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WP 13-1
Revision 30

Washington TRU Solutions LLC

Quality Assurance Program Description

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Quality Assurance Program Policy Statement

Washington TRU Solutions LLC (WTS) is the United States Department of Energy's (DOE) performance-based management and operating contractor at the Waste Isolation Pilot Plant (WIPP). WTS is committed to performing work activities in such a manner as to minimize risk and environmental impacts and to maximize safety, reliability, and performance.

Toward achievement of this goal, the WTS Quality Assurance Program Description (QAPD) is intended to provide an effective management system tailored to WIPP operations and activities through the deliberate and graded application of quality assurance (QA) elements. As a management tool, the graded approach determines the degree of application of controls commensurate with importance and relative risk to safety, waste isolation, and regulatory compliance, among other factors.

WTS's policy is for all employees to participate in establishing, implementing, assessing, and improving the QA program. Senior management's task is to provide planning and resources to accomplish the organization's objectives. The line organization is responsible for achieving the desired level of quality, and reviewing, evaluating, and improving work processes. Each individual is responsible for the quality of his or her own work. The QA Department verifies the achievement of quality.

As General Manager of WTS, I am committed to implementing the QA program defined in the WTS QAPD. I delegate to the manager of the Quality Assurance Department the authority for maintaining the WTS QAPD, and for providing assistance and support to the line organization for its effective implementation.

M. F. Sharif
General Manager
Washington TRU Solutions LLC

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CHANGE HISTORY SUMMARY

REVISION NUMBER	DATE ISSUED	DESCRIPTION OF CHANGES
30	11/15/10	Updated reference to the HWFP on Appendix A

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ACRONYMS AND ABBREVIATIONS

ASME	American Society of Mechanical Engineers
ASNT	American Society for Nondestructive Testing
CAQ	Condition Adverse to Quality
CAP	Corrective Action Plan
CBFO	Carlsbad Field Office
CCP	Central Characterization Project
CFR	*Code of Federal Regulations*
CH	Contact-handled
DEAR	U. S. Department of Energy Acquisition Regulations
DOE	U. S. Department of Energy
EDO	Environmental data operation
EPA	U. S. Environmental Protection Agency
HWFP	Hazardous Waste Facility Permit
ISMS	Integrated Safety Management System
GPDD	General Plant Design Description
M&DC	Monitoring and data collection (equipment)
M&TE	Measuring and test equipment
NARA	National Archives and Records Administration
NDE	Nondestructive examination
NEPA	National Environmental Policy Act
NIST	National Institute of Standards and Technology
NMAC	New Mexico Administrative Code
NMSA	New Mexico Statutes Annotated
NQA	Nuclear Quality Assurance
NRC	Nuclear Regulatory Commission
NUREG	Nuclear Regulatory Commission Report Designation
QA	Quality Assurance
QAPD	Quality Assurance Program Description/Document (CBFO)
QAPjP	Quality Assurance Project Plan
RIDS	Records Inventory and Disposition Schedule
SCAQ	Significant Condition Adverse to Quality
S/CI	Suspect/Counterfeit Item
SQA	Software Quality Assurance

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TRAMPAC	TRUPACT-II Authorized Methods for Payload Control
TRU	Transuranic
TRUPACT-II	Transuranic Package Transporter Model II
WAC	Waste Acceptance Criteria
WAP	Waste Analysis Plan
WIPP	Waste Isolation Pilot Plant
WTS	Washington TRU Solutions LLC

INTRODUCTION [1]

This Washington TRU Solutions LLC (WTS) Quality Assurance Program Description (QAPD) is the quality management document which identifies federal and industry quality requirements applicable to the WTS quality assurance (QA) program. This document establishes the minimum quality requirements for WTS personnel and guidance for the development and implementation of QA programs by WTS organizations.

Waste characterization activities performed under the Central Characterization Project (CCP) are excluded from the requirements of this QAPD except when specifically called out in CCP procedures. The CCP has established an independent QA program, documented in the CCP Transuranic Waste Characterization Quality Assurance Project Plan (QAPjP) and the CCP Transuranic Waste Certification Plan, which incorporate the applicable requirements of the U.S. Department of Energy (DOE) Carlsbad Field Office (CBFO) Quality Assurance Program Document (QAPD). Responsibilities that overlap between the two programs are documented in approved and controlled documents. Responsibility and authority for execution of the QA function for waste characterization, certification, and transportation activities performed at off-site facilities under the CCP is delegated to the CCP Site Project Quality Assurance Officer.

Requirements and guidance are based on criteria contained in Title 10 *Code of Federal Regulations* (CFR) Part 830, Subpart A, DOE Order 414.1C, and the CBFO QAPD, and supplemented with additional criteria/guidance from such sources as 10 CFR Part 71, 48 CFR §970.5204-2, DOE Policy 450.4, DOE Order 226.1A, and NQA [Nuclear Quality Assurance]-1 (1989 edition). Table 1 lists source documents, which fall into one of three categories:

- Regulatory documents that define the requirements necessary for 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 DOE nonreactor nuclear facility

- Commitment documents that are imposed by the DOE

- Guidance documents, some of which are not directly applicable to TRU waste disposal operations or activities, but which provide additional information useful in developing QA programs

This list of source documents is NOT all-inclusive.

This QAPD is organized to provide a description of general, management, performance, and assessment requirements, as well as supplementary quality assurance requirements for specific application areas (i.e., Sample Control and Software Requirements [ASME (American Society of Mechanical Engineers) NQA-2a, Part 2.7]).

WTS is required to develop a QA program description that describes how work is managed in order to achieve planned objectives and goals. QA implementing procedures shall be used to control these work activities.

The requirements and guidance contained in this QAPD are based on the principle that work shall be planned, documented, performed safely under controlled conditions, and periodically assessed to establish work item quality and process effectiveness and promote improvement. The requirements described in this document reflect the responsibilities assigned to management and personnel of WTS organizations and their responsibility for planning, achieving, verifying, and assessing quality and promoting continuous improvement. This QAPD further delineates the quality contributions of all personnel and encourages their active participation in accomplishing quality objectives.

TABLE 1 - QA PROGRAM SOURCE DOCUMENTS	
REGULATORY DOCUMENTS	TITLE
Title 10 CFR Part 21	"Reporting of Defects and Noncompliance"
Title 10 CFR Part 71, Subpart H	"Quality Assurance" (Packaging and Transportation)
Title 10 CFR Part 830, Subpart A	"Nuclear Safety Management," "Quality Assurance Requirements"
Title 40 CFR Part 191	"Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes"
Title 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"
Title 40 CFR Part 261	"Identification and Listing of Hazardous Waste"
Title 40 CFR §268.6	"Petitions to Allow Land Disposal of a Waste Prohibited under Subpart C of Part 286"
Title 48 CFR §970.5204-2	"Laws, Regulations, and DOE Directives"
ASME NQA-1-1989 Basic and Supplementary Requirements	*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 (excluding Section 2.1(b) and (c), and Section 17.1)	*Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories*
NM4890139088 – TSDF/WIPP	WIPP Hazardous Waste Facility Permit
NRC [Nuclear Regulatory Commission] 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	CNS 10-160B Certificate of Compliance
COMMITMENT DOCUMENTS	TITLE
DOE Order 226.1A	*Implementation of Department of Energy Oversight Policy*
DOE Order 414.1C	*Quality Assurance*
DOE Policy 450.4	*Safety Management System Policy*
DOE/CBFO-94-1012	*Quality Assurance Program Document*
DOE/CBFO 09-3442	*CBFO Integrated Safety Management System Description*

TABLE 1 - QA PROGRAM SOURCE DOCUMENTS	
SNT-TC-1A-1980	American Society for Nondestructive Testing (ASNT) "Recommended Practice No. 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 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance*
EPA (U. S. Environmental Protection Agency) QA/G-5	*EPA Guidance for Quality Assurance Project Plans*
NUREG [Nuclear Regulatory Commission Report Designation]-1297 (2/88)	*Peer Review for High-Level Nuclear Waste Repositories*
NUREG-1298 (2/88)	*Staff Position – Qualification of Existing Data for High-Level Nuclear Waste Repositories*
NUREG-0167 (1993)	*Software Quality Assurance Program and Guidelines*

SECTION 1 MANAGEMENT QUALITY ASSURANCE REQUIREMENTS

1.1 Quality Assurance Program and Organization

This section defines the requirements for the development of the WTS QA program. It also describes the WTS organizational structure, interfaces, functional responsibilities, and levels of authority for performing, managing, and assessing the adequacy of work. WTS is required to develop, implement, maintain, and document its QA programs in accordance with 10 CFR Part 830, Subpart A; 40 CFR Part 194; 10 CFR Part 71, Subpart H; DOE Order 414.1C; and the CBFO QAPD.

The QA program defines the aspects of the management systems to be employed to ensure that the requirements and guidance described by this QAPD are met. The purpose of specifying requirements and associated guidance for a QA program is to ensure that an effective management system is developed and implemented. The management system shall ensure that items, processes, and services such as the following meet or exceed the requirements of the QA program:

- Environmental monitoring, monitoring of the performance of the disposal system, and sampling and analysis activities
- Field measurements of geologic factors, ground water, meteorologic, and topographic characteristics
- Computations, computer codes, models and methods used to demonstrate compliance with the disposal regulations in accordance with the provisions of this program
- Design of the disposal system and actions taken to ensure compliance with design specifications
- Other systems, structures, components, and activities important to the containment of waste in the disposal system

This QAPD provides for efficient conduct of work that ensures protection of workers, the public, and the environment, taking into account the work to be performed and the associated hazards. This QAPD and other site management systems form the basis for the WIPP Integrated Safety Management System (ISMS), which provides a formal, organized process to plan, perform, assess, and improve the safe conduct of work. The WIPP ISMS is documented in DOE/CBFO 09-3442 and WP 15-GM.03. This QAPD functions with and supports the WIPP ISMS. The QA program provides processes and tools for ensuring that the ISMS achieves its objectives. Management controls established in this QAPD support the following attributes and objectives of the ISMS:

- Expectations for implementation (DEAR [Department of Energy Acquisition Regulations] 970.5204-2[c])

- Documentation of the Management System (ISMS Principle 7 Operations Authorization)
- Clear roles and responsibilities (ISMS Principle 2)
- Balanced priorities (resources) (ISMS Principle 4)
- Feedback and improvement (ISMS Core Function 5)
- Line management responsibility (ISMS Principle 1)
- Competence and qualifications (ISMS Principle 3)
- Standards and controls for work (ISMS Principle 5 and Core Function 4)
- Graded and tailored controls (ISMS Principle 6)

This QAPD establishes requirements for a comprehensive and integrated contractor assurance system, which in conjunction with established site management and oversight programs provides for:

- Identification of program and performance deficiencies and opportunities for improvement
- Reporting of deficiencies to responsible managers and authorities
- Corrective and preventive actions
- Sharing of lessons learned across all aspects of operations

QA management controls are applied to activities and items, including those that affect the ISMS and the contractor assurance system, using a graded approach in accordance with the Grading Items and Processes and Applying Quality Assurance Controls section of this QAPD.

Effective implementation of the WTS QA program is dependent on the efforts of all levels of the WTS organization. The individual performing the work is responsible for achieving and maintaining quality; line management is responsible for defining quality, developing appropriate plans to attain quality, and supporting the workers in pursuit of quality; and an independent assessor is responsible for independently assessing and verifying the quality of the work. The QA Department is responsible for defining, integrating, and ensuring effective implementation of the QA program.

The WTS management structure consists of the General Manager, Senior Staff managers, who are appointed by the General Manager according to the current needs of the organization, and section managers. An organization chart is shown in Figure 1-1. The Human Resources organization maintains and updates the organization chart.

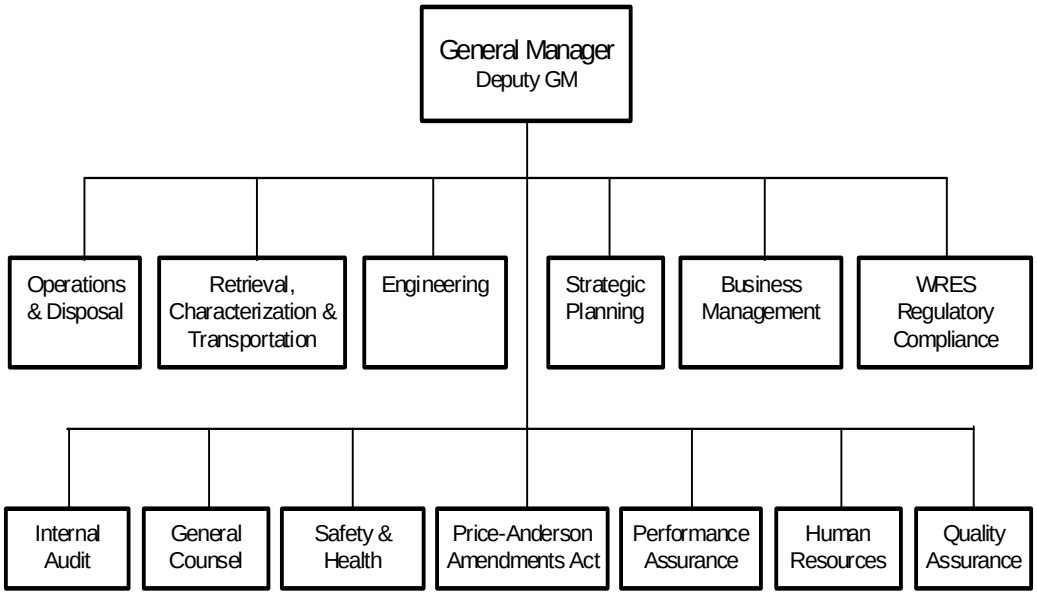

Figure 1-1 — WTS Organization

1.1.1 General Manager

The General Manager has overall responsibility and authority for the development and implementation of the QA program and for approving this document. Authority for execution of the QA function is delegated to the QA manager, who is authorized to establish the QA program and ensure its effective implementation.

1.1.2 Senior Management

Senior Staff managers represent primary functions such as the following:

- Operations and Disposal
- Retrieval, Characterization, and Transportation
- Engineering
- Strategic Planning
- Business Management
- Regulatory Compliance (Washington Regulatory and Environmental Services)
- Internal Audit
- General Counsel

- Safety and Health
- Price-Anderson Amendments Act
- Human Resources
- Quality Assurance
- Performance Assurance

Senior Staff managers, including the QA manager, report directly to the General Manager.

Senior Staff managers are responsible for implementing this QAPD. They provide the necessary planning, organization, direction, control, resources, and support to achieve their defined objectives. Senior Staff managers are required, and have the authority, to establish and implement policies and procedures that control the quality of work in accordance with this QAPD.

