** defined in this section apply to software used in the processing, control, or measurement of the radioactive and waste matrix materials of the TRU waste. These requirements also apply to software used to model the performance of the WIPP for purposes of compliance application and/or reapplication. The requirements also apply to safety software used by CBFO and its contractors.

4. Exempt from the requirements of this section of the QAPD is software that is considered to be "systems software" (e.g., operating systems, administrative and management systems, system utilities, compilers, assemblers, translators, interpreters, query languages, word processing programs, spreadsheets, database managers, and graphing programs) or other software that does not generate data that are used in the formulation of conclusions. Specific applications supporting Section QAPD-7.1, written for use within these types of software (e.g., detailed formulas or macros) that can be verified by hand calculations or other means, shall meet the following requirements of this section:

    A. A listing of the software code (i.e., details of formulas, file/table/cell references, and/or macros) shall be developed and maintained.

    B. Documentation shall be prepared to demonstrate by hand or other independent calculations that the specific application provides the correct results for the specified range of input parameters.

QAPD-7.2 Basic Requirements for Inventory and Classification of Software

1. An inventory of all applicable software shall be maintained that identifies the software name, version, classification, exemption status, operating environment, and the person and organization responsible for the software.

2. Software governed by this section of the QAPD shall be categorized. The criteria for classification shall be documented in the inventory and shall address the purpose of the software relative to its use in engineering, scientific, testing, data collection, design, analysis, and operations activities, as well as its importance to safety or its significance in managing information or augmenting mission-essential decisions.

QAPD-7.3 Software Quality Assurance

QAPD-7.3.1 Basic Requirements for Software Quality Assurance

Controls governing applicable software development projects shall be identified in controlled and documented plans. The plans shall be formally reviewed and approved. Controls governing the configuration and use of the software shall be identified in plans or procedures appropriate to the organizations using the software. The following activities shall be addressed in plans or procedures:

1. Software development

2. Software verification and validation

3. Software configuration control

4. Software operation and maintenance

Plans may be issued separately or as a single, composite plan, depending on the nature and complexity of the project. The software control plans may be a section of the overall project plan, provided that each software item is addressed and the software control portion of the plan prescribes the documentation, reviews, and controls required by this section.

QAPD-7.3.2 NQA-2 Part 2.7 Requirements for Software Quality Assurance

Plans for ensuring software quality shall be prepared for each new software project at the start of the software life cycle. For acquired software, the software quality plan shall be prepared before the software enters the purchaser organization. Plans may be prepared individually for each software project, may exist as a generic document to be applied to software prepared within or procured by an organization, or may be incorporated into the overall QA program. The plan shall identify:

1. The software products governed by the plan

2. The types of documentation to be prepared, reviewed, and maintained during the software design, development, implementation, test, and use

3. The organizations responsible for performing the work and achieving software quality, and their tasks and responsibilities

4. The process for reporting and documenting software discrepancies, evaluating the impact of discrepancies on previous calculations, and determining the appropriate corrective action(s)

5. The standards, conventions, techniques, or methodologies that guide the software development, as well as the methods used to ensure implementation of requirements

6. The procedure(s) used for establishing and maintaining the integrity of data, embodied mathematical models, and output files

QAPD-7.4 Software Procurement

QAPD-7.4.1 Basic Requirements for Software Procurement

This section of the QAPD identifies responsibilities of the sponsoring organization for acquired software upon receipt of the software.

All procured software governed by this section shall be tested in accordance with documented and approved test procedures using approved test-case specifications to ensure that the acquired software will perform satisfactorily in its operating environment. The installation tests (including the test procedures), the test case specifications, and the results of the installation tests shall be identified, documented, and maintained as records according to established procedures.

QAPD-7.4.2 NQA-2 Part 2.7 Requirements for Software Procurement

1. The procurement of software and related services shall be performed in accordance with Section QAPD-3.3 of this QAPD.

2. Once the software has been installed, but before its use, the sponsoring organization shall perform user acceptance to verify the functional capability of the software and the acceptability of the supplier's supporting documentation (e.g., the user manual, technical specifications, and the results of supplier testing).

3. For procured software, the supplier shall report software errors and failures to the sponsoring organization. The sponsoring organization shall also report software errors to the supplier.

QAPD-7.5 Software Developed Under Other QA Programs

QAPD-7.5.1 Basic Requirements

Software that has not been developed or approved in accordance with this QAPD shall be evaluated to determine its adequacy to perform intended functions. The evaluation shall be documented. The software shall be uniquely identified and controlled prior to the evaluation, clearly traceable to the software requirements, accepted by the sponsoring organization, and placed under configuration control prior to use.

QAPD-7.5.2 NQA-2 Part 2.7 Requirements

The evaluation of existing software developed in accordance with other QA programs shall serve as the basis to:

1. Determine the adequacy of existing verification and validation activities and software documentation to support operations and maintenance.

2. Identify the activities to be performed and the documentation necessary to accept the software for its intended use and place it under configuration control. The evaluation shall be documented and shall contain, at a minimum:

    A. User application requirements

    B. Test plans and test cases required to validate software acceptability

    C. User documentation as described in Section QAPD-7.9.2.6

QAPD-7.6 Software Development and Life Cycle

QAPD-7.6.1 Basic Requirements

The developmental activities of software projects subject to this QAPD shall be identified in documented and approved plans to ensure that the project proceeds in an orderly and traceable manner. Sufficient information shall be provided to clearly indicate the necessary tasks, the deliverables and baselines for each phase, the required reviews, appropriate milestones, and the responsibilities associated with each task.

Software project development plans shall identify the items that need to be baselined and the methods to be used for controlling the configuration of those baselines throughout the development process. Configuration control planning for software are addressed in Section QAPD-7.8 of this QAPD.

QAPD-7.6.2 NQA-2 Part 2.7 Requirements

1. The activities associated with the evolution of the software shall be accomplished using an iterative or sequential approach. The approach shall include the analysis of the problem under study, the transformation of the analysis into the design, the implementation of the design into validated computer software, and the development of sufficient documentation to demonstrate that the specified requirements have been successfully included in the computer software.

