Title 40 CFR Part 191
Compliance Certification
Application
for the
Waste Isolation Pilot Plant

Appendix QAPD

United States Department of Energy
Waste Isolation Pilot Plant

Carlsbad Area Office
Carlsbad, New Mexico

Quality Assurance Program Documents

U.S. DEPARTMENT OF ENERGY
CARLSBAD AREA OFFICE

QUALITY ASSURANCE PROGRAM DOCUMENT

CAO-94-1012

DRAFT Rev. 1.0 (4/22/96)

APRIL 1996

U.S. DEPARTMENT OF ENERGY
CARLSBAD AREA OFFICE

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U.S. DEPARTMENT OF ENERGY

CARLSBAD AREA OFFICE

QUALITY ASSURANCE PROGRAM DOCUMENT

REVISION 1

Prepared by: R. Donna Brown 4/22/96
QA Manager, CAO **Date**

Approved by: George E. Dials 4/22/96
Manager, CAO **Date**

POLICY STATEMENT

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

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

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

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

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

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

In support of this Policy Statement, all CAO personnel are expected to demonstrate their personal commitment to the achievement of quality through their active involvement in the implementation of the CAO QA Program.

George E. Dials — Manager, CAO

April 22, 1996 — Date

CHANGE HISTORY

Revision:	Changes to the QAPD
1	The QAPD has been substantially rewritten, the structure has been reorganized and the content supplemented to transition from a CAO internal requirements and participant guidance document to a CAO "program-wide" requirements document. The document elements that defined the extent of applicability regarding specific QA program requirements have been clarified through the identification of "general" and "additional" requirements. Requirements for the grading of management controls have been clarified and more fully developed. The requirement for SNL and WID QAPDs was deleted. A requirement was added for each organization to prepare, submit for review, and maintain a QA implementing procedures matrix. Revisions were made to incorporate all the requirements of 40 CFR Part 194; ANSI/NCSL Z540-1; and stakeholder comments. The use of the terms "will" and "shall" are interchangeable and denote requirements. Editorial changes were made throughout.

TABLE OF CONTENTS

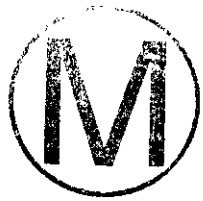


TABLE OF CONTENTS

TABLE OF CONTENTS

TABLE OF CONTENTS

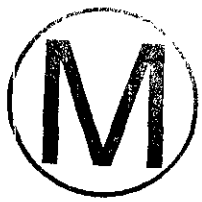


TABLE OF CONTENTS

TABLE OF CONTENTS

TABLE OF CONTENTS

LIST OF FIGURES AND TABLES

LIST OF ACRONYMS AND ABBREVIATIONS

ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
ASNT	American Society of Nondestructive Testing
ASTM	American Society for Testing and Materials
CAO	Carlsbad Area Office
CFR	Code of Federal Regulations
DOE	U.S. Department of Energy
DOE-AL	U.S. Department of Energy-Albuquerque
DOE-HQ	U.S. Department of Energy-Headquarters
EEG	Environmental Evaluation Group
EM	Office of Environmental Management
EPA	U.S. Environmental Protection Agency
M&TE	Measuring and Test Equipment
M&O	Management and Operating Contractor
NAS	National Academy of Sciences
NARA	National Archives and Records Administration
NDE	Nondestructive Examination
NFPA	National Fire Protection Association
NIST	National Institute of Standards and Technology
NMED	New Mexico Environment Department
NQA	Nuclear Quality Assurance
NRC	Nuclear Regulatory Commission
NUREG	Nuclear Regulatory Commission Report Designation
QA	Quality Assurance
QAPD	Quality Assurance Program Document
QAPjP	Quality Assurance Project Plan
QAPP	Quality Assurance Program Plan

QARD	Quality Assurance Requirements and Description
QC	Quality Control
SNL	Sandia National Laboratories
SQA	Software Quality Assurance
TRU	Transuranic
TRUPACT	Transuranic Package Transporter
WID	Westinghouse Waste Isolation Division
WIPP	Waste Isolation Pilot Plant

SECTION 1 – MANAGEMENT REQUIREMENTS

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

1.1 ORGANIZATION AND QUALITY ASSURANCE PROGRAM

This section describes the CAO organizational structure, primary interfaces, functional responsibilities, and levels of authority established to develop and implement the CAO QA Program. In addition, this section describes the basic elements of the QA Program and their applicability.