Senior Staff managers have various quality related responsibilities which include:

- Planning, performing, and improving work subject to the controls of this QAPD

- Ensuring that adequate technical and QA training is provided for personnel performing work subject to the controls of this QAPD

- Ensuring compliance with all applicable requirements, including regulations, DOE Orders, and laws

- Ensuring that personnel adhere to procedures for the generation, identification, storage, and disposition of QA records

- Determining and providing the necessary resources and environment to accomplish required activities and maintain the quality of work performed in accordance with this QAPD

- Establishing and controlling schedules to ensure that required activities are completed as planned and in accordance with applicable requirements

- Having the responsibility for halting unsatisfactory evolutions such that cost and schedule do NOT override environmental, health, safety, and quality considerations

- Developing, implementing, and maintaining plans, policies, and procedures that define how the work will be accomplished and implement applicable portions of the QA program

- Identifying, investigating, reporting, and correcting quality problems

1.1.3 Line Management (Section Managers)

Quality achievement is the responsibility of those performing the work. The line management is responsible for the achievement of quality in their area. Management shall identify the responsibilities and authorities of those organizational line management positions responsible for achieving quality.

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

Each line organization is responsible for indoctrination and training of personnel, as necessary.

The indoctrination and training, at a minimum, shall include the performance of activities important to safety and waste isolation and the process of receiving, handling, moving, monitoring, and disposal of TRU waste, and shall ensure that suitable proficiency is achieved and maintained.

1.1.4 Employee

Each 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. The requirements of this QAPD are binding on all personnel through the use of implementing documents.

1.1.5 Quality Assurance Manager

The QA manager has the overall responsibility and authority to perform independent assessments to verify the organization's achievement of quality and assure the effective implementation of the QA program. Additional responsibilities of the QA manager include the following:

- Develop, establish, and interpret the overall QA policy and ensure effective implementation
- Prepare, maintain, and improve this QAPD
- Interface with the CBFO staff, participants, and other stakeholders on QA matters
- Schedule and conduct QA independent oversight
- Maintain liaison with QA organizations from other WIPP participants and other affected organizations

- Review procedures:
  - That implement this QAPD
  - For proper application of the QA program to WTS items and activities
- Evaluate the adequacy of supplier QA programs
- Provide for the administrative processing of documentation concerning conditions adverse to quality
- Participate in the disposition of supplier-related nonconformances
- Assist other organizations with quality planning, documentation, measurement, problem identification, and the development of problem solutions
- Provide guidance to all applicable subordinate organizations concerning identification, control, and protection of QA records
- Track and perform trend analysis of quality problems, and report quality problem areas
- Ensure QA Department involvement in decisions or commitments which directly affect nuclear safety or waste isolation at WIPP

The 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 effectively communicate with other senior management positions
- Have no assigned responsibilities unrelated to the QA program that would prevent appropriate attention to QA matters

Management shall grant the QA organization sufficient authority, access to work areas, and organizational freedom to:

- Identify quality problems
- Participate in development of solutions

- Verify implementation of solutions
- Ensure that unsatisfactory conditions are controlled until proper disposition has occurred

1.1.6 Delegation of Work

Individuals or organizations responsible for the work may delegate that work to other individuals or organizations; however, the individuals or organizations making the delegation shall retain overall responsibility for that work.

1.1.7 Resolution of Disputes

Differences of opinion involving QA program requirements will be brought to the attention of the responsible manager and the QA manager. If NOT resolved, these differences will be elevated progressively to higher levels of management as necessary.

1.1.8 Establishment and Maintenance of Quality Assurance Programs

WTS shall incorporate into its QA program documents and implementing procedures the requirements described in the CBFO QAPD, Hazardous Waste Facility Permit (HWFP) Waste Analysis Plan (WAP), QAPjPs, Certification QA Plans, Waste Acceptance Criteria (WAC), and Certificates of Compliance for NRC-licensed nuclear packaging, as applicable.

This QAPD, and all changes to this QAPD, shall be reviewed and approved by the CBFO.

When the CBFO QAPD is revised, the WTS QAPD, QAPjPs, and implementing procedures shall be evaluated and appropriately revised to ensure that the WTS QA program meets the applicable requirements of the CBFO QA program.

1.1.8.1 Quality Assurance Project Plans

Each QAPjP, when required by other regulatory drivers, shall include the information required by the governing regulatory driver.

The QA manager shall review and approve all WTS QAPjPs.

When a QAPjP is revised, all affected implementing procedures are to be reviewed and changed as appropriate. QAPjP revisions will be approved by the QA manager and the cognizant Senior Staff manager.

1.1.8.2 Grading Items and Processes and Applying Quality Assurance Controls

The graded approach is a systematic determination by which items, services, and processes are analyzed to determine the extent to which the QA requirements of this QAPD are applied to each item, service, or process. The grading process provides the flexibility to design controls that best suit the facility or activity. The graded approach process shall determine the appropriate level of effort necessary in the performance of work important to safety and waste isolation at the WIPP facility. The requirements in this QAPD shall be applied to the items, services, and processes which require the greatest level of QA as determined by the grading process. A subset of these requirements may be applied to other items, services, and processes, as determined by the cognizant manager or the graded approach philosophy.

The level of QA controls shall be commensurate with the following criteria:

- Functional Classification, based on DOE-STD-3009-94, *Preparation Guide for U. S. DOE Nonreactor Nuclear Facility Safety Analysis Reports*; and DOE/WIPP-07-3372, *Waste Isolation Pilot Plant Documented Safety Analysis*
- The importance of an item or activity with respect to safety, waste isolation, and regulatory compliance
- The importance of the data to be generated
- The need to demonstrate compliance with specific regulatory, design, and QA requirements
- The impact on the results of performance assessments and engineering analyses
- The magnitude of any hazard or the consequences of failure
- The life-cycle stage of a facility or item
- The programmatic mission of a facility
- The particular characteristics of a facility, item, or activity (e.g., complexity, uniqueness, history, or the necessity for special controls or processes)
- The relative importance of radiological and nonradiological hazards

Grading methods shall provide for:

- The assignment of management and QA control levels

- The definitive criteria used in selecting those levels
- Detailed descriptions of the management and QA control provisions corresponding to those levels

The QA manager shall perform assessments to verify effective implementation of the graded approach process.

Procedures which establish and implement graded approach shall be submitted to the CBFO QA manager for approval.

1.1.8.3 Applicability

Requirements that are specified in this QAPD as applicable to items or activities important to compliance certification application, waste characterization, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP facility shall apply to the following:

- WIPP site activities or operations that process, store, or dispose of radioactive waste, perform waste management activities involving radioactive waste or materials, or design, manufacture, or assemble items for use with radioactive waste or materials in such a form and quantity that a nuclear hazard exists
- Waste characterization activities
- Environmental monitoring, monitoring the performance of the disposal system, and sampling and analysis activities
- Field measurements of geological factors, ground water, meteorology, and topography
- Computations, codes, models, and methods used to demonstrate compliance with disposal regulations
- Expert judgment elicitation to support applications for recertification or determination of compliance
- Design of the disposal system and actions taken to ensure compliance with design specifications
- The collection of data and information used to support compliance certification application(s) and/or any modifications to the compliance certification application
- Other structures, systems, components, and activities important to the isolation of waste in the disposal system

- Items and activities related to NRC-licensed packaging (e.g., TRUPACT-II, RH-TRU 72-B, CNS 10-160B) design, purchase, fabrication, handling, shipping, storage, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety

1.1.9 Contractor Assurance System

WTS has implemented a contractor assurance system which includes the following elements, in accordance with the requirements of this QAPD:

- Assessments (including self-assessments, management assessments, and internal independent assessments as defined by laws, regulations, and DOE directives such as quality assurance program requirements) and other structured operational awareness activities (e.g., management walk-throughs)
- Incident/event reporting processes, including accident investigations
- Worker feedback mechanisms
- Issues management, including causal analysis, identification of corrective actions and recurrence controls, corrective action tracking and monitoring, closure of corrective actions and verification of effectiveness, trend analysis, and identification of continuous improvement opportunities
- Lessons learned programs
- Performance indicators/measures

The contractor assurance elements, as described in the applicable sections of this QAPD, are applied to activities which affect the following, in accordance with the Grading Items and Processes and Applying Quality Assurance Controls Section of this QAPD:

- Environment, safety, and health (i.e., protection of the environment, workers, and the public from damage or injury)
- Safeguards and security
- Emergency management
- Cyber security

The contractor assurance system includes evaluations of compliance with the following, as applicable, using internal systems, such as independent and management assessments, supplemented by external resources (corporate audits, third-party certifications, or external reviews by experts), as needed:

- Laws
- Regulations
- National standards
- DOE directives
- DOE-approved plans and program documents (e.g., authorization basis documents and quality assurance program)
- Site-specific procedures/manuals
- Criteria review and approach documents
- Contractual performance objectives, and other contractually mandated requirements

Any deficiencies in DOE requirements (e.g., conflicting, unclear, or incomplete requirements contained in a DOE Order or other DOE document) identified through WTS oversight and assurance processes are brought to the attention of the CBFO.

Contractor assurance system data are documented and readily available to DOE. Results of assurance processes are periodically analyzed, compiled, and reported to the DOE. Access to information and facilities is available to the DOE to conduct oversight.

1.1.10 Interfaces

The CBFO is the approval authority for all external QA interface agreements and subsequent revisions between WIPP participants (Generator Sites, the DOE, and contractors).

Interface agreements between WTS and DOE Headquarters, EPA, DOE Albuquerque, DOE CBFO, and others are considered external interfaces.

Where more than one organization is involved in the execution of activities covered by the WIPP QA program, the responsibility and authority of each organization shall be clearly established 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.

1.1.11 Communications

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

- The status of development and implementation of the QA program
- The status and resolution of significant quality problems
- The lessons learned from significant quality problems and adverse conditions
- Quality management practices and improvements
- Trend analysis results

1.1.12 Planning Work

Planning shall be performed and documented to ensure that work is accomplished under suitably controlled conditions. Appropriate, nationally recognized standards (e.g., DOE Standards, American National Standards Institute, ASME, Institute of Electrical and Electronics Engineers) shall be used, whenever applicable, to develop and implement methods and processes to control the conduct of work. Standards used to develop the implementing procedures shall be documented in work activity planning.

When no recognized standard exists, the technical procedures shall be reviewed to ensure technical adequacy of the methods and processes to be implemented.

As appropriate, planning elements shall include:

- Definition of work scope and objectives, and a listing of the primary tasks involved
- Identification of scientific approach or technical methods used to collect, analyze, or study results of applicable work
- Identification of methods or procedures for field, laboratory, and engineering sampling, testing, and analysis activities
- Provisions for determining the resources and numbers of personnel required
- Provisions for developing, maintaining, and controlling schedules that ensure timely and safe completion of required activities

- Consideration of risks to employees, public, and environment, and identification of appropriate controls
- Consideration of risks to product quality and identification of appropriate controls
- Description of any management reviews, technical reviews, QA reviews, peer reviews, and readiness reviews, as appropriate
- Identification of applicable technical standards and quality criteria
- Identification of applicable implementation documents
- Identification of field and laboratory testing equipment or other equipment
- Identification of, or provisions for the identification of, required records and the recording of objective evidence of the results of the work performed
- Identification of prerequisites, special process controls, specific environmental conditions, processes, or skills
- Identification of computer software

1.1.13 Worker Feedback

Management shall promote effective achievement of performance objectives by obtaining timely, objective feedback on the effectiveness of planning and work to meet performance measures; and involving all employees to ensure that improvements are identified and implemented to enhance performance.

WTS uses processes such as the following to solicit feedback from workers:

- Issues management program
- Action Requests
- Employee concerns programs
- Telephone or intranet "hotline" processes for reporting concerns or questions
- Pre-job briefs
- Job hazard walk-downs by workers prior to work
- Post-job reviews
- Employee suggestion forms
- Safety meetings
- Employee participation in committees and working groups
- Labor organization input

1.1.14 Lessons Learned

WTS has established a program to communicate lessons learned during work activities, process reviews, and event analyses to potential users and apply them to future work activities. Lessons learned are identified, applied, and exchanged with the rest of the DOE complex. Lessons learned identified by external sources are reviewed and applied to prevent similar occurrences.

1.1.15 Performance Indicators/Measures

WTS has established a program to identify, gather, verify, analyze, trend, disseminate, and use performance indicators. Data measuring the performance of facilities, programs, and organizations are identified, monitored, and analyzed to demonstrate performance improvement or deterioration relative to identified goals, suggest further improvements, and identify good practices and lessons learned. The data are considered in allocating resources, establishing goals, identifying performance trends, identifying potential problems, and applying lessons learned and good practices.

1.1.16 Event Reporting

WTS has established a program to report, analyze, and address operational events, accidents, and injuries. Occurrences are reported and processed consistent with applicable DOE requirements, and associated corrective actions are evaluated, documented, and reported. Events, accidents, and injuries are analyzed for trends.

1.2 Personnel Qualification and Training

Personnel performing work will be qualified to ensure job proficiency. Management shall establish methods for the evaluation, selection, indoctrination, training, and qualification of personnel performing work.

Records generated by qualification and project or work-specific skill training programs are collected and maintained as part of the individual's training records.

1.2.1 Qualification

Qualification requirements for positions or job categories within WTS organizations will be established commensurate with the functions associated with the work performed. Initial experience and educational requirements are assured through the evaluation made for the position by the interviewing supervisor/manager and the hiring authority. The evaluation will be documented for positions that are directly related to compliance certification or recertification application, waste characterization, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP facility. These positions include but are not limited to managers, designers, scientists, independent assessment personnel, operators, maintenance personnel, technicians, auditors, and inspectors.

Senior Staff managers shall:

- Establish qualification requirements for positions commensurate with the scope, complexity, and nature of the work, including minimum education, training, and experience requirements

- Ensure that qualifications commensurate with the minimum requirements specified, including minimum education, experience, and proficiency, are met. When education and experience can NOT be specifically verified, provide a statement of justification for the personnel assignment

1.2.2 Training

Personnel performing activities important to compliance certification or recertification application, waste characterization, 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:

- Training shall emphasize correct performance of work and provide a description of why quality and nuclear safety requirements exist and shall describe the fundamentals of the work and its context

- Training shall be subject to ongoing review, using feedback from personnel performance, trainees and supervisors, accidents, and assessments where appropriate, to determine instruction and program effectiveness, and shall be upgraded whenever needed improvements or other enhancements are identified

Senior Staff managers shall:

A. Ensure that personnel are indoctrinated and trained, including on-the-job training as needed, to achieve initial proficiency; maintain proficiency; and adapt to changes in hazard conditions, technology, methods, job responsibilities and authority, and QA requirements identified in implementing procedures prior to performing assigned tasks.