2. The iterative or sequential approach to software development consists of phases, with each phase leading to the development of a specific work product representing components of the software baseline. The software phases are:

    A. Definition of requirements

B. Design

C. Implementation

D. Testing

E. Installation and checkout

F. Operations and maintenance

G. Retirement

3. Following the development of the software quality plan, no strict sequence of performing activities is required (i.e., activities may be performed serially or recursively) provided that all the specified requirements for each software development phase have been met and the intent of the requirements has not been subverted.

QAPD-7.6.2.1 Requirements Phase

Software requirements shall be specified, documented, and reviewed. These requirements shall pertain to functionality, performance, design constraints, data attributes, and external interfaces (e.g., hardware limitations) as outlined in Section QAPD-7.9.2.2. Each requirement shall be specified in sufficient detail to permit the accomplishment of design and validation activities. Software requirements shall be traceable throughout the software development cycle, and a verification and validation plan shall be prepared after the software requirements have been documented and approved.

QAPD-7.6.2.2 Design Phase

The software design shall be based on the software requirements and shall be documented and reviewed. The design shall specify the overall structure (control and data flow) and the reduction of the overall structure into physical solutions (algorithms, equations, control logic, and data structures). The design may necessitate the modification of the requirements documentation and the verification and validation plans.

QAPD-7.6.2.3 Implementation Phase

The software design shall be translated into a form (programming language) suitable for processing by a computer. The executable software shall be analyzed to identify and correct errors.

QAPD-7.6.2.4 Testing Phase

1. Test requirements and acceptance criteria shall be specified, documented, and reviewed and shall be based upon applicable design or other pertinent technical bases. Appropriate tests, such as verification tests, requirements-driven tests, hardware integration tests, and in-use tests, shall be controlled. Software testing, using documented test plans, test cases, and test results are the primary methods of software validation.

2. Testing of software shall be performed to the extent that unintended functions are identified and reviewed and their impact determined and corrected. If appropriate, determine if modifications are needed to the requirements, design, implementation, or test plans and test cases.

3. Design-driven tests shall be used to demonstrate the capability of the software to produce valid results for test problems encompassing the range of intended use as defined by the software documentation. Testing of software used for operational control shall demonstrate the required performance over the entire range of the controlled function or process. Acceptable test methods consist of:

   A. Hand calculations

   B. Calculations using comparable proven problems

   C. Empirical data and information from confirmed published data and correlations or technical literature

   D. Comparison with other validated software of similar purpose

   E. Manual inspections or qualitative checks not involving numerical manipulation (examples include visual inspection of database reformatting or data plotting)

4. Requirements-driven tests shall be used to validate software by comparing test results of software execution with objective evidence obtained by the above methods. The results of this evaluation shall be of sufficient scope and depth to prove the capabilities and limitations delineated in the software documentation.

5. Test records shall identify each of the following:

   A. Computer program tested

   B. Computer hardware used

   C. Test equipment and calibrations, where applicable

   D. Date of test

   E. Tester or data recorder

   F. Simulation models used, where applicable

   G. Test problems

   H. Results and acceptability

   I. Action taken in connection with any deviations noted

   J. Persons evaluating test results

QAPD-7.6.2.5 Installation and Checkout Phase

1. During installation and checkout, the software becomes part of a system consisting of applicable software components, hardware, and data. The process of integrating the software with other applicable components may consist of installing both the hardware and software, converting or creating databases, and verifying that all components of the system have been included in the installation. Test problems shall be developed and documented to permit confirmation of the acceptable performance of the software in its operating environment. Installation and checkout of software shall consist of:

   A. Execution of tests for installation and integration

   B. Documented acceptance of the software for operational use

   C. Placement of the software under configuration control prior to use

2. Completion of the installation and checkout activities establishes the software baseline.

QAPD-7.6.2.6 Operations and Maintenance Phase

1. Operation of the software is conducted by the user in accordance with the operation and usage instructions described in the software user documentation. Once the software has been made available for use, the software requirements and the design integrity shall be maintained. Maintenance activities shall be performed and documented in a traceable, planned, and orderly manner.

2. In all cases, verification and validation of software shall be completed and approved and corrective actions performed, as necessary, prior to relying upon the software to perform its intended function.

   A. Post Installation Maintenance

   Software shall be maintained to remove latent errors (corrective maintenance), to respond to new or revised requirements (perfective maintenance), or to adapt the software to changes in the operating environment (adaptive maintenance). Software modifications shall be approved by authorized personnel, documented, verified, validated, and controlled.

   B. In-Use Tests

   Test problems shall be run whenever the software is installed on a different computer or when significant hardware or system software configuration changes are made. These tests shall be documented, performed by an individual technically competent in the subject area(s), and serve as the basis for determining if the software still meets specified requirements.

   Periodic in-use manual or automatic self-check routines shall be prescribed and performed for that software where computer failure or electronic drift can affect required outcomes.

QAPD-7.6.2.7 Retirement Phase

Criteria shall be developed to determine when software can be retired from use. Methods shall be developed to prevent the use of software that is no longer controlled. Upon retirement, user support for a software product is terminated.

QAPD-7.7 Software Verification and Validation

QAPD-7.7.1 Basic Requirements

1. Verification and validation of software shall include the review of software activities, documentation, and tests to ensure that the software:

   A. Adequately and correctly performs all intended functions

   B. Does not perform any unintended function that either by itself, or in combination with other functions, can degrade the intended outcomes of the software

2. Verification and validation shall be performed by any competent individual(s) or group(s) other than those who performed the software design. The individuals may be from the same organization and may include the designer's supervisor, provided the supervisor:

   A. Did not specify a singular design approach

   B. Did not rule out certain design considerations

   C. Did not establish the design inputs used

   D. Is the only individual in the organization competent to perform the verification or validation

QAPD-7.7.2 NQA-2 Part 2.7 Requirements

QAPD-7.7.2.1 Verification

Verification is a formal checking activity performed throughout the evolution of the software life cycle. Verification activities shall be clearly documented, including the identification of those performing and approving the verification. The reviewed documents shall be updated and placed under configuration control. Documentation of review comments and their disposition shall be retained. Unincorporated comments and their disposition shall also be retained in accordance with established procedures.

QAPD-7.7.2.2 Requirements

Verification review(s) of software requirements shall ensure that the requirements are complete, verifiable through testing, consistent, and technically feasible as described in Section QAPD-7.6.2.1.