1.1.1 Organization

Effective implementation of the CAO QA Program is dependent on the efforts at all levels of the CAO and participant organizations. The CAO organization is structured such that the individual performing the work is responsible for achieving and maintaining quality. Management is responsible for defining quality, developing appropriate plans to attain quality, providing support of the workers in pursuit of quality, and verifying quality achievement. The QA Manager is responsible for defining, integrating, and ensuring effective implementation of the CAO QA Program.

The CAO Organization Chart is shown in Figure 1-1.

1.1.1.1 CAO Manager

The CAO Manager reports to the Assistant Secretary, Environmental Management, (EM-1) and has overall responsibility for the CAO QA Program. The CAO Manager is responsible for approving this QAPD and for maintaining an organizational environment conducive to the effective implementation of the CAO QA Program. Authority for execution of the CAO QA function, including the verification of effective implementation, is delegated to the CAO QA Manager.

1.1.1.2 CAO Management

A. CAO management has overall responsibility for the successful accomplishment of the CAO objectives. CAO management provides the necessary planning, organization, direction, control, resources, and support to achieve the CAO mission objectives. Management is responsible for planning, performing, assessing, and improving the work. For a description of the CAO Management system, see CAO operational plan, WIPP/CAO-95-1127.

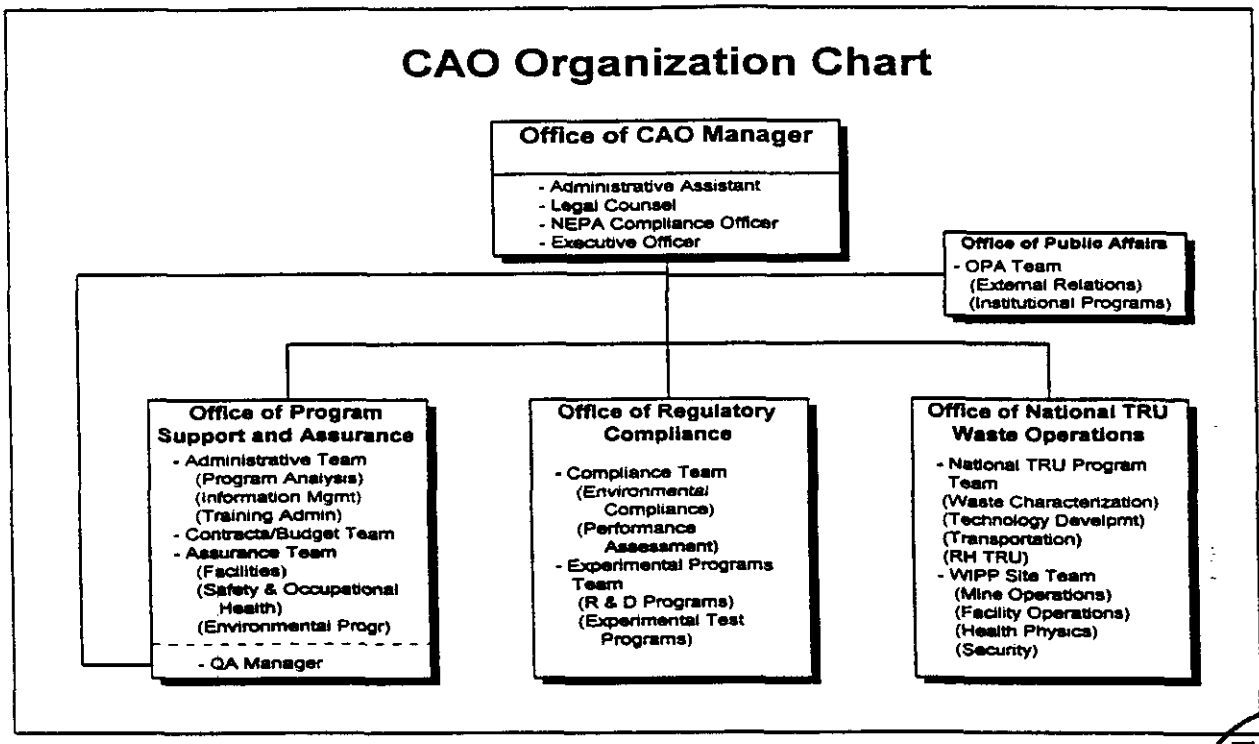


Figure 1-1

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

C. CAO management has various QA responsibilities that include:

1. ensuring that adequate technical and QA training is provided for personnel performing activities important to the satisfaction of CAO objectives;

2. ensuring compliance with all applicable regulations, DOE orders and requirements applicable to CAO programs, and applicable state and local laws;

3. ensuring that personnel adhere to procedures for the generation, identification, control, and protection of QA records;

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

5. developing, implementing, and maintaining plans, policies, and procedures that implement this QAPD; and

6. identifying, investigating, reporting, and correcting quality problems.