B. Ensure that personnel are indoctrinated in the following:

- General criteria, including quality requirements, applicable codes, regulations, and standards
- Applicable implementing procedures

C. Ensure that records generated during qualification, general indoctrination and training, or specific skill training activities are collected and maintained as QA records. Such records may take the form of:

- Attendance sheets
- Qualification cards
- Personnel training records

1.3 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.

The WTS quality improvement process focuses on preventive actions and on those quality problems that have the greatest potential for:

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

WTS shall establish and implement processes to detect and prevent quality problems, promote quality improvement, and manage issues. Preventive actions shall be taken, through design, procurement, and other process controls and assessment activities as described in this QAPD, to prevent or reduce the probability of occurrence of quality problems. Items, services, and processes that do NOT meet established requirements shall be identified, documented, reported, controlled, evaluated to determine their risk, significance, and priority, and corrected. The process shall provide for communication and documentation of dissenting opinions. Quality problems may be identified by WTS or by an external source.

All personnel are responsible for identifying quality problems and are encouraged by management to suggest improvements. Management at all levels should foster a "no-fault" attitude toward the identification of quality problems by:

- Endeavoring to "fix the problem, NOT the blame"
- Encouraging candid, frank, and open communications

1.3.1 Reporting

Nonconformances related to defects or failure to comply with requirements applicable to NRC-licensed packaging (e.g., TRUPACT II, RH-TRU 72-B, CNS 10-160B) shall be reported to the CBFO Office of the National TRU Program. WTS shall evaluate issues and nonconformances for reporting to the NRC under 10 CFR Part 21 or Part 71 and provide the results of the evaluation to the CBFO.

1.3.2 Quality Problems

Quality problems may involve:

- Nonconforming items, including suspect/counterfeit items and other items that do not conform to specified requirements

- Noncompliance with a QA program requirement. Noncompliances shall be classified as either Conditions Adverse to Quality (CAQs) or Significant Conditions Adverse to Quality (SCAQs)

1.3.3 Nonconforming Items

Items that do not conform to established requirements or whose conformance is indeterminate shall be controlled to prevent inadvertent installation or use. Controls shall provide for identification, documentation, evaluation, segregation when practical, disposition, and notification to affected organizations.

Nonconforming items shall be identified and documented. The documentation shall identify and describe the characteristics that do not conform to established criteria.

Further processing, delivery, installation, or use of nonconforming items shall be controlled pending evaluation and approved disposition by authorized personnel.

Nonconforming items shall be physically identified by marking, tagging, or other methods that do not adversely affect their end use. If physical identification of a nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be clearly identified. For installed items which cannot be directly identified, the identification shall be placed in an appropriate location, such as the doorway to an equipment room, remote switch, etc. The identification shall be legible and easily recognizable and shall be traceable to the reporting documentation.

Nonconforming items shall be segregated in a clearly identified and designated hold area, if practical, until properly dispositioned. If segregation is impractical or impossible due to physical conditions, then other precautions shall be employed to preclude inadvertent use. Installed nonconforming items which cannot be segregated shall be identified as nonconforming until disposition and corrective action are completed.

The disposition of nonconforming items shall be accomplished as follows:

A. The nonconforming characteristics shall be reviewed. The review shall include a determination of the need for corrective action in accordance with the requirements of the Corrective Action section of this QAPD. Recommended dispositions shall be proposed, evaluated, and approved in accordance with documented procedures. Organizations affected by the nonconformance shall be notified.

B. The responsibility and authority for reviewing, evaluating, and approving the disposition of nonconforming items and for closing nonconformance reports shall be defined in applicable QA plans or implementing procedures. Personnel performing evaluations to determine the disposition of nonconforming items shall have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.

C. The disposition of "use as is," "reject," "repair," or "rework" shall be identified and documented.

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

E. 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. The as-built records, if such records are required, shall reflect the accepted deviation.

1. 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.
2. 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.

F. The disposition of an item to be reworked or repaired shall contain a requirement to reexamine (inspect, test, or conduct nondestructive examination) the item to verify acceptability. Repaired or reworked items shall be reexamined using the original process and acceptance criteria unless alternative acceptance criteria or methods have been established as part of the nonconforming item disposition.

Nonconformance documentation shall be periodically analyzed by the QA organization to identify quality trends in accordance with the Corrective Action section of this QAPD.

1.3.4 Corrective Action

A CAQ occurs when a QA requirement has not been met. Classification of CAQs is based on the effect the CAQ has on compliance with regulatory requirements for safety, operability, TRU waste characterization, TRU waste containment, and the effective implementation of this QAPD.

1.3.4.1 Conditions Adverse to Quality

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

B. Responsible management shall perform the following for CAQs:

- Identify the cause of the adverse condition
- Determine the extent and impact of the adverse condition
- Notify affected organizations, including external organizations, as applicable
- Plan and complete action to correct the adverse condition
  - Complete remedial action as soon as practical
  - Include prevention of recurrence of the adverse condition as part of the corrective action planning

1.3.4.2 Significant Conditions Adverse to Quality

A. Implementing documents shall include criteria for determining if a CAQ is significant. These criteria shall be based on the criteria in the definition of SCAQ included in Appendix A.

B. 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.

C. Responsible management shall ensure that affected organizations, including external organizations, are notified, as applicable.

D. SCAQs will be reported to and evaluated by the responsible QA organization, relevant regulatory compliance functions, and the appropriate management responsible for the condition, to determine if a work suspension order is necessary. If necessary, work shall be suspended in accordance with the following:

- The responsible organization shall issue a work suspension order to the responsible management after a work suspension condition has been identified.
- Any WIPP employee having a concern for employee safety, the safety of the environment, or the quality or regulatory compliance of the activity has the responsibility and authority to suspend the performance of that activity.
- Management will take action to evaluate and correct the condition(s) that caused the suspension of work. QA shall verify and document the completion of applicable corrective actions prior to any management action releasing the work suspension order.

1.3.4.3 Corrective Action Planning

Corrective action plans (CAPs) are required for all SCAQs. SCAQ CAPs shall address:

- Remedial Action: actions necessary to resolve the initial condition
- Investigative Actions: assessment of the extent and impact of the SCAQ
- Root Cause Determination: identification of the root cause of the SCAQ
- Actions to Preclude Recurrence: actions necessary to prevent recurrence of the SCAQ
- Schedule: milestones for completion of the CAP, including expected completion dates for the required actions, and identification of responsible organizations/individuals

1.3.4.4 Corrective Action Follow-Up

Corrective action follow-up is required for SCAQ CAPs.

A system shall be established for SCAQ CAPs to:

- Verify effective implementation of scheduled corrective actions
- Complete corrective actions in a timely manner

QA shall evaluate the adequacy of corrective actions planned, assign responsibility for follow-up verification, perform the verification, and document the verification results. If results of verification are unsatisfactory, the CAP shall be revised appropriately, and corrective actions and verification performed.

1.3.5 Improvement Analysis

Quality performance data shall be identified, collected, and 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.

The analysis shall be performed semiannually to provide for prompt identification of trends adverse to quality. Reports of CAQs, including those identified during QA audits and surveillances as corrected during the audit/surveillance, shall be evaluated to identify adverse quality trends and root causes. Results of the evaluation shall be reported to the organization responsible for corrective action.

Trending information shall be reported to responsible management and to QA. Trending information will be provided to the CBFO.

1.3.6 Recurring Conditions Adverse to Quality

For recurring conditions adverse to quality, management shall, as appropriate:

- Determine the events leading to the occurrences
- Develop an understanding of the technical and work activities associated with the conditions adverse to quality
- Determine the extent to which similar quality problems, or precursors to the problem, have been identified
- Determine the effectiveness of any corrective actions that were taken

- Ascertain and identify any generic implications and impacts on completed work
- Consider suspending work associated with the applicable activity
- Suggest actions that can be taken by the responsible organization to preclude recurrence

1.4 Documents

Documents which prescribe processes, specify requirements, or establish design shall be prepared, approved, issued, and controlled.

1.4.1 Document Preparation, Review and Approval

Documents that specify or prescribe work shall be reviewed for adequacy, correctness, and completeness prior to approval and issuance as controlled documents. Management shall identify the individuals or organizations responsible for the preparation, review, approval, and issuance of controlled documents. This is to ensure that documents are accurate, adequate, and approved.

Documents that specify quality requirements, establish design, or prescribe work activities important to compliance certification application, waste characterization, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP facility, such as instructions, procedures, and drawings, shall be reviewed according to the requirements listed below. Documents, such as test plans, management plans, technical reports, performance reports, and test result reports, shall also be subject to the same review and approval criteria as presented below.

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

B. Review criteria shall be established. These criteria shall consider technical adequacy, accuracy, completeness, and compliance with established requirements.

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

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

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

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

G. The appropriate QA organization shall review documents that specify, translate, or implement QAPD or WAP requirements, including changes to such documents.

H. Review comments shall be resolved in accordance with approved procedures. A reviewer's signature for approval or concurrence on a document is considered to be adequate evidence of resolution of review comments. Evidence of review comment resolution shall be maintained on the applicable records inventory and disposition schedule (RIDS).

I. Documents will be approved by the designated approval authority in accordance with the requirements of this QAPD as authorized by the originating organization prior to distribution.

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

1.4.2 Implementing Procedures

A. Implementing procedures shall be reviewed, approved, and controlled.

B. Implementing procedures shall be developed, reviewed, and validated by technically competent personnel and approved by authorized personnel. Administrative process procedures may not require validation.

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

- Responsibilities of the organizations affected by the document
- Technical, regulatory, or other program requirements
- Sequential description of the work to be performed, including any allowance for out-of-sequence processing
- Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished
- Prerequisites, limits, precautions, process parameters, and environmental conditions
- Special qualification and training requirements

- Verification points and hold points
- 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)
- Identification of the records generated
- Records identified in implementing procedures shall be designated as QA records when applicable in the RIDS. QA records shall be classified according to their retention times in the RIDS.

1.4.3 Document Control and Distribution

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:

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

B. Effective dates shall be established for and placed on approved documents.

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

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

E. Controls shall be established identifying and defining the distribution of controlled documents.

1.4.4 Changes to Documents

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.

Document changes shall be:

- Reviewed by the organizations or technical disciplines affected
- Clearly indicated in the changed document

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:

- Correcting grammar or spelling (the meaning has not changed)
- Renumbering sections or attachments
- Updating organizational titles
- Changes to nonquality affecting schedules
- Revised or reformatted forms, providing the original intent of the form has not been altered
- Attachments marked "Example," "Sample," or exhibits that are clearly intended to be representative only
- Clarification changes that do not affect the purpose of the document

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

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

1.5 Records

Records shall be specified, prepared, reviewed, approved, controlled, and maintained to accurately reflect completed work and facility conditions and to comply with statutory or contractual requirements. A "quality assurance record" is a completed record or authenticated portion of a record (regardless of medium) that furnishes evidence of the quality of quality-affecting items and/or activities.

A QA records system shall be established, defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation. QA records may be managed within a general records management system, as long as the requirements of this section are met.

Documents referenced by final reports relating to WIPP site characterization, except readily available references such as encyclopedias, dictionaries, engineering handbooks, national codes and standards, etc., shall be retrievable from a QA records system. Preparers of such reports shall ensure the entry of such documents into a QA records system.

1.5.1 Generating QA Records

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

- Identify those records that shall become QA records
- Identify the organization responsible for submitting the QA records to the records management system

B. Records shall be designated as QA records if they meet any of the following:

- Records that relate to site characterization samples and data
- Records that relate to data used in the Performance Assessment of the WIPP facility
- Records that relate to the mixed TRU waste form characterization and acceptance of the mixed TRU waste form
- Records that document regulatory compliance
- Records that assist in preventing actions that could impair the long-term isolation of the waste
- 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
- Records providing information relevant to postclosure monitoring and assessment of performance of the repository system
- Records preserving for future generations information regarding the geologic setting relevant to mitigation of releases of radioactive materials
- Records which would be of significant value after decommissioning and closure of a repository

C. Individuals shall create QA records that are legible, accurate, and complete.

D. Individuals handling QA records shall provide reasonable protection for the records from damage or loss until the records are submitted to the records management system (this includes documents generated during field operations). For example, if a record is kept in a plastic binder, it should have protective sheets in front and back to ensure no toner is fused to the binder cover.

E. Records shall become QA records when stamped, initialed, or signed and dated as complete by authorized personnel. 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.

F. 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.

G. QA records may be originals or copies; however, original documents are preferred.

H. 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.

1.5.2 Classifying QA Records

QA records, as described above, shall be classified as either "POSTCLOSURE," "LIFETIME" or "NONPERMANENT."

A. Records that fall into one of the following categories shall be classified as "POSTCLOSURE" QA records:

- Records that assist in preventing actions that could impair the long-term isolation of the waste

- 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, shafts, and boundaries of the controlled area

- Records providing information relevant to postclosure monitoring and assessment of performance of the repository system

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

- Records which would be of significant value in exercising the retrieval option for waste packages after decommissioning and closure of the repository

Postclosure 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.

B. Records that cannot be classified as "POSTCLOSURE" records but that fall into one of the following categories shall be classified as "LIFETIME" QA records:

- Records used for repository permitting or certification

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

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

- Records that would be of significant value in demonstrating capability for safe operation

- Records that would be of significant value in maintaining, reworking, repairing, replacing, or modifying WIPP repository systems, components, or structures

- Records that would be of significant value in determining the cause of an accident or malfunction of an item

- Records that would be needed during decommissioning and closure of the repository

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- Records relating to site characterization samples and data
- Records relating to data used in performance assessment of the WIPP facility
- Records that document regulatory compliance
- Records that provide required baseline data for in-service inspections

C. Records that provide objective evidence that the QA program has been properly implemented but do NOT meet the above criteria for postclosure or lifetime records shall be classified as "nonpermanent" QA records. The retention period for nonpermanent records shall be established in writing.

D. Records shall be classified in accordance with the regulatory requirements documents listed in Table 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.

1.5.3 Indexing QA Records

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

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

B. The indexing system shall include, at a minimum, record retention times and the location of the record within the records system in order to facilitate the disposition of scheduled QA records and support planned times for the retrievability of QA records.