QAPD-7.7.2.3 Design

Verification review of software design shall evaluate the technical adequacy of the design approach and ensure that all the requirements have been addressed and that the design is complete, verifiable (through testing, using approved test plans and test cases), consistent, technically feasible, and traceable to the software requirements as described in Section QAPD-7.6.2.2.

QAPD-7.7.2.4 Implementation

Verification of the implementation of software design shall consist of the examination of software logic and source code to ensure adherence to standards and conventions and to ensure that the design has been implemented as described in Section QAPD-7.6.2.3.

QAPD-7.7.2.5 Testing

Verification of software testing shall consist of reviews to ensure that the specified test criteria, the expected results, and the software development documentation have been met as described in Section QAPD-7.6.2.4.

QAPD-7.7.2.6 Installation and Checkout

Verification of installation and checkout activities consists of reviews to ensure that the software baseline has been established.

QAPD-7.7.3 Validation

1. Software validation is primarily a formal testing activity that shall be performed prior to installation and checkout. It shall be used to demonstrate that the computational model embodied in the software is an acceptable representation of the process or system for which it is intended and that the software produces correct solutions within defined limits for each parameter employed.

2. Validation methods, test data, software-generated results, and conclusions shall be documented in a form that can be understood by an independent individual technically competent to use the software for the particular problem under study. The documentation shall be reviewed to assure the test requirements have been satisfied .

3. When the adequacy of the conceptual, mathematical, or computational models or the suitability of procedures and methods cannot be established through testing, alternate calculations, or reference to previously established standards and practices, a documented peer review shall be performed to meet the software validation requirements.

4. The validation of software modifications shall be subject to selective regression testing to

    A. Detect errors introduced during the modification of the systems or system components

    B. Verify that the modifications have not caused unintended adverse effects

C. Verify that the modified systems or system components still meet specified requirements

QAPD-7.8 Software Configuration Management

QAPD-7.8.1 Basic Requirements

1. A. Implementation of baseline and change control processes are fundamental to configuration management. A baseline is a collection of all approved components of the software development cycle. As each component is approved, it is added to the overall software baseline. A software baseline serves as the basis for further development and maintenance that can be changed only through the use of formal change control procedures. Change control is the process by which a change to a baseline is proposed, evaluated, and approved or rejected.

2. B. Software configuration controls shall be planned, including the identification of organizational positions that are authorized to make changes, and the methods, procedures, and instructions to be used to control the identification of, access to, changes to, and the status of computer software. Configuration control documents shall indicate how changes will be validated, including regression testing, and how the tests will be documented. These control documents shall be formally reviewed, approved, and in place before the software is released for use.

QAPD-7.8.2 NQA-2 Part 2.7 Requirements

QAPD-7.8.2.1 Configuration Identification

Software shall be placed under configuration control as each configuration item is approved. A software baseline shall define the most recent approved software configuration. The configuration items and their associated documentation shall be traceable to one another. A labeling system for configuration items shall be implemented that:

1. Uniquely identifies each configuration item

2. Identifies changes to configuration items by revision or version identifier

3. Provides the ability to uniquely identify each approved configuration of the revised software that is available for use

QAPD-7.8.2.2 Configuration Change Control

1. Changes to software shall be systematically proposed, evaluated, documented, and approved to ensure that the impact and rationale for making the change is carefully assessed prior to updating the software baseline. Changes to previously accepted software shall be subject to the same level of control as the original software.

2. Information concerning approved changes shall be transmitted to all affected organizations. All changes shall be formally evaluated and approved by the organization responsible for the

original design, unless an alternate organization has been given the authority to approve the changes. Only authorized changes shall be made to software baselines. Software verification activities shall be performed for the change as necessary to ensure that the change is appropriately reflected in the software documentation and to ensure that traceability is maintained. The degree of software validation shall be commensurate with the nature and scope of the change.

QAPD-7.8.2.3 Configuration Status Accounting

Information shall be maintained that reflects the current status of the software baseline. This includes the identity and version of the approved configuration and the status of any proposed and approved changes to the baseline components. This information shall be available to all designated users of the software upon request.

QAPD-7.9 Documentation

QAPD-7.9.1 Basic Requirements

Software shall be described in one or more documents that detail user instructions, technical bases, functional requirements, and maintenance-related information sufficient to allow independent verification and maintenance and to provide traceability of the documentation to the software. The documentation shall be reviewed by an individual competent in the technical subject area for which the use of the software is intended. The review shall verify that the documentation adequately and accurately reflects the software that constitutes the system, and is sufficient to objectively demonstrate that the software requirements have been successfully implemented. Appropriate documentation shall be made available to all designated users of the software.

QAPD-7.9.2 NQA-2 Part 2.7 Requirements

QAPD-7.9.2.1 Procurement Documentation

The applicable quality assurance requirements shall be specified and the required vendor-supplied software documentation, plans, and procedures shall be identified in the software procurement documentation.

QAPD-7.9.2.2 Requirements Documentation

1. Software requirements documentation shall outline the requirements that the proposed software must satisfy. The software requirements shall, as applicable, address the following:

    A. Functionality – the functions the software performs

    B. Performance – the time-related issues of software operation such as speed, recovery time, and response time

C. Constraints – limits imposed on implementation activities; any elements that will restrict design options

D. Attributes – non-time-related issues of software operation such as portability, acceptance criteria, access control, and maintainability

E. External interfaces – interactions with people, hardware, and other software

2. Software requirements shall be traceable throughout the software development cycle.

QAPD-7.9.2.3 Design and Implementation Documentation

Software design and implementation documentation consists of a document or series of documents that:

1. Describe the major components of the software design as they relate to the software requirements

2. Describe the theoretical basis, embodied mathematical model, control flow, control logic, and data structure(s) of the software

3. Describe the allowable or prescribed ranges for inputs and outputs

4. Describe the design in a manner that can be translated into executable code

QAPD-7.9.2.4 Verification and Validation Documentation

1. Software verification and validation documentation shall consist of associated plans and shall describe the activities (including the results of reviews and tests) and the criteria for accomplishing the verification of the software throughout the software evolution process. The documentation shall also specify the hardware and software configurations pertinent to the software verification and validation.

2. Software verification and validation documentation shall be organized in a manner that allows traceability from the software requirements to both the software design and to the validated capabilities of the software.