D. Quality achievement is the responsibility of those performing the work. Members of CAO management are responsible for the achievement and verification of quality in their area. CAO management shall identify the responsibilities and authorities of those organizational line management positions responsible for achieving and verifying quality.

E. CAO management empowers employees by delegating authority and decision making to the lowest appropriate level in the organization.

1.1.1.3 CAO Employees

Each CAO employee, including contractor personnel working to CAO procedures, is responsible for the quality of his or her work and for promptly reporting all existing, developing, or potential conditions adverse to quality to the responsible management for evaluation and action.

1.1.1.4 CAO QA Manager

The CAO QA Manager has the authority and overall responsibility to independently assess the effective implementation of the CAO QA Program, both within the CAO organization, and participant organizations.

A. Additional authorities and responsibilities of the QA Manager include the following:

1. scheduling and conducting QA assessments;

2. maintaining liaison with participant QA organizations and other affected organizations;

3. preparing, as appropriate, and reviewing internal procedures that implement the provisions of this QAPD;

4. reviewing and approving, with line management concurrence, supplier and sub-tier participant QA plans;

5. tracking, performing trend analysis, and reporting quality problem areas; and

6. providing for the administrative processing of documentation concerning conditions adverse to quality.

B. The CAO QA Manager shall:

1. have direct access to responsible management at a level where appropriate action can be effected;

2. be sufficiently independent from cost and schedule considerations;

3. have the organizational freedom to communicate with management; and

4. have no other assigned responsibilities unrelated to the quality assurance program that would prevent full attention to quality assurance matters.

C. CAO management policy grants the QA organization sufficient authority, access to work areas, and organizational freedom to:

1. identify quality problems;

2. recommend solutions;

3. verify implementation of solutions; and

4. assure that unsatisfactory conditions are controlled until proper disposition has occurred.

D. In addition to the above responsibilities and authorities, the CAO QA Manager shall:

1. develop, establish, interpret, CAO QA policy and ensure effective implementation.

2. prepare, issue, and maintain the CAO QAPD and review CAO implementing procedures;

3. interface with the CAO staff, participants, and other stakeholders, on quality assurance matters;

4. review and jointly approve, with CAO line management, subordinate QA plans including the Quality Assurance Program Plan (QAPP) and participant Quality Assurance Project Plans (QAPjPs);

5. assist other CAO organizations with quality planning, documentation, quality measurement, and problem identification and resolution; and

6. provide guidance to all CAO organizations concerning identification, control, and protection of QA records.

1.1.1.5 Participant Organization

A. Participant Management

1. Management within each participant organization shall provide the necessary planning, organization, direction, control, resources, and support to achieve their defined objectives. Management is responsible for planning, performing, assessing, and improving work.

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

3. Participant management has various QA responsibilities that include:

   a. ensuring that adequate technical and QA training is provided for personnel performing activities subject to this QAPD;

   b. ensuring compliance with all applicable regulations, DOE orders and requirements applicable to activities subject to this QAPD;

   c. ensuring that personnel adhere to procedures for the generation, identification, control, and protection of QA records;

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

   e. developing, implementing, and maintaining plans, policies, and procedures that implement this QAPD; and

   f. identifying, investigating, reporting, and correcting quality problems.

4. Quality achievement is the responsibility of those performing the work. Members of participant management are responsible for the achievement and verification of quality in their area. Participant management shall identify the responsibilities and authorities of those organizational line management positions responsible for achieving and verifying quality.

5. Participant management shall ensure that each participant employee is responsible for the quality of his or her work and for promptly reporting all existing, developing, or potential conditions adverse to quality to the responsible management for evaluation and action.

B. Participant QA Management

1. Participant QA management shall have the authority and responsibility to independently assess the effective implementation of the CAO QA Program, both within the participant organization, and their sub-tier organizations. Additional authorities and responsibilities of the participant QA managers include the following:

   a. scheduling and conducting QA assessments;

   b. maintaining liaison with the CAO QA organization and sub-tier organizations;

   c. preparing and reviewing internal procedures that implement the provisions of their QA plans;

   d. reviewing and approving lower-tier organizational QA plans;

   e. tracking, performing trend analysis, and reporting quality problem areas; and

   f. providing for the administrative processing of documentation concerning conditions adverse to quality.