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

1.5.4 Receiving QA Records

WTS shall designate the person or organization responsible for receiving QA 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 the following:

A. The receipt control system shall contain a current and accurate status of QA records.

B. A method shall be established for identifying the records required to be included in the records system.

C. A method shall be established for identifying the records that have been received.

D. Procedures shall be established 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.

E. QA records shall be controlled and protected from damage, deterioration, or loss during the receiving processes.

F. QA records shall be submitted to storage without unnecessary delay after the receipt process has been completed.

1.5.5 Storing, Preserving, and Dispositioning QA Records

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

- Description of the storage facility
- Description of the filing and indexing system to be used
- Method for verifying that the QA records received are in agreement with the transmittal document
- Method for receipt acknowledgment to the sender, for records submitted for final storage
- Description of controls governing QA record access, retrieval, and removal

- Method for filing supplemental information and documenting the authorization for corrections

- Method for disposition of superseded QA records

B. 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:

- Natural disasters such as winds, floods, or fires

- Environmental conditions such as high and low temperatures, humidity, dust, and particulate matter

- Infestation of insects, mold, or rodents

- Excessive light, stacking, or electromagnetic fields (special processed records)

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

D. Records that require special processing and control, such as software and related documentation or information on high density media or optical disks, hardware and software required to maintain and access records, shall be controlled to ensure records are useable.

E. Retention times of QA records depend upon their classification. 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 of 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 postclosure records prior to their destruction.

Waste characterization data for each TRU mixed waste container transmitted to WIPP shall be maintained 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 the New Mexico Environment Department 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. These records will then be offered to the National Archives.

Nonpermanent QA records shall be retained for three years or as otherwise specified. QA records shall NOT be destroyed until the following conditions are met:

1. The appropriately assigned National Archives and Records Administration (NARA) authorized disposition specifies destruction.

2. Regulatory requirements are satisfied.

3. The operational status permits the disposal of such records.

4. The related contractual requirements have been satisfied.

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

F. Design and construction of a single records storage facility shall meet the applicable requirements of NQA-1-1989, NQA-3-1989, 10 CFR Part 71, and current requirements of NARA.

G. 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 single records storage facility requirements of F, above, but shall meet all other records storage requirements prescribed in this QAPD.

H. 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 one-hour fire-rated container. The procedures shall specify the maximum allowable time limit for temporary storage. The container shall bear an Underwriter's Laboratory label (or equivalent) certifying one-hour fire protection, or be certified by a person competent in fire protection.

I. Measures shall be established to preclude the entry of unauthorized personnel into the storage area. These measures shall guard against larceny and vandalism.

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

1.5.6 Retrieval of QA Records

A. The records management system shall provide for retrieval of QA records based upon record type (Nonpermanent, Lifetime, or Postclosure).

B. Access to storage facilities shall be controlled. A list designating personnel who are permitted access to the QA records shall be generated, maintained, and posted.

1.5.7 Correcting Information in QA Records

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

B. Corrections to QA records shall be approved by the originating organization.

C. 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 through the use of correction fluids or tapes.

SECTION 2 PERFORMANCE QUALITY ASSURANCE REQUIREMENTS

2.1 Work Processes

Work shall be performed to established, approved, and documented technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements. Work shall be performed under controlled conditions using approved instructions, procedures, drawings, 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.

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. To ensure that the person doing the work achieves 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 as established in this QAPD.

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 will help ensure that the definition of "acceptable work performance" is clearly communicated and that personnel are provided the necessary training, resources, and administrative controls to accomplish their tasks properly.

2.1.1 Work

A. 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.

B. 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.

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

D. Work shall be planned, authorized, and accomplished under controlled conditions using technical standards, quality requirements, and implementing procedures commensurate with the complexity and risk of the work. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied.

E. Management shall ensure that the following are clearly identified and conveyed to workers prior to beginning work:

- Requirements, technical standards, and acceptance criteria for the work and final product
- Hazards associated with the work
- Safety, administrative, technical, and environmental controls to be employed during the work

F. Workers, supervisors, and management shall self-assess work, to identify and resolve deficiencies at the lowest level practicable (e.g., workplace inspections and post-job reviews).

2.1.2 Implementing Procedures

Individuals performing work will comply with implementing procedures; however, when work can NOT be accomplished as described in the implementing procedure or accomplishment of such work would result in an undesirable situation, condition adverse to quality, or an unacceptable safety risk, the work shall be suspended and the procedures changed in accordance with the approved procedure change process.

2.1.3 Item Identification and Control

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

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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 the item's 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:

- Be applied using materials and methods that provide clear, permanent, and legible identification
- NOT be detrimental to the function or service life of the item
- Be transferred to each part of an identified item when the item is subdivided
- NOT be obliterated or hidden by surface treatments, or 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 records), then identification and traceability methods shall be implemented to ensure 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, and stamps), or other means (such as travelers, inspection or test records), and the authority for applying and removing status indicators shall be specified.

F. Where specified, items having limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired.

2.1.4 Suspect/Counterfeit Items

WTS shall:

- Establish a program to control suspect/counterfeit items (S/CIs)
- Identify a management point of contact responsible for the S/CI program
- Prevent the introduction and use of S/CIs through engineering involvement, design, procurement, testing, inspection, maintenance, evaluation, disposition, reporting, trend analysis, and lessons learned work process controls
- Identify and dispose of S/CIs on-site

S/CIs shall be identified, evaluated, and dispositioned through the S/CI program. Only those items that have been found acceptable through engineering analysis and formal disposition shall be used. Items not found acceptable shall be removed.

S/CI controls shall be applied to safety and non-safety applications, as specified in this section. Safety applications are those whose failure could adversely affect the environment, safety, or health of the public or workers, including but not limited to safety-related systems, structures, and components, as defined in the WIPP Documented Safety Analyses.

Managers, supervisors, and workers shall be informed of and trained on S/CI processes and controls, as applicable, including prevention, detection, and disposition of S/CIs. The most accurate, up-to-date information from all available sources on S/CIs and suppliers shall be collected, maintained, disseminated, and used. Sources include:

- Government Industry Data Exchange Program
- Institute of Nuclear Power Operators
- DOE Occurrence Reporting and Processing System
- DOE S/CI website

The following work process controls shall be implemented using available S/CI information:

- Engineering involvement in the development of procurement specifications; during inspection and testing; and when replacing, maintaining, or modifying equipment

- Procurement processes that prevent introduction of S/CIs by:
  - Identifying technical and QA requirements in procurement specifications
  - Accepting only those items that comply with the procurement specifications, consensus standards, and commonly accepted industry practices
  - Inspecting inventory and storage areas to identify, control, and disposition S/CIs
- Inspection, identification, evaluation, and disposition of S/CIs installed in all safety applications and other applications that create potential hazards
- Engineering evaluations and disposition of S/CIs installed in safety applications/systems or in applications that create potential hazards (The evaluations must consider potential risks to the public and worker and cost/benefit impact, and include a schedule for replacement [if required].)
- Ensuring that S/CIs identified in non-safety applications during routine maintenance and/or inspection are reported, evaluated, and dispositioned to prevent future use in safety applications
- Contacting the DOE Inspector General (IG) before destroying or disposing of S/CIs and their documentation to determine whether to retain them for criminal investigation or litigation
- Testing procured or installed S/CIs as necessary using approved engineering test methods
- Reporting S/CIs in accordance with DOE O 231.1A, *Environment, Safety, and Health Reporting*, and DOE O 221.1A, *Reporting Fraud, Waste, and Abuse to the Office of Inspector General*
- Conducting trend analysis and issuing lessons learned reports for use in improving the S/CI program

2.1.5 Special Processes

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

- The results are highly dependent on the control of the process
- The results are highly dependent on the skill of the operator

- The quality of the results can NOT be readily determined by inspection or test of the product

The following activities are examples of special processes:

- Nondestructive examination (NDE)/testing
- Code welding

B. Implementing procedures shall be established to ensure special process parameters are controlled and specified environmental conditions are maintained. In addition to the guidance provided in the Implementing Procedures section of this QAPD special process implementing procedures shall include or reference:

- Requirements for qualification of personnel, process(es), and equipment
- Conditions necessary for completing the special process, including equipment, statistical process control, controlled parameters of the process, and calibration requirements

2.1.6 Handling, Storage, and Shipping

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

A. 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.

B. 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 be applied and removed by authorized personnel.

C. 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.

- If special protective equipment and environments are used, provisions shall be made for verifying their adequacy
- Special handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling
- 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
- Operators of special handling and lifting equipment shall be sufficiently experienced and trained to use the equipment

D. If storage of items is required, then 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:

- Maintenance or replacement of markings and identification tags damaged during handling or aging
- Protection of identification markings that are subject to excessive deterioration due to environmental exposure
- Update of related identification records and documentation

2.1.7 Status Indicators

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

2.2 Design Control

Items and processes shall be designed using sound engineering/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. The adequacy of design products shall be verified/validated by individuals or groups other than those who performed the work. Work shall be verified/validated before approval and implementation of the design.

Designs (from conceptual through final) shall be defined, controlled, and verified. In establishing design controls, management is responsible to ensure 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.

2.2.1 Design Input

Applicable design inputs (such as, but not limited to, design bases, conceptual design reports, performance requirements, regulatory requirements, codes, and standards) will be controlled by those responsible for the design in accordance with the following requirements:

A. Design inputs will be identified and documented, and their selection reviewed and approved by those responsible for the design.

B. Design inputs shall be specified and approved on a timely basis and 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.

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

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

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2.2.2 Design Process

The design process shall be controlled by Functional Classification, based on DOE-STD-3009-94 and DOE/WIPP-07-3372, as defined in the General Plant Design Description (GPDD) and analyzed in the WIPP Documented Safety Analyses, and end use according to the following requirements:

A. 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.

B. 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.

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

D. 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.

E. 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.

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

G. Drawings, specifications, and other design implementation documents shall contain appropriate inspection and testing acceptance criteria.

2.2.3 Design Analyses

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

B. Documentation of design analyses shall include:

- Definition of the objective of the analyses

- Definition of design inputs and their sources
- Results of literature searches or other applicable background data
- Identification of assumptions and designation of those assumptions which shall be verified as the design proceeds
- 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
- Identification of the reviewer and approver

C. 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.

D. Computer software used to perform design analyses shall be developed, qualified, and used according to the requirements of the Software Requirements section of this QAPD.

2.2.4 Design Interface

Design interfaces shall be identified and controlled so that efforts are coordinated among affected organizations.

A. Design interface controls shall include 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.

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

C. 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.

2.2.5 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 commensurate with Functional Classification, based on DOE-STD-3009-94 and DOE/WIPP-07-3372, as defined in the GPDD; the complexity; and the risk associated with the end use application of the design.

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

- Design review
- Alternate calculations
- Qualification testing

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

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

D. 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 verification may be performed by the originator's supervisor, provided that:

- 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, or

- The supervisor is the only individual in the organization competent to perform the verification, and

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

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

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

- Design verification shall be completed before relying on the item to perform its function

F. The extent of the design verification required shall be based on the complexity, risk, uniqueness of the design, degree of standardization, state of the art, and similarity with 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.

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

- The applicability of standardized or previously proven designs shall be verified with respect to meeting pertinent design inputs for each application
- Known problems affecting standard or previously proven designs and their effect on other features shall be considered
- The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design
- Changes in previously verified designs shall require reverification. Such reverifications shall include the evaluation of the effect of those changes on the overall previously verified design and on any design analyses upon which the design is based

2.2.5.1 Design Reviews

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

A. The design inputs were correctly selected and incorporated.

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

C. An appropriate design method was used.

D. The 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.

Disposition of review comments shall be documented.

2.2.5.2 Alternative Calculations

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

2.2.5.3 Qualification Testing

If design adequacy is to be verified by qualification tests, the tests shall be pre-identified. Qualification testing requirements are listed below.

A. The test configuration shall be defined and documented.

B. 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.

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

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

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

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

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

2.2.6 Design Change

Design changes shall be controlled according to the following requirements:

A. 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.

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

C. Changes shall be approved by the same groups or organizations that reviewed and approved the original design documents.

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

- 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.

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

E. 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 the Corrective Action section of this QAPD.

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

G. Design changes that impact related implementing procedures or training programs shall be communicated to appropriate organizations.

2.3 Procurement

WTS shall ensure that procured items and services meet established technical and QA requirements and perform as specified. Prospective suppliers shall be evaluated and selected on the basis of documented criteria. WTS shall verify that approved suppliers continue to provide acceptable items and services.

2.3.1 Procurement Planning Requirements

The procurement of items and services shall be planned and controlled to ensure that procurement requirements are accurate, complete, and clearly understood by suppliers.

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.

2.3.1.1 Procurement Planning

Procurement activities shall be planned and documented to ensure a systematic approach to the procurement process. Planning shall be accomplished as early as possible, but not later than the start of the procurement activities that are required to be controlled.

NOTE: As a minimum, **ALL** service contracts that are related to activities subject to the QA program will require QA review.

Procurement planning shall include the following, as appropriate, based on the risks associated with the end use of the product/service:

A. Identify procurement methods and organizational responsibilities, which includes the QA organization.

B. Identify and document the sequence of actions and milestones needed to effectively complete the procurement. Provide for the integration of the following activities:

- Procurement document preparation, review, and change control
- Selection of procurement sources
- Proposal/bid evaluation and award
- Purchaser evaluation of supplier performance
- Purchaser verifications including any hold-point and witness-point notifications
- Control of nonconformances
- Corrective action
- Acceptance of the item or service
- Identification of QA records

2.3.1.2 Supplier Selection

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

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

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

- Evaluation of the supplier's history for providing an identical or similar product that performs satisfactorily in actual use
- An evaluation of the supplier's current QA documentation supported by any documented qualitative and quantitative information
- On-site evaluation of the supplier's technical and QA capability based on an evaluation of the supplier's facilities, personnel, and quality program implementation. This evaluation will include an assessment of QA program definition and implementation and will be performed by a qualified Lead Auditor

C. The results of procurement source selection shall be documented.

2.3.1.3 Proposal/Bid Evaluation

A. The proposal/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 QA organization, and shall include, as required, the following:

- Technical considerations
- QA program requirement
- Supplier personnel skills
- Supplier production capability
- Supplier past performance\
- Alternatives
- Exceptions

B. Before the contract is awarded, WTS shall resolve, or obtain commitments to resolve, deficient quality conditions identified during the proposal/bid evaluation.

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C. Changes made as a result of the bid evaluations or precontract negotiations shall be incorporated into the procurement documents. The review of such changes and their effects shall be completed prior to contract award. This review shall include the following considerations:

- Procurement document requirements
- Determination of any additional or modified design criteria
- Analysis of exceptions or changes requested or specified by the Supplier and determination of the effects such changes may have on the intent of the procurement documents or quality of the item or service to be furnished

D. Supplier QA programs shall be evaluated and accepted by QA management before the supplier starts work.

2.3.2 Procurement Document Requirements

The following requirements are established to ensure that procurement documents, and any changes thereto, contain appropriate technical and QA requirements.