QAPD-7.9.2.5 Change Documentation

Changes to software shall be formally documented. This documentation shall contain a description of the change, the rationale for the change, and the identification of affected configuration items of the software baseline.

QAPD-7.9.2.6 User Documentation

User documentation should be sufficient to allow any qualified user (i.e., one having adequate technical background) to install and run the software and properly respond to errors. User documentation, at a minimum, shall include:

1. The software name and version identifier

2. Statements of functional requirements and system limitations, including hardware

3. An explanation of the mathematical models and derivation of the numerical methods used in the software design (physical and mathematical assumptions on which the software is based shall be included, along with an explanation of the capabilities and limitations inherent in the software)

4. Instructions that describe user interaction with the software, user messages initiated as a result of improper input and how the user can respond, the identification and description of input and output specifications and formats, and input parameters

5. A description of any required training necessary to use the software

6. Information for obtaining operation and maintenance support

QAPD-7.9.2.7 Error Documentation

Documentation of errors detected during the use of the software following installation and checkout shall be maintained. This documentation can be used for process improvement and to prevent recurrence of errors during the development and maintenance of other software. This documentation shall contain the identity of the software, the classification of the error in terms of its significance to the integrity of the software output, and the corrective action(s).

QAPD-7.10 Problem Reporting and Corrective Action

QAPD-7.10.1 Basic Requirements

Problems (e.g., errors, faults, failures) detected in released software shall be promptly reported in accordance with documented procedures. When problems are detected in a software item, work previously performed using versions of the software that contain that problem shall be evaluated to determine the impact on the completed work. The evaluations shall be documented and retained in accordance with records requirements.

QAPD-7.10.2 NQA-2 Part 2.7 Requirements

1. A system shall be established and maintained to record, classify, analyze, track, and report software problems (in released versions) and the associated corrective actions. Problems shall be promptly reported to any affected organizations and the resolution shall be formally processed.

2. When problems are discovered in software or software results, the sponsoring organization shall determine the affect on previous uses and the need for corrective action based on sufficient information obtained from the affected users. Corrective action shall ensure that

   A. Problems are identified, evaluated, documented and, if required, corrected

B. Problems are assessed for their impact on past and present uses of the software

C. Changes to software are in accordance with the software configuration management requirements of this section of the QAPD

D. Results are provided to the affected users, along with any revised software documentation

3. Problems that could significantly affect decisions based upon prior use or that require significant modification to the software shall be identifiable to all users. Errors that have been determined to represent a condition adverse to quality shall be controlled in accordance with Section QAPD-2.3 of this QAPD.

QAPD-7.11 Access Control

To the extent appropriate, controls shall be established to permit authorized and prevent unauthorized access to software that has been accepted in accordance with this section.

QAPD-8.0 Glossary

Acceptance: The documented determination by the receiving organization that a work project is suitable for the intended purpose.

Acquired Software: Computer software obtained that was not developed by the user organization.

Alternative Calculations: Calculations that are made with alternative methods to verify correctness of the original calculation.

Approval: The documented determination by a responsible individual that a work product is suitable for the intended purpose and shall be used as required.

Assessment/Evaluation: The act of reviewing, inspecting, testing, checking, conducting surveillances, auditing, or otherwise determining and documenting whether items, processes, or services meet specified requirements. Assessments are performed by or for management. Evaluations are performed by the line organization.

Assessment, External: An assessment of those portions of an organization's quality assurance program not under the direct control or within the organizational structure of the auditing organization.

Assessment, Internal: An assessment of those portions of an organization's quality assurance program retained under its direct control and within its organizational structure.

Assessor: An individual who is qualified to perform assigned portions of an assessment.

Audit: A planned and documented independent assessment to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

Auditor: An individual who is qualified to perform assigned portions of an audit.

Audit (or Assessment) Team Leader: A lead auditor (or assessor) who is assigned to direct the efforts of an audit (or assessment) team.

Calibration: The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, and the corresponding standard or known values derived from the standard.

Certificate of Conformance: A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.

Certification: The act of determining, verifying, and attesting to, in writing the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

Characteristic: A property or attribute of an item, process, or service that is distinct, describable, and measurable.

Commercial Grade Item: An item that is (1) not subject to design or specification criteria unique to a CBFO program or facility, (2) used in applications other than the nuclear industry, and (3) ordered from the manufacturer or supplier on the basis of specifications set forth in the manufacturer's published product description.

Compliance Certification Application: The compliance certification application submitted to the EPA pursuant to section 8 (d) (1) of the WIPP Land Withdrawal Act of 1992 (Pub. L. 102-579, 106 Statue 4777) or any compliance re-certification applications submitted to the EPA pursuant to section 8(f) of the WIPP Land Withdrawal Act.

Condition Adverse to Quality: An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, nonconformances, and technical inadequacies. A condition adverse to quality is considered significant when

- if uncorrected, the condition adverse to quality could have a serious effect on safety, operability, waste isolation, TRU waste site certification, regulatory compliance demonstration, or effective implementation of the QA program
- the condition adverse to quality requires immediate notification of regulatory entities (e.g., 10 CFR Part 21, HWFP Module I.E.13)
- the condition adverse to quality indicates a significant failure or breakdown in the implementation of QA Program requirements
- repeated attempts to resolve a condition adverse to quality have been unsuccessful
- the condition adverse to quality is identified in items or activities important to safety or waste isolation and compromises the ability to prevent or mitigate the consequences of an accident, thereby presenting a significant hazard to safety and health of workers and/or the public

Configuration Control: The process of identifying and defining the configuration items in a system, controlling the release and change of these items throughout the system life cycle, and the recording and reporting of the status of configuration items and change requests.

Configuration Item: A collection of hardware or software elements treated as a unit for the purpose of configuration control.

Controlled Document: A document that is prepared, reviewed, approved, and distributed in accordance with established implementation procedures. Controlled documents are subject to controlled distribution and to a defined and controlled change process.

Corrective Action: Measures that are taken to rectify conditions adverse to quality and, where necessary, to preclude recurrence.

Corrective Action Report (CAR): A document used to identify and rectify conditions adverse to quality (CAQ), and track the associated corrective actions. CARs address CAQs that are primarily programmatic in nature, as opposed to nonconformance reports (NCRs) which address CAQs relating to a specific item(s) such as a piece of hardware or data. The category of CARs includes: corrective action reports or corrective action requests, nonconformance corrective action reports (NCARs), management corrective action reports (MCARs), deficiency reports (DRs), process deficiency reports (PDRs), audit findings, condition adverse to quality reports(CAQR), etc.