2. Participant QA Management shall:

   a. have direct access to responsible management at a level where appropriate action can be effected;

   b. be sufficiently independent from cost and schedule considerations;

   c. have the organizational freedom to communicate with management; and

   d. have no other assigned responsibilities unrelated to the quality assurance program that would prevent full attention to quality assurance matters.

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

   a. identify quality problems;

   b. recommend solutions;

   c. verify implementation of solutions; and

d. assure that unsatisfactory conditions are controlled until proper disposition has occurred.

1.1.1.6 Communication and Interface Responsibilities

A. Communication Responsibilities

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

1. the status of development and implementation of the QA program;
2. the status and resolution of significant quality problems;
3. the lessons learned from significant quality problems and adverse conditions;
4. quality management practices and improvements; and
5. trend analysis results.

B. Interface Responsibilities

The primary CAO interfaces are shown in Figure 1-2.

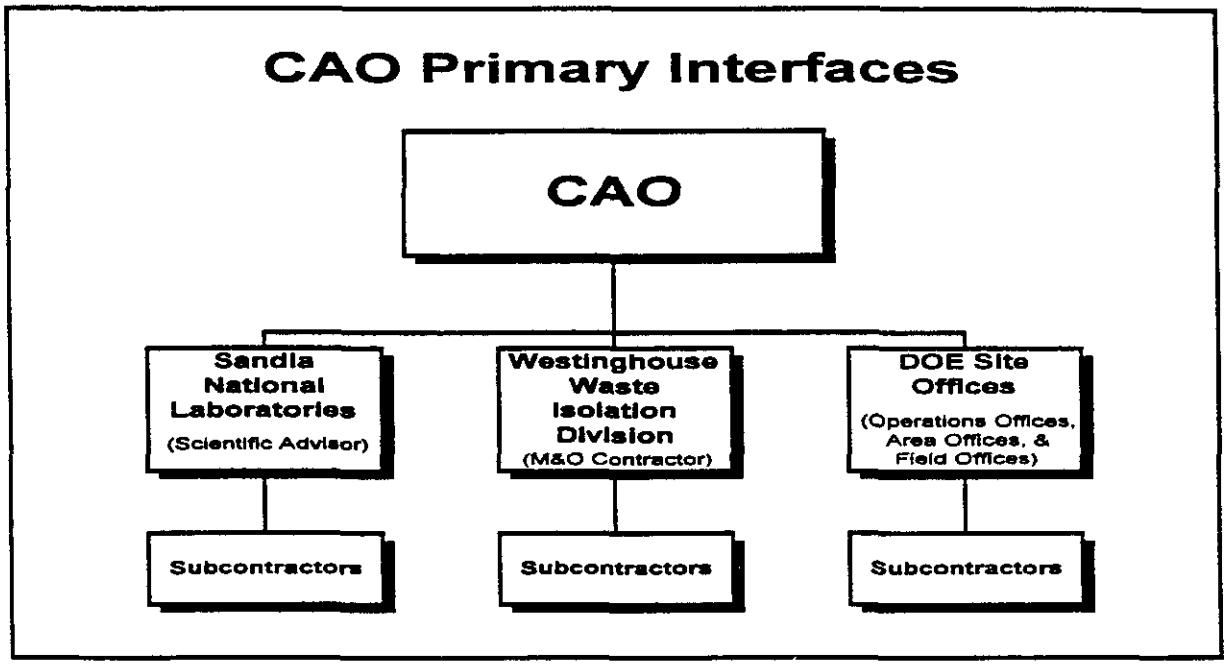


Figure 1-2

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

2. CAO external interfaces include other DOE elements, CAO program participants, suppliers, the Environmental Protection Agency (EPA), the Environmental Evaluation Group (EEG), and the New Mexico Environment Department (NMED).

3. The management of CAO organizations that interface with other DOE elements, program participants, and regulatory agencies, shall be responsible to notify the CAO QA Manager of all issues related to quality assurance, including new or proposed quality assurance requirements and questions regarding the CAO QA policies or program.

4. CAO sponsored activities, performed by organizations external to the CAO, include, but are not limited to, waste characterization, repository performance assessment, and management and operation of the WIPP facility. Responsible CAO organizations cognizant of such activities shall be responsible to ensure the effective implementation of the CAO QA Program.