2.3.2.1 Procurement Document Preparation

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

A. The scope of work shall be defined.

B. Technical requirements shall be specified, including:

- Design bases shall be identified or referenced
- 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
- Tests, inspections, hold points, or acceptance criteria that WTS will use to monitor and evaluate the performance of the supplier shall be specified

C. QA program requirements shall be specified, including:

- The supplier shall have a documented QA program or program requirements that implements a nationally recognized QA requirements program (e.g., NQA-1 or equivalent), as required by contract language, or equivalent requirements from other recognized sources as required, and that satisfies the applicable QA criteria of 10 CFR §830.122. The level of detail of the QA program plan and subsequent implementing procedures shall depend on the scope, nature, or complexity of the item or service being procured, but shall be specified in the purchase order or contract

- The supplier shall incorporate the appropriate technical and QA program requirements into any subtier supplier-issued procurement document. QA program requirements shall be flowed down to suppliers at any tier to the extent necessary to ensure compliance with the requirements

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

- WTS shall ensure that its subcontractors performing work on the WIPP site meet the applicable environment, safety, and health, including quality assurance and integrated safety management; safeguards and security and cyber security; and emergency management requirements

D. Right of access to supplier facilities and records for inspection or audit by WTS or other designee authorized by WTS shall be established.

E. Documentation required to be submitted for information, review, or approval by WTS shall be identified. The time of submittal shall also be established. If WTS requires the supplier to maintain documentation that will become QA records, the retention, classification, and disposition requirements shall be identified. The Supplier's nonpermanent records shall not be disposed of until the related items are released for shipment.

F. When required, purchaser requirements for the supplier to report nonconformances and requirements for WTS's approval of the disposition of nonconformances shall be established.

G. Spare and replacement parts or assemblies and the appropriate technical and QA data required for ordering shall be identified.

H. Requirements for the use, control, and calibration of measuring and test equipment (M&TE) shall be identified.

2.3.2.2 Procurement Document Review and Approval

A. 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. Any technical or quality changes shall require the same level of approval signatures as on the original documents. Procurement document reviews shall be performed and documented prior to issuance to the supplier of the procurement documents or changes thereto.

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

C. Procurement document reviews shall include representatives from the technical and QA organizations.

D. Procurement documents shall be approved by appropriate management.

2.3.3 Supplier Performance Evaluation Requirements

WTS shall establish measures to interface with the supplier of items and services and to verify the supplier's performance, as necessary. The measures shall include:

- Establishing an understanding between WTS and the supplier of the requirements and specifications identified in the procurement documents
- Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements
- Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement requirements
- Identifying and processing necessary change information
- Establishing the method to be used to document information exchanges between WTS and the supplier
- Establishing the extent of assessment activities and inspection

2.3.4 Methods of Acceptance of Items and Services

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

WTS shall accept items and services by one or a combination of the following methods.

2.3.4.1 Source Verification

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

The extent of source verifications 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 in any case prior to the start of those activities that are required to be controlled and shall include the active involvement of WTS'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, the requisitioner, and the supplier.

C. Source verification shall be performed by qualified QA personnel.

2.3.4.2 Receiving Inspection

When a receiving inspection is used to accept an item:

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

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

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

D. The inspection shall be planned and executed according to the requirements stated in the Inspection Planning section of this QAPD.

E. Receiving inspection shall include a review of adequacy and completeness of any required supplier documentation submittal.

F. Receiving inspections shall be performed by qualified personnel.

2.3.4.3 Post-Installation Testing

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

2.3.4.4 Supplier Certificate of Conformance

When a Certificate of Conformance is required and used, the minimum criteria below shall be met:

A. The certificate shall identify the purchased material or equipment, such as by the purchase order number or other identification that is traceable to the requirements of the procurement document.

B. The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of the specific requirements or by providing, on-site, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.

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

D. The certificate shall be signed or otherwise authenticated by a person who is responsible for this QA function and whose function and position are described in the purchaser's or supplier's QA program.

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

F. 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 QA organization at intervals commensurate with the supplier's past quality performance.

2.3.4.5 Acceptance of Services

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

- Technical verification of data produced
- Surveillance and/or audit of the activity
- Review of objective evidence for conformance to the procurement document requirements such as certifications or test reports

2.3.5 Control of Supplier Nonconformance

WTS and the supplier shall establish and document the process for disposition of items that do NOT meet procurement document requirements according to the following:

A. The supplier shall submit a report of nonconformance to WTS that includes a supplier-recommended disposition (e.g., "use as is" or "repair") and provide technical justification for such disposition.

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

- Technical or material requirements are violated
- A requirement in supplier documents that has been approved by WTS is violated
- The nonconformance can NOT be corrected by continuation of the original manufacturing process or by rework
- The item does NOT conform to the original requirement even though the item can be restored to a condition such that the item's capability to function is unimpaired (i.e., a waiver is requested)

B. WTS shall evaluate and approve the supplier's recommended disposition.

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C. WTS shall verify implementation of the disposition.

D. WTS shall maintain records of supplier-submitted nonconformances.

2.3.6 Commercial Grade Items

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

A. The commercial grade item shall be identified in an approved design output 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 applicable to both the replaced item and its application.

B. Supplier evaluation and selection, where determined necessary by WTS based on complexity and importance to compliance certification application, waste characterization, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP facility, shall be in accordance with the requirements of the Supplier Selection section of this QAPD.

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

D. After receipt of a commercial grade item, WTS shall ensure that:

- Damage was not sustained during shipment
- The item received was the item ordered
- Inspection or testing is accomplished, to the extent determined by WTS, to ensure conformance with the manufacturer's published requirements
- Documentation, as applicable to the item, was received and is acceptable

2.3.7 Commercial Grade Item Dedication

A. Commercial grade items shall be dedicated, when intended for use in the following applications:

- Safety Class (SC) or Safety-Significant (SS) structure, system, and component (SSC), or service associated with a SC or SS SSC which has been determined to provide a critical design/safety function

- Type "B" packaging components, structures, services, and/or systems used to transport radioactive material, which has been determined to provide a critical design/safety function

B. Critical design characteristics shall be identified by the design organization during item selection.

C. Critical design characteristics and appropriateness of the item for use shall be verified by:

- Testing the item,

- Inspecting the item, and/or

- Evaluating the supplier's ability to consistently supply the item at a level of quality that meets the safety and reliability requirements for the item

2.4 Inspection and Testing

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, parameters or characteristics to be evaluated, techniques to be used, acceptance and performance criteria, hold points, and the organizations responsible for performing the tests and inspections. Inspection and testing of specified items and processes shall be conducted using established criteria. Inspections and tests shall verify that physical and functional aspects of items, services, and processes meet requirements and are fit for use and acceptance. The acceptance of a specified item shall be documented and approved by qualified and authorized personnel. Equipment used for inspections and tests shall be calibrated and maintained.

2.4.1 Qualification of Personnel

2.4.1.1 Qualification of Inspection and Test Personnel

This section provides 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 or to personnel performing routine equipment operability and safety inspections required during the conduct of their assigned work.

The individual who performs an inspection or test to verify conformance of an item to specified acceptance criteria shall be qualified. Inspections by persons during on-the-job training for qualification shall be performed under the direct observation and supervision of a qualified person and verification of conformance shall be by the qualified person until certification is achieved. 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 inspector.

The inspection shall be performed by personnel other than those who performed or directly supervised the work being performed. Inspection personnel shall not report directly to the immediate supervisors who are responsible for performing the work being inspected.

A. The responsible organization shall designate those activities that require qualified inspection and test personnel and the minimum requirements for such personnel. 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.

B. 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.

C. 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.

D. 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.

E. 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.

F. The job performance of inspection and test personnel shall be reevaluated for capability at periodic intervals not to exceed three years; for personnel qualified as QA Inspectors, the interval shall not exceed two 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 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.

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

- Employer's name
- Identification of person being certified
- Activities certified to perform
- 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
- Results of periodic evaluation
- Results of physical examinations, when required
- Signature of employer's designated representative who is responsible for such certification
- The date of certification and date of certification expiration

H. 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.

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

2.4.1.2 Qualification of Nondestructive Examination Personnel

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

A. The American Society for 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.

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

C. Records of personnel qualification shall be prepared and maintained by the employer.

2.4.2 Inspection Requirements

2.4.2.1 Inspection Planning

Inspection planning shall be performed and documented to include:

- Identification of work operations where inspections are necessary
- Identification of the characteristics to be inspected and the identification of when, during the work process, inspections are to be performed
- Identification of suitable environmental conditions and required safety measures
- Identification of inspection or process monitoring methods to be employed
- Identification of acceptance criteria
- Identification of sampling requirements
- Methods to record inspection results

- Selection and identification of the M&TE to be used to perform the inspection

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

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

The type of item and the length of time it is expected to remain in storage should be considered during inspection planning.

2.4.2.2 Inspection Hold and Witness Points

When mandatory hold/witness points are used to control work that is NOT to proceed without the specific consent of the organization placing the hold/witness point, the specific hold/witness points shall be indicated in implementing procedures/work instructions. Only the organization responsible for the hold/witness point may waive it. Approval to waive specified hold/witness points shall be documented before continuing work beyond the designated inspection point.

2.4.2.3 In-Process Inspections and Monitoring

A. 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 method.

B. 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.

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

2.4.2.4 Final Inspections

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

B. 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.

C. Records review shall be undertaken for adequacy and completeness.

D. Modifications, repairs, or replacements of items performed subsequent to final inspection shall require reinspection or retest, as appropriate, to verify acceptability.

2.4.2.5 In-Service Inspections

A. 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.

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

C. 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.

2.4.2.6 Inspection Documentation

Inspection documentation shall identify the:

- Item inspected and date of inspection
- Inspector's unique identifier or name of the inspector who documented, evaluated, and determined acceptability
- Method of inspection
- Inspection criteria, sampling plan, or reference documents (including revision designation) used to determine acceptance
- Results or acceptability
- Measuring and test equipment used during the inspection, including the identification number and the calibration due date
- Reference to information on actions taken in connection with nonconformances, as applicable

2.4.3 Test Requirements

Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design of the item to be tested unless otherwise designated. 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 preoperational tests. Test requirements and acceptance criteria shall be based on applicable design or other pertinent technical documents.

2.4.3.1 Test Planning

Test planning shall include:

- Identification of the implementing procedures to be developed to control and perform tests
- In lieu of specially prepared written test procedures, appropriate sections of related documents such as American Society for Testing and Materials methods can be used. If used, they shall incorporate the information directly into the approved test implementing procedure, or shall be incorporated by reference in the approved test implementing procedure
- Identification of item to be tested and the test requirements and acceptance limits, including required levels of precision and accuracy
- Identification of the M&TE to be used to perform the test and provisions to ensure that the equipment being used is calibrated and is of the proper type, range, accuracy, and tolerance to accomplish the intended function
- Test prerequisites that address calibrated instrumentation, software, appropriate and adequate test equipment and instrumentation, trained personnel, and suitably controlled environmental conditions
- Mandatory hold points
- Methods to record data and results
- Provisions for ensuring that prerequisites for the given test have been met

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2.4.3.2 Test Documentation

Test documentation shall identify:

- The applicable test requirements, plans, and procedures, including revisions
- The item or work product tested
- Date of test
- Name of the tester and data recorders
- Type of observation and method of testing
- Identification of test criteria or reference documents used to determine acceptance
- Results and acceptability of the test
- Actions taken in connection with any nonconformances noted
- Name of the person evaluating the test results
- Identification of the M&TE used during the test (including the identification number and calibration due date)

2.4.3.3 Test Results

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

2.5 Monitoring, Measuring, Testing, and Data Collection Equipment

The following sections establish requirements to ensure equipment used for inspection and testing is properly controlled, calibrated and maintained. For the purposes of these requirements, equipment discussed in the following sections includes M&TE, monitoring and data collection (M&DC) equipment, equipment (either hand-held or installed) used for data indication, and other equipment used for data indication and/or collection.

2.5.1 Calibration

A system to control the use and calibration of M&TE shall be established and documented. 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. The prescribed calibration intervals shall be established and maintained to ensure acceptable reliability, where reliability is described as the probability that M&TE will remain in tolerance throughout the interval. Intervals may be based on usage or time since last calibration.

A. Calibration standards shall have a greater accuracy than the required accuracy of the monitoring, measuring, testing, and data collection equipment being calibrated. The responsible organization shall ensure that the calibration uncertainties do NOT affect the adequacy of the measurement. Well defined and documented measurement assurance techniques or uncertainty analyses may be used to verify the adequacy of a measurement process. If such techniques or analyses are NOT used, then the collective uncertainty of the measurement standard shall NOT exceed 25 percent of the acceptable tolerance (e.g., manufacturer's specification) for each characteristic of the M&TE being calibrated or verified.

B. The method and interval of calibration for each device shall be defined based on the importance to waste isolation and safety and on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting measurement control. For monitoring, measuring, testing, and data collection equipment used in one-time-only applications, the calibration shall be done both before and after use based on the importance of the data to waste isolation and safety.

C. A calibration shall be performed when the accuracy of calibrated monitoring, measuring, testing, and data collection equipment is suspect.

D. Calibrated monitoring, measuring, testing, and data collection equipment shall be uniquely identified to provide traceability to calibration data and subsequent recall for calibration.

E. All calibrated monitoring, measuring, testing, and data collection equipment shall be labeled 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.)

F. All calibrations performed shall be traceable, through auditable documentation, to NIST [National Institute of Standards and Technology] standards, international standards or intrinsic standards, when available and appropriate. If no nationally recognized standards exist, the bases for calibration shall be documented.

G. When applicable, all calibrations shall be performed in controlled environmental conditions giving due consideration to temperature, humidity, lighting, vibration, dust control, cleanliness, electromagnetic interference, and any other factors affecting the results of calibration measurements. Where pertinent, these factors shall be monitored and recorded and, when appropriate, correcting compensations shall be applied to measurement results.

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

I. A program shall be established and maintained to recall for calibration, or remove from service, M&TE that has exceeded its calibration interval, has broken calibration seals, has been modified, repaired, has had components replaced, or is suspected to be malfunctioning because of mishandling, misuse, or unusual results.

J. Documented procedures shall be established and maintained to evaluate the adequacy of the calibration system and to ensure compliance with the requirements of this QAPD.

K. M&TE shall be handled, stored, and transported in a manner that does not adversely affect the calibration or condition of the equipment.

L. Where calibration 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.

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

N. 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.

O. Calibration services shall be acquired from suppliers having a verified program for controlling calibration activities in accordance with the appropriate Standards applicable to the item being calibrated.