Data Accuracy: The degree to which data agree with an accepted reference or true value. Accuracy is a measure of the bias in a system.

Data Comparability: A measure of the confidence with which one data set can be compared to another.

Data Completeness: A measure of the amount of valid data obtained compared to the amount that was planned.

Data Precision: A measure of the mutual agreement between comparable data gathered or developed under similar conditions, usually expressed in terms of a standard deviation.

Data Representativeness: The degree to which data accurately and precisely represent a characteristic of a population, a parameter, variations at a sampling point, or environmental conditions.

Data Quality Objectives (DQOs): Qualitative and quantitative statements derived from outputs of the first six steps of the DQO Process (see below). DQOs 1) clarify the study objective, 2) define the most appropriate type of data to collect, 3) determine the most appropriate conditions from which to collect the data, and 4) specify tolerable limits on decision errors which will be used as the basis for establishing the quantity and quality of data needed to support compliance decisions. DQOs are used to develop a scientific and resource-effective data collection design.

DQO Process: A strategic planning approach based on the Scientific Method that is used to prepare for a data collection activity. The DQO process provides a systematic procedure for defining the criteria that a data collection design should satisfy, including when to collect samples, where to collect samples, the tolerable level of decision errors for the study, and how many samples to collect. By using the DQO process, DOE will assure that the type, quantity, and quality of environmental data used in decision making will be appropriate for the intended application. In addition, DOE will guard against committing resources to data collection efforts that do not support a defensible decision. The DQO process consists of seven steps and is more fully described in EPA 1994b.

Design Basis: Information that identifies the specific functions to be performed by items and the specific values or ranges of values chosen for controlling parameters as reference bounds for design.

Design Input: Those criteria, parameters, bases, or other design requirements upon which the detailed final design is based.

Design Output: Drawings, specifications, and other documents resulting from the translation of design input requirements.

Design Process: The technical process that begins with the identification of design input and ends with the issuance of design output documents.

Design Review: A documented evaluation of design output during the design process to determine the design adequacy and the conformance to specified acceptance criteria.

Disposal System: Any combination of engineered and natural barriers that isolate transuranic waste after disposal. For the purposes of the WIPP, this will include the combination of the repository/shaft system and the controlled area.

Document: Written or pictorial information that describes, specifies, reports, or certifies activities, requirements, procedures, or results.

Document Control: The process that provides for document adequacy review, approval for release by authorized personnel, and distribution for use at the prescribed work locations.

Error: A discrepancy between a computed, observed, or measured value or condition and the true, specified, or theoretically correct value or condition.

Graded Approach: The process by which the level of analysis, documentation, verification, and other controls necessary to comply with QA program requirements are developed commensurate with specified factors.

Independent Assessment: An assessment, conducted by a group or organization having authority and freedom from the line organization, to evaluate the scope, status, adequacy, programmatic implementation, or effectiveness of a program or process.

Item: 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.

Lead Auditor: An individual trained, qualified, and certified to organize and direct an audit, report audit findings, and evaluate corrective actions.

Lifetime Records: Records required to be maintained for the useful life of the items to which they pertain while the items are installed in the plant or facility (life of the item), or for the lifetime of the equipment, facilities, or programs to which the records apply.

Line Management: Those management positions that are directly responsible for task products and services. Includes CBFO supervisors and team leaders and contractor management within the context of the definition.

Line Organization: The organization directly responsible for task products and services. Includes CBFO offices and teams and contractor organizations within the context of the definition.

Macro: Single computer instructions invoked by a symbol, name, or key that represents commands, actions, or keystrokes.

Management Assessment: Assessment performed by management that focuses on how well the integrated quality assurance program is working. The management assessment should identify management problems that hinder the organization from achieving its objectives in accordance with quality, safety, and environmental requirements.

Measuring and Test Equipment: All devices used to calibrate, measure, gage, test, inspect, or otherwise determine compliance with prescribed technical requirements.

Monitoring and Data Collection (M&DC) Equipment: A subcategory of M&TE that is used in the collection of measurement data for the establishment of test conditions and general information and the collection of general measurement data not utilized to verify the conformance of an item or equipment to specified criteria.

Nonconformance: A deficiency in a characteristic or record that renders the quality of an item or sample unacceptable or indeterminate.

Nonpermanent Records: Records having value for a specific, limited time and authorized by the National Archives and Records Administration to be destroyed after that time.

Nonreactor Nuclear Facility: Those activities or operations that involve radioactive or fissionable materials in such form and quantity that a nuclear hazard potential exists to the employees or the general public. Incidental use and the generation of radioactive materials in a facility operation (e.g., check and calibration sources, radioactive isotopes used in research and experimental and analytical laboratory activities, electron microscopes, and x-ray machines) would not ordinarily require the facility to be included in this definition. The transportation of radioactive materials, accelerators, and reactors and their operations are not included.

Participant: A DOE contractor organization that furnishes items or services in support of CBFO-sponsored programs, including those TRU waste generator and storage sites characterizing waste for shipment to WIPP.

Peer: A person having technical expertise in the subject matter to be reviewed to a degree at least equivalent to that needed for the original work.

Peer Review: A documented, critical review performed by peers who are independent of the work being reviewed. A peer review is an in-depth critique of assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of conclusions drawn in the original work. Peer reviews confirm the adequacy of work.

Periodic: Occurring or recurring at regular intervals. For the purposes of this QAPD, these intervals are determined by the responsible management unless otherwise specified.

Post-Closure QA Records: QA records required to be maintained beyond the operating life of the WIPP repository, for periods of several hundreds of years, and in a manner that would permit

future generations to maintain them longer, if desired, using present reasonably available technology.

Procedure: A document that specifies or describes how an activity is to be performed. The term "procedure" also includes instructions and drawings.

Process: A series of actions that achieve an end or result.

Procurement Document: Purchase orders, contracts, specifications, or other documents used to define technical and quality assurance requirements for the procurement of items or services.

Qualification (Personnel): The characteristics or abilities gained through education, training, or experience, as measured against established requirements such as standards or tests, that qualify an individual to perform a required function.