1.1.1.7 Delegation of Work

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

1.1.1.8 Resolution of Disputes

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

1.1.2 Implementation of the CAO QA Program

1.1.2.1 Quality Assurance Program Documents

A. The CAO and each program participant shall develop and follow procedures that effectively implement the requirements described herein, as applicable to the

activities they perform in support of the CAO. The principal participants (i.e. the WIPP M&O Contractor, and Science Advisor) may implement the requirements of the QAPD directly through internal implementing plans and procedures prepared and maintained by their respective organization. The principal participants may choose to maintain their own QAPDs to support their implementation of the CAO QA Program.

B. The Transuranic Waste Characterization QAPP is prepared, issued, and maintained by CAO, in order to prescribe program-specific QA and quality control (QC) provisions that apply to multiple participants. The QAPP shall indicate that the requirements described supplement those of this QAPD.

C. QAPjPs are prepared, issued, and maintained by CAO participants, as appropriate, to identify project QA and QC provisions, and implementing procedures.

D. The following requirements apply to the development and implementation of QAPPs, QAPjPs, and the associated implementing procedures.

1. Participants are expected to develop QA implementing procedures, that provide for top-down implementation of the QAPD, QAPP and QAPjPs, as applicable.

2. CAO and participant QA plans and implementing procedures shall provide control over internal and external interfaces. An interface exists when one participant prescribes an activity or requirement to, or shares an activity orrequirement with, another participant. Interfaces shall be defined, documented, and controlled.

The CAO Document Hierarchy is shown in Figure 1-3.

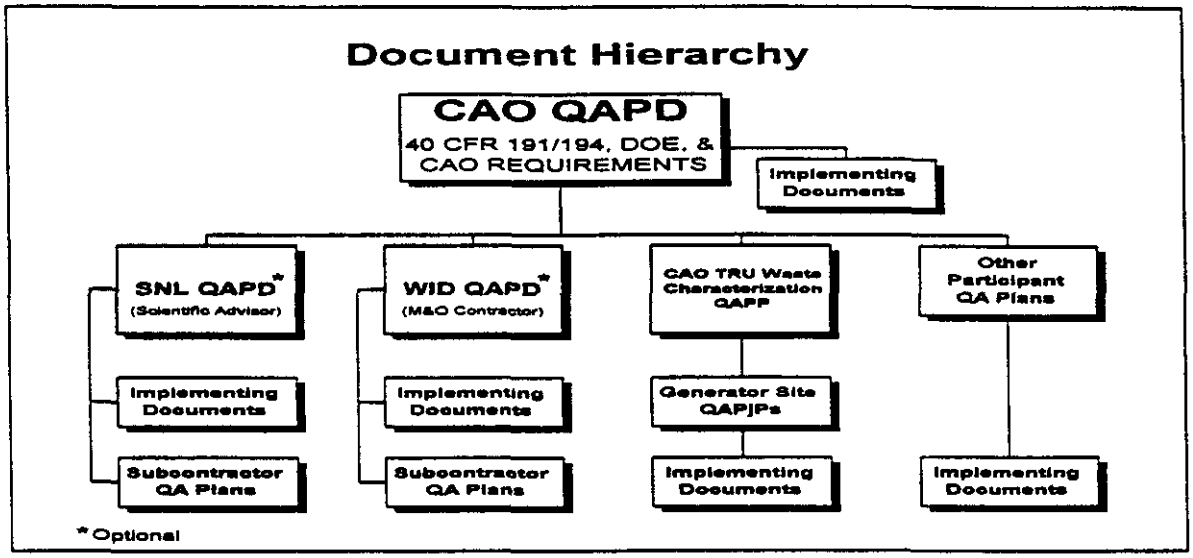


Figure 1-3

1.1.2.2 Procedures Matrix

Each organization that directly supports CAO activities shall prepare and maintain a procedures matrix, identifying all current and applicable documents of each organization or project that serve to implement each applicable requirement of this QAPD. The procedure matrix shall be submitted to the CAO QA Manager for review. The matrix shall be updated as implementation procedures are revised.

When this QAPD is revised, all QAPP, QAPjPs, and implementing procedures are to be evaluated and revised as necessary to ensure that the QA program of each organization continues to satisfy the applicable requirements of the CAO QA Program.

1.1.2.3 Applicability of QAPD Requirements

The CAO QA Program, as described in this QAPD, is driven by a variety of source requirements, as identified in Table I-1. The objective of this QAPD is to effectively and efficiently satisfy the QA program requirements through the application of management controls appropriate to the varied activities of the CAO and participants. In pursuit of this objective, the QAPD establishes two primary categories of requirements, identified as "general requirements" and "additional requirements".