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2.5.1.1 Control of Out-of-Calibration Equipment

A. Monitoring, measuring, testing, and data collection equipment shall be considered to be out-of-calibration and shall NOT be used until calibrated if any of the following conditions exist:

- The calibration due date has passed without recalibration
- The device produces results known or suspected to be in error
- The equipment has been damaged

B. Out-of-calibration monitoring, measuring, testing, and data collection equipment shall be controlled. The controls shall include the following requirements:

- Out-of-calibration monitoring, measuring, testing, and data collection equipment shall be tagged, segregated, or otherwise controlled to prevent use until they have been recalibrated

- When M&TE is found to be out-of-calibration during recalibration, the validity of results obtained using that equipment since its last valid calibration shall be evaluated

  -The evaluation shall include the determination of acceptability of previously collected data, processes monitored, or items previously inspected or tested

  -The evaluation shall be documented

  -The user and QA management shall be notified

  -Corrective actions shall be taken, as applicable

C. Recall intervals shall be established and re-evaluated based on instrument calibration history.

D. If any monitoring, measuring, testing, and data collection equipment is consistently found to be out-of-calibration during the recalibration process, it shall be repaired or replaced.

2.5.1.2 Documenting Calibration of Monitoring, Measuring, Testing, and Data Collection

WTS shall 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:

- Description or identification of the item
- Calibration Interval
- Date calibrated
- Identification of the calibration source
- Calibration results, including data and status
- Calibration action taken (adjusted, repaired, new value assigned, derated, etc.)
- Evaluation and corrective action taken in response to out-of-calibration conditions

SECTION 3 ASSESSMENT REQUIREMENTS

Planned and periodic assessments shall be conducted to measure management effectiveness, item and service quality and process effectiveness, and to promote improvement. Management assessments shall be performed or directed by managers to assess the effectiveness of their organization's management processes. Independent assessments shall be performed by a group or organization having authority and freedom, sufficient to carry out its responsibilities, from the line organization being assessed. Persons conducting assessments shall be technically qualified and knowledgeable of the items and processes to be assessed.

3.1 Management Assessment

Managers at every level shall periodically assess the performance of their organizations and functions to determine how well it meets customer requirements and expectations, and mission objectives, so that improvements can be made. This assessment shall place emphasis on the use of human and material resources to achieve the organization's goals and objectives. The management assessment should include an introspective evaluation to determine if the entire integrated management system effectively focuses on meeting strategic goals.

Managers shall retain responsibility for management assessments of processes and organizations under their cognizance. Direct participation by all levels of management is essential to the success of the process because management is in the position to view the organization as a total system.

Management assessments should focus on the identification and resolution of both process and management issues and problems. Problems that hinder the organization from achieving its objectives shall be identified and corrected.

Processes being assessed should include strategic planning, organizational interfaces, cost control, use of performance indicators, staff training and qualifications, procedures, the actual work process, 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. Management assessments shall also include analysis of collective results of lower-level self-assessments, such as workplace inspections and post-job reviews.

Management assessments shall be conducted regularly. Overall management assessment results shall be reported to the General Manager at least annually.

Management assessment results should be used as input to the organization's continuous improvement process.

3.2 Independent Assessment

A process of planned periodic independent assessments shall be established and implemented. Independent assessments shall be planned, performed, documented, and reported to appropriate management personnel. Independent assessments shall focus on improving items, services, and processes by emphasizing line organization's achievement of quality. The types and frequencies of independent assessments shall be based on the status, risk, complexity, and importance to safety, waste isolation, and the demonstration of compliance to regulatory and other statutory requirements.

Independent assessments shall include reviews, inspections, testing, checking, conducting surveillances, and auditing or otherwise determining whether items, processes, or services meet specified requirements.

Surveillances shall accomplish the following:

- Monitor work in progress, if applicable
- Document compliance or noncompliance with established requirements and procedures
- Identify actual and potential deficiencies
- Initiate timely corrective action commitment from cognizant manager for identified deficiencies
- Provide notification to responsible managers of the status and performance of work under assessment
- Verify timely implementation of corrective action(s)

3.2.1 Planning Independent Assessments

Assessments shall include technical evaluations of the applicable procedures, instructions, activities and items, as appropriate. The scope shall include the work to be assessed and corrective actions taken since the previous assessment.

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

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

Internal independent assessments should incorporate criteria related to the core functions of the ISMS, as applicable to the assessed activity (DOE P 450.4):

- Define the Scope of Work
- Analyze the Hazards
- Develop and Implement Hazard Controls
- Perform Work within Controls
- Provide Feedback and Continuous Improvement

3.2.1.1 Planning Audits

In addition to the above, the organization performing an audit shall develop and document an audit plan for each audit. This plan shall include the scope, requirements, purpose, assessment personnel, work to be assessed, organizations to be notified, applicable documents, written procedures to be used, and schedule.

3.2.2 Scheduling Independent Assessments

A. Independent assessments shall be scheduled to begin as early in the life of the work as practical and shall be scheduled to continue at intervals consistent with the schedule for accomplishing the work. Internal independent assessments of work to verify QA program compliance shall be performed on a risk based prioritization.

B. Regularly scheduled independent program assessments shall be supplemented by additional technical assessments (e.g., surveillances and limited scope audits) of selected work products and/or work processes.

3.2.2.1 Scheduling Audits

In addition to the above, the QA Department will maintain a schedule of audits. The audit schedule shall be developed annually and revised as necessary.

The scope and frequency of scheduled audits must ensure that:

- Required assessments by applicable DOE directives are being performed;
- The effectiveness of safety management programs, including programs that are credited in the safety basis for nuclear facilities, is being assessed adequately;
- Deficiencies are being self-identified; and
- Corrective actions are being taken in a timely and effective manner.

3.2.3 Independent Assessment Team Selection

Assessment team members shall be identified prior to the start of the assessment activity. The team members shall be selected on the basis of technical qualification, knowledge of the item and/or process being assessed and shall be independent from the items and/or processes being assessed. Assessment 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.

A. An assessment team leader shall be appointed to indoctrinate and supervise the team, organize and direct the assessment, coordinate the preparation and issuance of the assessment report, and evaluate responses. When a formal QA audit is performed, the assessment team leader shall be a lead auditor.

B. Before starting the assessment, the assessment 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 assessed.

C. In the performance of an audit, technical specialists, with appropriate technical expertise or experience in the work being audited, shall be used when assessing the adequacy of technical processes.

3.2.4 Assessment Personnel Qualifications

3.2.4.1 Lead Auditor Qualifications

A lead auditor shall be capable of organizing and directing audits and other assessments, reporting assessment observations, and evaluating planned and implemented corrective action. A lead auditor shall be certified as meeting the requirements provided in this section for education and experience, communication skills, training, audit participation, and passing the lead auditor examination.

3.2.4.1.1 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)

1. 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.

2. 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)

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 for this aspect of experience.

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

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

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

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

5. 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).

3.2.4.1.2 Communications 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 manager.

3.2.4.1.3 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 and assessments. Training in the following areas shall be accomplished and its completion verified based upon management evaluation of the particular needs of each prospective lead auditor:

- Knowledge and understanding of this QAPD and other program related procedures, codes, standards, regulations, DOE orders, and regulatory guides
- General structure of QA plans and implementation procedures, as a whole, and as related to specific elements of this QAPD
- Auditing or assessment techniques of examining, questioning, evaluating, and reporting; and methods of identifying, following up, and closing corrective action items
- Audit planning in functional areas of nuclear QA
- On-the-job training to include applicable elements of the assessment program

3.2.4.1.4 Audit Participation

The prospective lead auditor shall have participated in a minimum of five QA audits within a period of time NOT to exceed three years prior to the date of the qualification. At least one of the five QA audits shall be a nuclear audit and shall have been performed within the last year.

3.2.4.1.5 Lead Auditor Examination

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

B. The development and administration of the examination for a lead auditor is the responsibility of the QA Department. The QA Department may delegate administrative duties related to this responsibility. The QA Department (or designee) shall:

- Maintain the integrity of the examination through confidentiality of files and, where applicable, proctoring of examinations
- Develop and maintain objective evidence regarding the type and content of the examination

3.2.4.1.6 Lead Auditor Certification

The lead auditors will be certified by the QA organization and the Training organization as being qualified to lead audits and assessments. This certification will document the:

- Name of the organization performing the certification
- Name of the lead auditor
- Date of certification or recertification
- Basis of certification (such as education, experience, communication skills, and training)
- Signature of the designated representative of the organization responsible for certification

3.2.4.1.7 Lead Auditor Proficiency Maintenance

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

- Regular and active participation in the audit process
- Review and study of codes, standards, QA implementation procedures, instructions, and other documents related to QA program auditing or assessment
- Participation in training programs

B. QA management 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.

C. Lead auditors who fail to maintain their proficiency for a two-year period shall require requalification to the requirements for a lead auditor of this section. Participation in only one nuclear QA audit is required for this requalification.

3.2.4.2 Technical Specialist Qualifications

Technical specialists selected for independent assessment assignments shall be indoctrinated by the lead auditor commensurate with the scope, complexity, or special nature of the work being assessed. In addition they shall be trained to the requirements of the assessment process associated with their duties.

3.2.4.3 Independent Assessor Qualifications

Independent assessors shall be technically qualified and knowledgeable in their assigned roles. In addition, they shall have appropriate training or orientation to develop their assessment skills and techniques. Competence of personnel performing various assessment functions shall be developed by one or more of the following methods:

A. Orientation to provide a working knowledge and understanding of the program QA requirements and implementing procedures used to perform assessments and report assessment results.

B. Training that provides fundamentals, objectives, and techniques of performing assessments. Training shall include methods of examining, questioning, evaluating, and documenting specific assessment items and methods of evaluating the effectiveness of corrective actions for conditions adverse to quality.

C. On-the-job training, guidance, and counseling under the direct supervision of a lead auditor may be substituted for the training above. Such training shall include planning, performing, reporting, and follow-up action involved in conducting assessments.

3.2.5 Performing Independent Assessments

A. Independent assessments shall be performed using written procedures or checklists related to the activity being audited.

B. Elements that have been selected for independent assessment shall be evaluated against specified requirements. Objective evidence related to the planning and technical aspects of the work performance shall be examined to the depth necessary to determine if these elements are being implemented effectively.

C. Independent assessment results shall be documented by assessment personnel and reported to and reviewed by management having responsibility for the area assessed. Conditions requiring prompt corrective action shall be reported immediately to management of the assessed organization.

D. CAQs shall be documented and corrected according to the requirements of the Corrective Action section of this QAPD.

3.2.6 Reporting Independent Assessment Results

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

- A description of the assessment scope
- Identification of the assessors
- Identification of persons contacted during the assessment
- 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)
- A summary of the results, including a statement of the QA program adequacy, implementation, and effectiveness, as applicable to the assessment scope
- A description of each reported condition adverse to quality in sufficient detail to enable corrective action to be taken by the assessed organization
- Commendable practices

Findings of a common nature will be grouped together whenever possible so that systematic breakdowns can be identified. Findings will be evaluated based on the relative importance to indicate the degree of impact on compliance certification application, waste characterization, waste isolation, waste transportation, nuclear safety, environmental protection, or management and operation of the WIPP facility.

3.2.7 Assessment Response and Follow-Up

A. Management of the assessed organization will investigate conditions adverse to quality in accordance with the Corrective Action section of this QAPD.

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B. The adequacy of corrective actions taken for conditions adverse to quality shall be evaluated and approved by the assessing organization.

C. Follow-up action shall be taken by the assessing organization to verify that corrective action is accomplished as scheduled.

3.2.8 Audit Records

The following documents shall be controlled as QA records in accordance with the Records section of this QAPD: audit and assessment plans, reports, responses, and documentation of corrective action completion and follow-up.

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SECTION 4 SAMPLE CONTROL AND QUALITY ASSURANCE REQUIREMENTS

This section defines the requirements for the control of samples of waste and environmental media, including identification, handling, storing, shipping, and archiving. This section also defines requirements for the disposition of samples, including nonconforming samples. The following general control requirements apply to samples:

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

B. Sample controls shall define responsibilities such as interfaces between organizations for documenting and tracking sample possession from sample collection and identification through handling, preservation, shipment, transfer, analysis, storage, and final disposition.

C. Sample controls shall specifically describe the location and orientation from which the sample was collected.

4.1 Sample Control

The controls for samples shall address the following requirements, as applicable:

A. 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.

B. If samples have limited hold times, then methods shall be established that preclude using the sample beyond its intended hold time.

C. If sample storage is required, then methods shall be established for the control of sample identification that are commensurate with the planned duration and conditions of storage. These methods shall provide for, as applicable,

- Maintenance or replacement of markings and identification tags damaged during handling or aging
- Protection of identification markings subject to excessive deterioration resulting from environmental exposure

D. Methods shall be established to provide for sample preservation, including protection to prevent contamination from outside sources and temperature preservation requirements.

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

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F. If a need to archive samples is identified, then the management of all archive samples shall be specified in an implementing procedure.

4.2 Sample Identification

A. Samples shall be clearly and uniquely identified at the time of their initial collection, and the identification shall be maintained until final disposition.

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

C. All sample numbers, sample locations, and sample dates shall be documented. Documentation shall be maintained and verified at a minimum until the final disposition of all collected samples.

D. At a minimum samples shall be clearly and legibly identified wherever possible with a label, tag, or other marker to denote the sample number, the sample date, the name of the sampler, and the sample location. If physical markings are used, they shall not be obliterated or hidden by surface treatments or sample preparation unless other means of identification are substituted. 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).

E. Care shall be taken to ensure that sample identification does not compromise or cross-contaminate the sample.

F. If samples are to be split or subdivided then sample identification and documentation shall reference the sample identification on the original sample. Extreme care must be taken to ensure that cross-contamination does not occur when samples are split. Samples to be split shall have field blanks.

G. Sample traceability, including identification and documentation, shall ensure that the sample can be traced at all times from its collection through final disposition.

4.3 Handling, Storing, and Shipping Samples

Handling, storing, cleaning, packaging, shipping, and preservation of samples shall be conducted in accordance with established work and inspection implementation procedures or other specified documents. Controls shall provide for the maintenance of sample characteristics, sample integrity, and sample identification during storage. These measures include:

A. Methods requirements shall be identified, where applicable (e.g., EPA SW-846, Test Methods for Evaluating Solid Waste, Physical/Chemical Methods).

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

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

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

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

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

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

H. If required for particular samples, personal protective equipment, special protective equipment (such as containers), and special protective environments (such as inert gas, and moisture and temperature limits) shall be specified and provided. Such controls shall be verified and documented.