Qualification Testing: A test that is intended to provide a desired level of confidence that an item meets specified criteria.

Quality: The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

Quality Assurance: All those planned and systematic actions necessary to provide adequate confidence that an item will perform satisfactorily in service.

Quality Assurance Objectives: Objectives that represent the required quality of data necessary to draw valid conclusions regarding program objectives.

Quality Assurance Program: The program established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

Quality Assurance Record: A completed record or any authenticated portion of a record that provides objective evidence of the quality of items or activities.

Quality System: See *Quality Assurance Program*.

RCRA Related Deficiency: A deficiency that is a violation of the requirements of the WIPP Hazardous Waste Facility Permit.

Readiness Review: A systematic documented review of the readiness for startup or continued extended use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to commencement of a major phase of work activities.

Receipt Inspection: A method of accepting an item or related service from a supplier by examination or testing of the item or related service to verify conformance to specified requirements.

Records: Books, papers, maps, photographs, machine readable materials or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations or other activities of the government or because of the informational value of the data they contain.

Records Holding Facility: A CBFO records storage facility meeting regulatory requirements for the storage of inactive records pending their final disposition.

Repair: The process of restoring an item to a condition such that the capability of an item to function reliably and safely is unimpaired even though that item still does not conform to the original requirement.

Rework: The process by which an item is restored to original specifications by completion or correction.

Safety: An all-inclusive term used synonymously with environment, safety, and health to encompass protection of the public, the workers, and the environment.

Safety Software: Includes the following:

1. Safety System Software. Software for a nuclear facility that performs a safety function as part of a structure, system, or component and is cited in either (a) a DOE approved documented safety analysis or (b) an approved hazard analysis.

2. Safety and Hazard Analysis Software and Design Software. Software that is used to classify, design, or analyze nuclear facilities. This software is not part of a structure, system, or component (SSC) but helps to ensure the proper accident or hazards analysis of nuclear facilities or an SSC that performs a safety function.

3. Safety Management and Administrative Controls Software. Software that performs a hazard control function in support of nuclear facility or radiological safety management programs or technical safety requirements or other software that performs a control function necessary to provide adequate protection from nuclear facility or radiological hazards. This software supports eliminating, limiting, or mitigating nuclear hazards to workers, the public, or the environment.

Sample: A subset of a population (e.g., wastes, environmental media, materials, cores) whose properties are used to gain information about the population.

Scientific and Engineering Software: Software that uses numerical methods to complete scientific, engineering, and mathematical calculations.

Scientific Investigation: Any research, experiment, test, study, or activity that is performed for the purpose of investigating a natural system or the man-made aspects of a geologic repository, including the investigations that support design of the facilities and the waste package.

Scientific Notebook: A record of the methods and results of scientific investigations that is used when the work involves a high degree of professional judgment or trial and error methods, or both.

Service: The performance of work, such as design, construction, fabrication, inspection, nondestructive examination, testing, environmental qualification, equipment qualification, repair, installation, or similar activities.

Significant Condition Adverse to Quality: See *Condition Adverse to Quality*.

Site Characterization: The program of exploration and research both in the laboratory and the field that is undertaken to establish the natural conditions and the ranges of parameters of a particular site.

Software: Computer programs, procedures, rules, and associated documentation and data pertaining to the operation of a computer system.

Software Baseline: An item or product that has been formally reviewed and agreed upon, that serves as the basis for further development, and that can be changed only through formal change control procedures.

Software Quality Assurance Plan: A plan for the development of software products necessary to provide adequate confidence that the software conforms to established requirements.

Software Routine: A collection of computer macros or script files, a spreadsheet application, or other stand-alone software application (either acquired or developed) that generally operates within another program, such as a spreadsheet, and must be independently verified by visual inspection and/or hand calculation.

Software Validation: The process of test and evaluation of the completed software to ensure compliance with software requirements.

Software Verification: The process of determining whether or not the product of a given phase of the software development cycle fulfills the requirements imposed by the previous phase.

Software Verification and Validation: The process of determining whether the requirements for a system or component are complete and correct, the products of each development phase fulfill the requirements or conditions imposed by the previous phase, and the final system or component complies with specified requirements.

Source Verification: A purchaser method of accepting an item or related service from a supplier by monitoring, auditing, surveillance, witnessing, or observing activities performed by the supplier.

Special Process: A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

Supplier: Any individual or organization who furnishes items or services in accordance with a contract. An all-inclusive term used in place of any of the following: vendor, seller, source, participant, contractor, or subcontractor.

Surveillance: The act of monitoring or observing to verify whether an item, activity, system, or process conforms to specified requirements. Surveillance of a technical work activity is normally done in real time (i.e., the surveillance is accomplished as the work is being performed).

Suspect/Counterfeit Items (S/CIs): An item is suspect when inspection or testing indicates that it may not conform to established Government or industry-accepted specifications or national consensus standards or whose documentation, appearance, performance, material, or other characteristics may have been misrepresented by the supplier or manufacturer. A counterfeit item is one that has been copied or substituted without legal right or authority or whose material, performance, or characteristics have been misrepresented by the supplier or manufacturer. Items that do not conform to established requirements are not normally considered S/CIs if nonconformity results from one or more of the following conditions (which must be controlled by site procedures as nonconforming items):

1. defects resulting from inadequate design or production quality control;
2. damage during shipping, handling, or storage;
3. improper installation;
4. deterioration during service;
5. degradation during removal;
6. failure resulting from aging or misapplication; or
7. other controllable causes.

System Software: Software which is used exclusively in the preparation, installation, or operation of executable software applications. Examples of such software include operating systems, administrative and management systems, system utilities, compilers, assemblers, translators, interpreters, automated protocols, utilities and tools, teleprocessing managers, and query languages.

Technical Review: A documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of the work but collectively have equivalent technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.

Technical Specialist: An individual assigned to an assessment team when the scope, complexity, or special nature of the work to be examined warrants assessment of the technical adequacy of the work or the effectiveness of the technical process.

Testing: An element of verification to determine the capability of an item to meet specified requirements or processes that facilitate the collection of data in conducting scientific investigations by subjecting the item or environment to a set of physical, chemical, environmental, or operating conditions.