4.4 Disposition of Nonconforming Samples

A. Samples taken that are sensitive to data quality requirements and that do NOT meet requirements specified in work controlling documents (such as job packages, travelers, or work requests) shall be documented, evaluated, identified, and segregated in accordance with the Quality Improvement section of this QAPD.

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

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

4.5 Environmental Data Operation Samples

Guidance for environmental data operation (EDO) sample planning must address the following items as a minimum. Additional information is contained in EPA QA/G-5 and SW-846.

All EDO sample plans will address that the following quality indicators for the collection of data and information used to support a compliance certification application have been and will continue to be achieved:

A. Data accuracy (i.e., the degree to which data agree with an accepted reference or true value)

B. Data precision (i.e., a measure of agreement between comparable data gathered or developed under similar conditions expressed in terms of a standard deviation)

C. Data representativeness (i.e., the degree to which data accurately and precisely represent a characteristic of a population, a parameter, variations at a sample point, or environmental conditions)

D. Data completeness (i.e., a measure of the amount of valid data obtained compared to the amount that was expected)

E. Data comparability (i.e., a measure of the confidence with which one data set can be compared to another)

F. Data reproducibility (i.e., a measure of the variability among measurements of the same sample at different laboratories)

G. Data validation (i.e., a systematic process for reviewing a body of data against a set of criteria to provide assurance that the data are adequate for their intended use)

H. Data verification (i.e., a systematic process for reviewing a body of data to verify completeness)

4.6 Data Documentation, Control, and Validation

4.6.1 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.

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, 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.

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 derived from the data and measurement systems prior to use of the data.

4.6.2 Data Validation

Data validation is a systematic process used to review data, to assure 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.

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

B. Data that are important to safety and waste isolation shall be validated. Validation shall include the following:

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

2. Calculations shall be checked on a sample basis;

3. The results of the data review shall be documented; and

4. The reviewer shall be independent of the data collector.

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

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

SECTION 5 SCIENTIFIC INVESTIGATION QUALITY ASSURANCE REQUIREMENTS

This section is included as a contingency should WTS become responsible for Scientific Investigations. When and if WTS becomes responsible for the performance of any Scientific Investigations the requirements of this section will be implemented into this QAPD commensurate with the degree of the responsibilities by the appropriate organization.

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SECTION 6 SOFTWARE REQUIREMENTS

6.1 General

This section establishes Software Quality Assurance (SQA) requirements for the development, acquisition, maintenance, and use of certain computer software to support WTS activities. It supplements, where specified herein, the basic requirements of this QAPD.

The QA requirements specified in this section are based on the CBFO QAPD, ASME industry consensus standards NQA-1-1989 (supplements 3S-1 and 11S-2), NQA-2a-1990 (Part 2.7), and guidance from NUREG/BR-0167 and NUREG-1297.

6.1.1 Applicability

A. 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 any of the following:

  - Performance of the waste confinement, waste characterization, waste transportation, or waste acceptance processes

  - Modeling the performance of WIPP for purposes of compliance certification application and/or reapplication

  - Activities that affect or are directly related to compliance with the HWFP

- Safety Software

  1. Safety System Software - software 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.

The application of these requirements shall be prescribed in written plan(s), policies, procedures, or instructions.

B. 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. For applications built using systems software, see paragraph C, below.

C. However, specific applications, such as detailed formulas or macros, which:

- Support quality-related activities addressed in paragraph A, above
- Are used with exempt software addressed in paragraph B, above, and
- Can be verified by hand calculations or other means

shall meet the following requirements:

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

6.1.2 Inventory of Software

Each organization shall identify software for which it maintains responsibility. Software governed by this section of the QAPD shall be inventoried. This inventory shall identify the software's name, version, classification, exemption status, operating environment, and the person and organization responsible for the software.

6.1.3 Classification of Software

Each organization shall classify software identified in the inventory. The criteria for the classification shall be documented in the inventory and shall address the purpose of the software relative to its use in engineering, testing, data collection, design, analysis, and operations activities and its importance to safety or significance in managing information or augmenting mission-essential decisions.

6.1.4 Plans (or Procedures)

WTS shall develop plans that specify applicability, methods, techniques, and responsibilities required to implement the requirements of this section. Plans and revisions to the plans shall be forwarded to the QA manager for review and concurrence.

6.1.5 Software Quality Assurance

Software used to support WTS activities at WIPP is primarily commercial software purchased off-the-shelf and does not require any development effort by WTS. In those cases where WTS or its subcontractor develops software for use at WIPP, the following requirements for software controls shall be implemented, as appropriate.

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 organization(s) using the software.

The following activities shall be addressed in plans or procedures:

A. Software development
B. Software verification and validation
C. Software configuration control
D. Software operation and maintenance

Plans may be issued separately or as a single, composite plan, depending upon 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.

A plan(s) for assuring software quality shall be prepared for each new software project at the inception of the software, or for procured software before it enters the purchaser's 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 quality assurance program. Plans shall:

A. Identify the software products governed by the plan.

B. Identify the methods to be used to develop functional performance requirements, translate those requirements into a detailed design, and implement that design in a computer program.

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

D. Identify the methodology for establishing software baselines and baseline updates (changes) and for tracking changes throughout the evolution of the software.

E. Identify the process to be used for verification and validation of the software developed for or applied to engineering and scientific analysis.

F. Identify the process for reporting and documenting software discrepancies, evaluating impacts of discrepancies on previous calculations, and determining appropriate corrective action(s).

G. Identify the procedure(s) for establishing and maintaining the integrity of data, embodied mathematical models, and output files.

H. Identify the organizations responsible for performing the work and achieving software quality and their tasks and responsibilities, including design authority involvement in identifying specifications, acquisition, design, development, verification and validation, configuration management, maintenance, and retirement of safety software.

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

6.2 Software Procurement

The procurement of software and related services shall be in accordance with the Procurement section of this QAPD; the applicable requirements of this section shall become the responsibility of the sponsoring organization upon receipt of the software.

These requirements shall apply to all software governed by this section in accordance with the applicability criteria in the Section 6.1.1, above, including freeware and shareware, regardless of the method of acquisition (i.e., whether purchased, provided by a government agency, downloaded from the internet, or obtained by other means).

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 procured 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.

Once the software has been installed, and prior to its use, the sponsoring organization shall perform user acceptance of the software to verify the software's functional capability and the acceptability of the vendor-supplied supporting documentation (e.g., user manual, technical specification, results of vendor testing, etc.).

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.

6.3 Software Developed Under Other QA Programs

Software that has NOT been developed or approved in accordance with this section and has NOT been previously approved in accordance with a QA program that is consistent with this QAPD shall be evaluated using this section as the review criteria to determine adequacy to perform its intended functions. The evaluation shall be documented. This software shall be uniquely identified and controlled prior to evaluation, clearly traceable to the software requirements, accepted by the sponsoring organization and placed under configuration control prior to use.

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

A. Adequacy of existing verification and validation and software documentation to support operation and maintenance; and

B. 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 contain at a minimum:

A. User application requirements
B. Test plans and test cases required to validate the software acceptability
C. User documentation

Exceptions from the requirements of this section and their justification for acceptance shall be documented as part of the evaluation. Exceptions shall be approved by the QA manager.

6.4 Software Development and Maintenance

Software used to support WTS activities at WIPP is primarily commercial software purchased off-the-shelf and does not require any development effort by WTS. In those cases where WTS or its subcontractor develops software for use at WIPP, the following requirements for software controls shall be implemented, as appropriate.

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 the baselines for each phase, the required reviews, appropriate milestones, and the responsibilities associated with each task. For safety software, risks to successful completion of the project shall be evaluated, and methods of controlling the risks shall be identified.

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.

The activities associated with the software's evolution shall use a systematic (iterative or sequential) approach. This approach shall address the analysis of the problem under study, the transformation of the analysis into design, the implementation of the design into validated computer software, and the development of sufficient documentation (which may constitute records) to demonstrate that the specified requirements have been successfully implemented into the computer software.

The systematic approach of software consists of the activities of Requirements, Design, Implementation, Testing, Installation and Checkout, Operations and Maintenance, and Retirement. Each leads to the development of specific work products representing components of the software's baseline. Both the processes and work products associated with the systematic approach are measurable and are verified for completeness and accuracy, approved, and their quality maintained throughout the evolution of the software.

Following the development of the Software Quality Assurance Plan (for each project), no strict chronology of activity performance is required (i.e., activities may be performed serially, recursively, or concurrently) providing all activities are addressed, and all requirements of each development phase are met.

6.4.1 Requirements

Software requirements shall be specified, documented, and reviewed. These requirements shall pertain to functionality, performance, design constraints, data attributes, and external interfaces as outlined in the Requirements Documentation section of this QAPD. For safety software, potential failures shall be identified and evaluated during the requirements phase, for their consequences and probability. The requirements shall define the response of the software to anticipated classes of input data. Each requirement shall be specified in sufficient detail to permit its design in software and its validation. Software requirements shall be traceable throughout the software's evolution, and a verification and validation plan shall be prepared after the software requirements have been documented and approved.

6.4.2 Design

Software design, based on specified requirements, shall be developed, 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).

For safety software, measures to mitigate the safety consequences of software failures shall be an integral part of the design.

The design may necessitate the modification of the requirements documentation and the verification and validation plans.

Design phase software verification and validation activities shall consist of:

- The generation of test plans based on the requirements and design;
- The generation of design-based test cases; and
- The review of the software design to ensure that the requirements are addressed.

6.4.3 Implementation

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

6.4.4 Testing

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, hardware integration tests, and in-use tests, shall be controlled. Software testing, using documented test plans, cases, procedures, and results, is the primary method of software validation.

Testing of software shall be performed to the extent that unintended functions are identified and their impact determined and corrected, as appropriate, to prevent degradation of the software's required performance. The design as implemented in code shall be exercised by executing the test cases. Failure to successfully execute the test cases shall be reviewed. Requirements, design, implementation, or test plans and test cases shall be modified, if required.

6.4.4.1 Verification Tests

Verification tests are design-driven and shall demonstrate the capability of the software to produce valid results for test problems encompassing the range of permitted use defined by the software documentation. Testing of software used for operational control shall demonstrate required performance over the range of operation of the controlled function or process.

Acceptable test problem methods consist of:

A. Hand calculations;

B. Calculations using comparable proven problems;

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

D. Comparison to other validated software of similar purpose; and

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

6.4.4.2 Validation Tests

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

6.4.4.3 Test Plans/Procedures

Test procedures or plans shall specify the following, as applicable:

- Required tests and test sequence
- Required ranges of input parameters
- Identification of the stages at which testing is required
- Criteria for establishing test cases
- Requirements for testing logic branches
- Requirements for hardware integration and system software
- Anticipated output values
- Acceptance criteria
- Reports, records, standard formatting, and conventions

6.4.4.4 Test Records

Test records shall identify each of the following:

- Computer program tested
- Computer hardware used
- Test equipment and calibrations, where applicable
- Date of test
- Tester or data recorder
- Simulation models used, where applicable
- Test problems
- Results and acceptability
- Action taken in connection with any deviations noted
- Persons evaluating test results

6.4.5 Installation and Checkout

During installation and checkout software becomes part of a system consisting of applicable software components, hardware, and data. The process of integrating the software with applicable components may consist of installing both 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 acceptable performance of the software in its operating environment.

Installation and checkout of software shall consist of the following:

A. Execution of tests for installation and integration;
B. Documented acceptance of the software for operational use; and
C. Placing the software under configuration control prior to use.

Completion of the installation and checkout activities establishes the software's current baseline.

6.4.6 Operations and Maintenance

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

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.

6.4.6.1 Post-Installation Maintenance

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

6.4.6.2 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 for which computer failure or electronic drift can affect required outcomes.

6.4.7 Retirement

Criteria shall be developed to determine if software can be retired from use and methods shall be developed to prevent the use of retired software. During retirement the support for a software product is terminated.

6.5 Software Verification and Validation

Verification and validation of software shall include reviews of software activities and documentation and tests to ensure that software:

- Adequately and correctly performs all intended functions
- Does NOT perform any unintended function that either by itself or in combination with other functions can degrade the intended outcomes of the software

Software verification and validation activities shall be planned and performed for each system configuration which may impact the software. The results of software verification and validation activities shall be documented.

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

- Did NOT specify a singular design approach
- Did NOT rule out certain design considerations
- Did NOT establish the design inputs used
- Is the only individual in the organization competent to perform the verification or validation

6.5.1 Verification

Verification is primarily a checking activity, which shall be performed throughout the development of the software to ensure that the products of a given cycle phase fulfill the requirements of the previous phase or phases. It shall be clearly documented, including the identification and specific responsibilities of those who performed and approved the verification. The reviewed documents shall be updated and placed under configuration control. Documentation of review comments and their disposition (including unincorporated comments) shall be retained in accordance with established procedures.

6.5.1.1 Requirements

A verification review of software requirements shall be performed at the completion of the software requirements documentation. Verification of software requirements shall ensure that the requirements are complete, verifiable through testing, consistent, and technically feasible. The review shall also assure that the requirements will result in

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feasible and usable code.

6.5.1.2 Design

A software design review shall be held at the completion of the software design documentation. Verification of software design shall evaluate the technical adequacy of the design approach and ensure that the design is complete (meets all requirements and meets design completion criteria), verifiable (through testing or other means), consistent, clear and correct, technically feasible, and traceable to the software's requirements. This verification shall meet the design verification requirements of the Design Control section of this QAPD.

6.5.1.3 Implementation

Verification of the implementation of software design shall consist of the examination of software logic and source code (if available) to ensure adherence to standards and conventions and that the design has been implemented according to specification.

6.5.1.4 Testing

Verification of software testing shall consist of reviews to ensure that specified test criteria and expected results have been met. The development cycle documentation shall be reviewed and approved at the completion of the testing phase (and the installation phase if necessary) to assure it is complete and acceptable.

6.5.1.5 Installation and Checkout

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

6.5.2 Validation

Software validation is primarily a testing activity that shall be performed at the end of the implementation phase and prior to installation and checkout to ensure that the code satisfies the requirements. 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.

Software validation activities, such as the development of test plans and test cases, shall be integrated into each phase of the software life cycle. Testing shall be the primary method of software validation.

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 that the test requirements have been satisfied.

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 as the means to accomplish the requirements for software validation.

The validation of software modifications shall be subject to selective regression testing to detect errors introduced during the modification of systems or system components, to verify the modifications have not caused unintended adverse effects, and to verify that a modified system(s) or system component(s) still meets specified requirements.