Traceability: The ability to trace the history, application, and location of an item, data, or sample using recorded documentation. As related to metrology, traceability means the ability to relate individual measurement results through an unbroken chain of calibrations to one or more of the following:

- U.S. national standards maintained by National Institute of Standards and Technology or the U.S. Naval Observatory
- Fundamental or natural physical constants with values assigned or accepted by the National Institute of Standards and Technology
- National standards of other countries which are correlated with NIST

Transuranic Waste: Waste containing more than 100 nCi of alpha-emitting TRU isotopes per gram of waste, with half-lives greater than 20 years, except for (1) high-level radioactive waste, (2) waste that the Secretary has determined, with the concurrence of the Administrator, does not need the degree of isolation required by the disposal regulations, or (3) waste that the NRC has approved for disposal on a case-by-case basis in accordance with 10 CFR § 61.

TRU Mixed Waste: TRU waste that is also a hazardous waste as defined by the Hazardous Waste Act and 20 NMAC 4.1.200 (incorporating 40 CFR § 261.3).

Use As Is: A disposition permitted for a nonconforming item when it can be established that the item is satisfactory for its intended use.

Validation: An activity that demonstrates or confirms that a process, item, data set, or service satisfies the requirements defined by the user.

Waiver: Documented authorization to depart from specified requirements.

WIPP: The Waste Isolation Pilot Plant, as authorized pursuant to Section 213 of the Department of Energy National Security and Military Applications of Nuclear Energy Authorization Act of 1980 (Pub. L. 96-164; 93 Stat. 1259, 1265) to provide a research and development facility for demonstrating the safe disposal of radioactive wastes produced by national defense activities.

Work: The process of performing a defined task or activity, for example, research and development, operations, maintenance and repair, administration, software development and use, inspection, safeguards and security, data collection, and analysis.

Work Suspension: A formal directive issued by management that work must be stopped until the related significant condition adverse to quality or nonconformance has been resolved.

QAPD-9.0 References

10 CFR Part 71, Subpart H, Packaging and Transportation of Radioactive Material, Quality Assurance

10 CFR Part 830, Nuclear Safety Management

40 CFR Part 194, Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance with 40 CFR Part 191 Disposal Regulations

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

ASME NQA-2a-1990 addenda, Part 2.7, Quality Assurance Requirements of Computer Software for Nuclear Facility Applications

ASME NQA-3-1989, Quality Assurance Program Requirements for the Collection of Scientific and Technical information for Site Characterization of High-Level Nuclear Waste Repositories

DOE/WIPP- 02-3122, Contact-Handled Transuranic Waste Acceptance Criteria for the Waste Isolation Pilot Plant

DOE, Division of Nuclear Safety, G-830.120, Implementation Guide for use with 10 CFR Part 830.120 Quality Assurance

DOE O 414.1C, Quality Assurance

National Fire Protection Association (NFPA) Standard 232-1986, Standards for the Protection of Records

NUREG-1297 (1988), Peer Review for High-Level Nuclear Waste Repositories

NUREG/BR-0167 (1993), Software Quality Assurance Program and Guidelines

SNT-TC-1A, Current Revision, The American Society of Nondestructive Testing (ASNT) Recommended Practice

Waste Isolation Pilot Plant Hazardous Waste Facility Final Permit, EPA No. NM4890139088

TRUPACT II Certificate of Compliance, Certificate Number 9218

HalfPACT Certificate of Compliance, Certificate Number 9279

RH 72-B Certificate of Compliance, Certificate Number 9212

10-160B Certificate of Compliance, Certificate Number 9204

ATTACHMENT A: CBFO Organization, Responsibilities, and Interfaces

Effective implementation of the CBFO QA program is dependent on efforts at all CBFO levels. The CBFO organization is structured such that those assigned responsibility for performing the work are responsible for achieving and maintaining quality. Management is responsible for defining quality, developing appropriate plans to attain quality, and providing support of the workers in pursuit of quality. Persons or organizations not directly responsible for performing the work verify quality achievement. Management empowers employees by delegating authority and decision making to the lowest appropriate level in the organization.

The CBFO Manager is responsible for overall implementation of DOE programs, policies, orders, and guidance pertaining to TRU waste disposal at WIPP. As such, the Manager provides policy direction and oversight of activities that affect TRU waste characterization and grants DOE waste certification authority to the TRU waste sites. This responsibility includes policy direction and oversight for waste characterization, certification, packaging, and transportation activities at participating sites. Overall responsibility for the development and implementation of the CBFO QA program belongs to the CBFO Manager. Authority for execution of the QA function, which ensures effective implementation, is delegated to the CBFO QA Manager in accordance with the allowable delegations as defined by EM-1.

The Office Director of the National TRU Program (NTP) is responsible to ensure that program requirements are met with regard to TRU waste testing, sampling, analysis, sample handling and custody, associated data management, and waste transportation.

CBFO Deputy Manager, Assistant Manager for Operations, and Office Directors are responsible for planning, organizing, directing, controlling, and evaluating those activities in their area of responsibility that support the CBFO mission and implement the QAPD. Their responsibilities include, but are not limited, to:

- Ensuring that adequate technical and QA training is provided for personnel performing activities important to the satisfaction of CBFO organizational and quality objectives
- Ensuring compliance with all applicable regulations, DOE orders, applicable state, and local laws, and other requirements applicable to CBFO programs
- Ensuring that personnel adhere to procedures for the generation, identification, control, and protection of QA records
- Exercising the authority and responsibility to stop unsatisfactory work such that cost and schedule do not override environmental, safety, health, or quality considerations
- Developing, implementing, and maintaining plans, policies, and procedures that implement the QAPD
- Identifying, investigating, reporting, and correcting quality problems

Each CBFO employee, including contractor personnel working to CBFO procedures, is responsible for the quality of his or her work and for promptly reporting all existing, developing, or potential conditions adverse to quality to the responsible management for evaluation and action.

Organizations at all management levels shall establish communication channels that provide timely, routine, and wide dissemination of information pertinent to quality performance.

Where more than one CBFO organization is involved in the execution of activities covered by the QAPD, the responsibility and authority of each organization shall be clearly established and documented. The internal interfaces between organizational units are depicted in CBFO organizational charts. CBFO external interfaces include other DOE elements, CBFO program participants, suppliers, the Environmental Protection Agency, the independent oversight contractor, and the New Mexico Environment Department.