6.6 Software Configuration Management

Fundamental to configuration management are the concepts of a baseline and change control. A baseline is a collection of all approved components of the software representing an "evolving" configuration. As each component is approved it is added to the overall software baseline. Each baseline serves as the basis for further development and maintenance that can be changed only through formal change control procedures. Change control is the process by which a change to a baseline is proposed, evaluated, approved or rejected, scheduled, implemented, and tracked.

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 planning documents shall be formally reviewed, approved, and in place before the release of the software for use.

6.6.1 Configuration Identification

A software baseline shall define the most recent approved software configuration. Software shall be placed under configuration control as each configuration item is approved. These items consisting of software source code, executable software, and associated documentation shall be traceable to one another by some means.

A labeling system for configuration items shall be implemented that:

A. Uniquely identifies each configuration item;

B. Identifies changes to configuration items by revision or version identifier; and

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

6.6.2 Configuration Change Control

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

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 the change is appropriately reflected in 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.

6.6.3 Configuration Status Accounting

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

6.7 Documentation

Software shall be described in one or more documents which detail user instructions, technical basis, functional requirements and maintenance-related information sufficient to be independently verified and allow maintenance of the software and its documentation. The documentation shall be reviewed by an individual competent in the technical subject area for which the use of the software is intended; that 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.

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6.7.1 Procurement Documentation

The applicable QA requirements shall be specified and vendor-supplied software documentation, plans, and procedures shall be identified in software procurement documentation.

6.7.2 Requirements Documentation

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 is to perform;

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

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

Software requirements shall be traceable throughout the software development cycle.

An item is a software requirement only if its achievement can be verified and validated.

6.7.3 Design and Implementation Documentation

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

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

B. Describe the software's theoretical basis, embodied mathematical model, control flow, data flow, control logic, and data structure(s);

C. Describe the allowable or prescribed ranges for inputs and outputs; and

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

6.7.4 Verification and Validation Documentation

Software verification and validation documentation shall describe the activities and criteria for accomplishing the verification of the software throughout the software's evolution and the validation of the software at the end of the development cycle. The documentation shall also specify the hardware and software configurations pertinent to the software's verification and validation.

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

This documentation shall include:

- Results of the verification and validation activities, including reviews and tests
- A summary of the status of the software

6.7.5 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's baseline.

6.7.6 User Documentation

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

- Software name and version identifier
- Statement(s) of functional requirements and system limitations, including hardware
- An explanation of the mathematical model(s) 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
- Instructions that describe the user's interaction with the software, 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, input parameters

- A description of any required training necessary to use the software
- Information for obtaining operation and maintenance support

6.7.7 Error Documentation

Documentation of errors detected during the use of the software following its installation and checkout shall be maintained. This documentation can be used for process improvement and to prevent future recurrence during development and maintenance of 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's output, and the disposition of the error corrective action(s).

6.8 Problem Reporting and Corrective Action

Problems (e.g., errors, faults, failures, etc.) detected in released software shall be promptly reported in accordance with documented procedures. When a problem is 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.

A system shall be established and maintained to record, classify, analyze, track, and report software problems and associated corrective actions. Problems shall be promptly reported to affected organizations and their resolution formally processed.

For procured software, the supplier shall report software errors, or failures, to the sponsoring organization, and the sponsoring organization shall report software errors to the supplier.

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

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

B. Problems are assessed for 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.

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

Problems which could significantly impact decisions based upon prior use or that require significant modification to the software shall be identifiable to all users. Errors that have been determined as a material attribute to a nonconformance or may represent a condition adverse to quality shall be controlled in accordance with the Quality Improvement section of this QAPD.

6.9 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.

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

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

Assessment/Verification: The act of reviewing, inspecting, testing, checking, conducting surveillances, auditing, or otherwise determining and documenting whether items, processes, or services meet specified requirements. The terms assessment and verification are synonymous; their use is determined by who is performing the work. Assessments are performed by or for senior management. Verifications are performed by the line organizations.

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

Audit: A planned and documented independent QA program assessment performed to determine by investigation of objective evidence the adequacy of and compliance with established QA implementation procedures 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.

Baseline Software: Software that has been formally reviewed and agreed upon, and that can only be changed through formal change control procedures.

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 in writing to the qualification 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 that are unique to nuclear facilities, (2) used in applications other than nuclear facilities, and (3) ordered from the manufacturer or supplier on the basis of specifications set forth in the manufacturer's published product description.

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Condition Adverse to Quality: An all inclusive term used in reference to deficiencies, failures, malfunctions, defective items, and nonconformances.

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 taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

Design Authority: The organization having the responsibility and authority for approving the design bases, the configuration, and changes thereto.

Design Bases: 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 detailed final design is based.

Design Output: Drawings, specifications, and other documents used to define technical requirements of structures, systems, components and computer programs.

Design Process: Technical process that commences with 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 design adequacy and conformance to specified acceptance criteria.

Document: Recorded information that describes, specifies, reports, certifies, requires, or provides data or results. A document is NOT considered a record until it meets the definition of record.

Document Control: The process for controlling documents that provides for 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.

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Hold Point: A mandatory inspection point, beyond which work shall not proceed, until the inspector is present to perform the inspection or the hold point has been waived. Hold points are typically used for completed work steps which require inspection before work continues.

Independent Assessment: An assessment that is conducted by an independent group or organization, having authority and freedom from the line organization, to evaluate the scope, status, adequacy, programmatic compliance, or effectiveness of a program or activity.

Inspection: Examination or measurement to verify whether an item or activity conforms to specified requirements.

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, or support systems. Item may also refer to samples, software, 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 below senior management that are directly responsible for work task products and services.

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 (M&TE): All devices used to measure, gage, test, inspect, or otherwise determine compliance with prescribed technical requirements. Measuring instruments used in taking quantitative and/or qualitative measurements. "Indication Only" devices, which do not require calibration, are not considered M&TE.

Metrology: The science of precision measurement.

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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 used to verify the conformance of an item or equipment to specified criteria. "Indication Only" devices, which do not require calibration, are not considered M&DC equipment.

Nonconformance: A deficiency in characteristic, or record that renders the quality of an item 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.

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, acceptance criteria employed, and conclusions drawn in the original work. Peer reviews confirm the adequacy of work. In contrast to peer reviews, the term "technical review" refers to a review to verify compliance to predetermined requirements, industry standards, or common scientific, engineering, and industry practice.

Periodic: Occurring or recurring at regular intervals. For the purposes of this QAPD, these intervals are determined by the responsible management unless otherwise specified.

Postclosure 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" is also inclusive of instructions and drawings.

Process: A series of actions that achieves an end or result.

Procurement Document: Purchase orders, contracts, specifications, or other documents used to define technical and QA requirements for the procurement of items or services.

Qualification (Personnel): The characteristics or abilities gained through education, training, or experience as measured and documented against established requirements, such as standards or tests, that qualify an individual to perform a required function.

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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-Affecting: Any item or activity which specifies, translates, or implements quality assurance program requirements or is subject to quality assurance program controls, in accordance with the graded approach.

Quality Assurance: All those actions that provide confidence that quality is achieved.

Quality Assurance Implementing Procedure: A document that prescribes an approved process for accomplishing work in compliance with QAPD requirements.

Quality Assurance Program (QAP): The overall 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 authenticated portion of a record (regardless of medium) that furnishes evidence of the quality of quality-affecting items and/or activities.

Quality System: See *Quality Assurance Program*.

Readiness Review: A systematic documented review of the readiness for start-up 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.

Record: 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.

Recurring Condition Adverse to Quality: More than one similar adverse condition that resulted from the same cause (i.e., is assigned the same trend or cause code), for which corrective action/actions to prevent recurrence have been previously implemented, and which are determined by formal performance evaluation and trend analysis to represent an adverse trend or inclination.

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Remedial Action: The actions taken to correct specifically identified conditions adverse to quality.

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.

Root Cause: The identified cause of a condition adverse to quality that, if corrected, will preclude recurrence or greatly reduce the probability of recurrence of the same or a similar condition adverse to quality.

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 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 (Material): A physical part of a whole whose properties are sampled to gain information about the whole.

Scientific and Engineering Software: Software that uses numerical methods to complete scientific, engineering, and mathematical calculations.

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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: A significant condition adverse to quality is one that:

- If uncorrected, could lead to a serious effect on safety/operability, the ability to isolate waste, TRU waste site certification, regulatory compliance demonstration, or effective implementation of the QA program; or
- Is noncompliant with the Compliance Recertification Application; or
- Requires immediate notification of regulatory entities (e.g., 10 CFR Part 21, HWFP reporting requirements); or
- Indicates a significant failure or breakdown in the implementation of QA program requirements; or
- Has not been resolved after repeated attempts; or
- 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; or
- Constitutes an adverse trend or inclination, as determined by formal performance evaluation and trend analysis.

Site Characterization: The program of exploration and research both in the laboratory and the field that is undertaken to establish the geologic 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 Life Cycle: The period of time that starts when a software product is conceived and ends when the software product is no longer available for routine use. The software life cycle typically includes a requirements phase, a design phase, and implementation phase, a test phase, an installation and checkout phase, an operation and maintenance phase, and sometimes a retirement phase.

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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. See Validation and Verification.

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 observing real-time activities and/or reviewing documentation to verify conformance with specified requirements and to evaluate their adequacy and effectiveness.

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.

Suspend Work Order: A formal directive issued by management that work must be stopped until resolution of the related significant condition adverse to quality or nonconformance.

System Software: Software which is used exclusively in the preparation, installation, or operation of executable software applications. Examples of such software include Operating Systems, Compilers, Assemblers, Translators, Interpreters, Automated Protocols, Utilities and Tools, Teleprocessing Managers, and Query Languages.

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Technically Competent Personnel: The characteristics or abilities gained through education, training, or experience, as measured against established requirements, that qualify an individual to perform a required function as determined by management.

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 collectively equivalent in 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 who is assigned to an assessment team when the scope, complexity, or special nature of the work to be audited warrants assistance from a technical standpoint.

Testing: An element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item 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:

A. U. S. national standards maintained by NIST or the U. S. Naval Observatory

B. Fundamental or natural physical constants with values assigned or accepted by NIST

C. National Standards of other countries which are accepted by NIST

Transuranic (TRU) Mixed Waste: TRU waste that is also a hazardous waste as defined by the New Mexico Hazardous Waste Act of 1978 (Section 74-4-1 NMSA [New Mexico Statutes Annotated] and 20.4.1.200 NMAC (New Mexico Administrative Code), *Adoption of 40 CFR Part 261.*

Transuranic (TRU) 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 Part 61.

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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. See *Software Verification and Validation.*

Verification: See *Assessment* and *Software Verification and Validation*.

Waiver: Documented authorization to depart from specified requirements.

Waste Isolation: As it applies to this QAPD, the confinement of radioactive and hazardous wastes through the process of receiving, handling, moving, monitoring, and disposal of TRU waste.

Witness Point: A mandatory inspection point beyond which work shall not proceed until the inspector is notified of the witness point and consents to the work continuing. Witness points are typically used for monitoring in-process work or verifying satisfactory quality of items and activities by indirect means (e.g., documentation review). Work shall not proceed beyond a witness point until the inspector has made arrangements to perform the inspection/monitoring or the witness point has been waived.

Work: The process of performing a defined task or activity (e.g., research and development, operations, maintenance and repair, administration of maintenance activities, software development and use, inspection, safeguards and security, data collection, and analysis).

Appendix B - Quality Assurance Requirements Cross-Reference Matrix

	10 CFR §830.122 CRITERIA	DOE ORDER 414.1C CRITERIA	ASME NQA-1 (1989) REQUIREMENTS
MANAGEMENT	(a) CRITERION 1 – MANAGEMENT/ PROGRAM	1. PROGRAM	1. ORGANIZATION 2. QUALITY ASSURANCE PROGRAM
	(b) CRITERION 2 – MANAGEMENT/PERSONNEL TRAINING & QUALIFICATION	2. PERSONNEL TRAINING & QUALIFICATION	2. QUALITY ASSURANCE PROGRAM
	©) CRITERION 3 – MANAGEMENT/QUALITY IMPROVEMENT	3. QUALITY IMPROVEMENT	15. CONTROL OF NONCONFORMING ITEMS 16. CORRECTIVE ACTION
	(d) CRITERION 4 – MANAGEMENT/DOCUMENTS & RECORDS	4. DOCUMENTS & RECORDS	6. DOCUMENT CONTROL 17. QUALITY ASSURANCE RECORDS
PERFORMANCE	(e) CRITERION 5 – PERFORMANCE/WORK PROCESSES	5. WORK PROCESSES	5. INSTRUCTIONS, PROCEDURES, DRAWINGS 8. IDENTIFICATION & CONTROL OF ITEMS 9. CONTROL OF PROCESSES 12. CONTROL OF MEASURING & TEST EQUIPMENT 13. HANDLING, STORAGE, & SHIPPING
	(f) CRITERION 6 – PERFORMANCE/DESIGN	6. DESIGN	3. DESIGN CONTROL
	(g) CRITERION 7 – PERFORMANCE/ PROCUREMENT	7. PROCUREMENT	4. PROCUREMENT DOCUMENT CONTROL 7. CONTROL OF PURCHASED ITEMS & SERVICES
	(h) CRITERION 8 – PERFORMANCE/INSPECTION & ACCEPTANCE TESTING	8. INSPECTION & ACCEPTANCE TESTING	10. INSPECTION 11. TEST CONTROL 12. CONTROL OF MEASURING & TEST EQUIPMENT 14. INSPECTION, TEST, & OPERATING STATUS
ASSESSMENTS	(I) CRITERION 9 – ASSESSMENT/MANAGEMENT ASSESSMENT	9. MANAGEMENT ASSESSMENT	2. QUALITY ASSURANCE PROGRAM
	(j) CRITERION 10 – ASSESSMENT/INDEPENDENT ASSESSMENT	10. INDEPENDENT ASSESSMENT	18. AUDITS

Appendix C - Referenced Documents not Included in Table 1, QA Program Source Documents

- DOE O 221.1A, *Reporting Fraud, Waste, and Abuse to the Office of Inspector General*
- DOE O 231.1A, *Environment, Safety, and Health Reporting*
- DOE-STD-3009-94, *Preparation Guide for U. S. DOE Nonreactor Nuclear Facility Safety Analysis Reports*
- EPA SW-846, *Test Methods for Evaluating Solid Waste, Physical/Chemical Methods*
- New Mexico Hazardous Waste Act of 1978 (Section 74-4-1 NMSA)
- 20.4.1.200 New Mexico Administrative Code, *Adoption of 40 CFR Part 261*
- DOE/WIPP-07-3372, *Waste Isolation Pilot Plant Documented Safety Analysis*
- WP 15-GM.03, *Integrated Safety Management System Description*