ATTACHMENT B: CBFO Quality Assurance Manager Responsibilities

The CBFO Manager has overall responsibility for the CBFO QA program. Authority for execution of the CBFO QA function, including the independent verification of effective implementation, is delegated to the CBFO QA Manager in accordance with the allowable delegations as defined by EM-1. It is the policy of CBFO to grant the CBFO QA organization sufficient authority, freedom, and access to all work areas to:

- Identify quality problems
- Recommend solutions
- Verify implementation of solutions
- Ensure that unsatisfactory conditions are controlled until proper disposition has occurred

The CBFO QA Manager shall:

- Have direct access to responsible management at a level where appropriate action can be effected
- Be sufficiently independent from cost and schedule considerations
- Have the organizational freedom to communicate with management
- Have the authority and responsibility to stop unsatisfactory work such that cost and schedule do not override environmental, safety, or health considerations
- Have no other assigned responsibilities related to the quality assurance program that would prevent adequate attention to quality assurance matters

The CBFO QA Manager has the authority and overall responsibility to independently assess the effective implementation of the CBFO QAPD, both within the CBFO organization and in those participant organizations supporting CBFO.

The CBFO QA Manager has the following additional authorities and responsibilities:

- The organizational freedom to communicate with management
- Scheduling and conducting independent QA assessments, including WIPP core participant organizations
- Scheduling and conducting audits of activities related to waste generating site certification when notified by the Office Director of the Office of the National TRU Program, that the waste generating site is ready

- Scheduling and conducting recertification audits and surveillances of waste generating sites
- Preparing, as appropriate, and reviewing internal procedures that implement the provision of the QAPD
- Tracking, performing trend analysis, and reporting quality problem areas
- Developing, establishing, and interpreting CBFO QA policy and ensuring effective implementation
- Preparing, issuing, and maintaining the CBFO QAPD
- Interfacing with the CBFO staff, participants, and other stakeholders on quality assurance matters
- Reviewing and approving subordinate QA plans, including participant Quality Assurance Project Plans
- Performing adequacy reviews of QA program documents
- Certifying all CBFO lead auditors and qualifying auditors and technical specialists
- Assuring the independence of lead auditors, auditors, and technical specialists

ATTACHMENT C: TRU Waste Characterization and Certification Organizational and Individual Responsibilities

1. CBFO Office Director, Office of the National TRU Program

The Office Director (OD), Office of the National TRU Program (NTP) executes program functions related to characterization of waste for disposal at the WIPP. The OD of the NTP also manages activities that prepare waste sites for certification and notifies the CBFO QA Manager when new sites are ready for independent audit.

2. CBFO Assistant Manager for Operations

The Assistant Manager for Operations is responsible for regulatory compliance of the WIPP. The Assistant Manager for Operations manages the Compliance team, which is responsible for environmental activities at the WIPP. The Assistant Manager for Operations is responsible for the preparation of compliance documentation and the implementation of programs to meet the requirements specified in final operating permits for the WIPP facility.

3. CBFO Office Director, Office of Site Operations

The Office Director, Office of Disposal, is responsible for operations, safety and health oversight at the WIPP.

4. DOE Site Offices

The DOE site offices are responsible for ensuring that the requirements of the QAPjPs are in compliance with all DOE orders and that the resources and funding are available to accomplish Program activities. The DOE site offices are responsible for providing a liaison between the site contractors and the CBFO.

5. TRU Waste Sites

Each participating site shall develop and implement a QAPjP that demonstrates compliance with and implementation of WIPP TRU waste characterization requirements and the applicable requirements of the WIPP Hazardous Waste Facility Permit and its associated Waste Analysis Plan. These QAPjPs shall include or reference the appropriate management and technical criteria of the Program, as well as qualitative or quantitative criteria for determining that Program activities are being satisfactorily performed. QAPjPs shall identify the organizations and positions responsible for their implementation. The QAPjPs shall also reference site-specific documentation that details how each of the required elements of the Program will be performed. QAPjPs and subsequent revisions must be reviewed for concurrence by the site project manager, site project QA manager, the cognizant DOE site office, the CBFO OD NTP and the CBFO QA Manager.

Prior to the implementation of Program activities at participating sites, standard operating procedures (SOPs) will be developed for all activities affecting Program quality that require written instructions or procedures. For the purposes of the Program, the term SOP refers to any site-specific implementing document. Compliance with SOPs will ensure that tasks are performed in a consistent manner that results in achieving the quality required for the Program. The organization, format, content, and designation of SOPs must be described in the QAPjPs.

6. Site Project Manager

Each participating site's contractor designates a site project manager to oversee characterization program activities at the site. A description of the site project manager's role in relation to the other organizational functions at the site must be included in the site's QAPjP. The site project manager (or designee) reviews and recommends approval of the site QAPjP and subsequent revisions before it is submitted to CBFO for review. Specific Program responsibilities assigned to the site project manager include the following:

- Waste selection and tracking
- Data validation/verification
- Data reconciliation with DQOs
- Assignment of EPA Hazardous Waste Numbers
- QA/QC reports to DOE site office
- Data transmission to CBFO

7. Site Project Quality Assurance Management.

Each participating site's contractor designates a site project QA manager. The site project QA manager shall have the responsibilities and authorities described in section QAPD-2.1.1.3 of this QAPD. This individual will have the authority to stop Program activities at a participating site if quality is not assured or controlled.

The site project QA manager shall summarize all relevant information on the QA/QC activities during the period in a semiannual report. This semiannual report shall be distributed to the DOE site office and the site project manager at the same time. The site project manager shall review the report, comment if appropriate, and then forward a copy of the report with comments to the DOE site office.

8. Site Waste Certification Official. Each participating site's contractor designates a waste certification official who must document and certify that all TRU waste payload containers prepared for shipment to WIPP meet all the requirements specified in the *Contact Handled Transuranic Waste Acceptance Criteria for the Waste Isolation Pilot*

Plant (CH-WAC; DOE 2002) and transmit the waste certification data to the WIPP M&O contractor.

9. Site Transportation Certification Official. Each participating site's contractor designates a transportation certification official who documents and certifies that payload assemblies for shipment to WIPP meet all the requirements of the *TRUPACT-II Authorized Methods for Payload Control* (TRAMPAC; NRC 1997).