The requirements of QAPD sections that do not identify specific applications, are "general requirements", that shall apply to all items, activities, and processes under the cognizance of the CAO. In most cases the "general requirements" form the introductory portion of a given section, followed by any "additional requirements". Several sections of the QAPD have a more limited application, as specifically identified within the given section. The requirements of QAPD sections identified as "additional requirements" shall apply to all items and activities listed below, unless otherwise specified in this QAPD.

The terminology "items or activities important to compliance application, nuclear safety, waste characterization, or waste isolation" is used generically throughout this QAPD to refer to the following:

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

B. waste characterization activities and assumptions;

C. environmental monitoring, monitoring the performance of the disposal system, sampling, and analysis activities;

D. field measurements of geological factors, ground water, meteorology, and topography;

E. computations, codes, models, and methods used to demonstrate compliance with disposal regulations;

F. expert judgement elicitation to support applications for certification or determination of compliance;

G. design of the disposal system and actions taken to ensure compliance with design specifications;

H. the collection of data and information used to support compliance application(s);

I. other systems, structures, components, and activities important to the isolation of waste in the disposal system; or

J. those items and activities related to NRC licensed packaging (e.g., Transuranic Package Transporter (TRUPACT)-II): design, purchase, fabrication, handling, shipping, storage, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification or components of packaging which are important to safety.

1.1.2.4 Grading Items and Activities and Applying Management Controls

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

1. the relative importance of an item or activity with respect to safety, safeguards, security, waste isolation, and other mission objectives (e.g., cost and schedule);

2. the importance of the data to be generated;

3. the need to demonstrate compliance with specific regulatory design and QA requirements;

4. the impact on the results of performance assessments and engineering analyses;

5. the magnitude of any hazard or the consequences of failure;

6. the life-cycle stage of a facility or item;

7. the programmatic mission of a facility;

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

9. any other relevant factor.

B. The extent of management and QA controls applied to an item or activity will vary as a function of the degree of confidence needed to achieve the desired quality of the item or activity. The grading process provides the flexibility to design and implement controls that best suit the facility or activity. The graded approach process is not intended to reduce or in any way degrade the full implementation of requirements specified in this QAPD. The use of the graded approach shall determine the appropriate controls necessary to manage the items, systems, and activities under the cognizance of the CAO.

C. Implementing procedures for each organization shall provide for:

1. the assignment of management and QA control levels;

2. the definitive criteria used in the selecting those levels; and detailed descriptions of the management and QA control provisions corresponding to those levels, based on the above requirements.

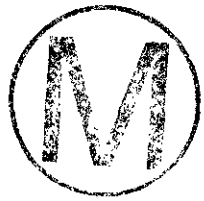
D. It is not the intent of this QAPD to require a CAO-specific process for participant organizations that have already implemented a site- or company-wide grading process, as long as the provisions of such control systems satisfy the requirements of this QAPD. Participant procedures that establish and implement a graded approach for items and activities under the cognizance of the CAO shall submit those procedures to the next higher-tier participant QA organization and the CAO QA Manager for approval for use in CAO programs.

1.1.2.5 Planning Work

A. General Requirements

Planning shall be performed and documented to ensure that work is accomplished under suitably controlled conditions. Programmatic planning documentation shall include a description of the applicable management systems and processes, including those that govern planning, scheduling, and resource considerations.

Appropriate, nationally recognized standards shall be used, where applicable, to develop and implement methods and processes to control items, processes, and activities, as appropriate. Standards used to develop the implementing procedures shall be identified and documented in work activity planning. When no recognized standard exists, the procedures shall be reviewed to assure the technical adequacy and validity of the methods and processes to be implemented.



B. Additional Requirements

For programs, projects, items, activities, and processes related to compliance application, nuclear safety, waste characterization, or waste isolation, planning shall be coordinated among the responsible organizations and shall include the following elements, as applicable:

1. the definition of the program, project, or task work scope, objectives, applicable QA controls, and a listing of the primary activities involved;

2. the identification of the specific scientific and technical information to be collected and analyzed;

3. the identification of methods or procedures for field, laboratory, and engineering sampling, testing, and analysis activities;

4. the identification of applicable technical and quality assurance standards and criteria, including provisions for quality verification; provisions for determining the resources and numbers of personnel required;

5. a description of any management reviews, technical reviews, QA reviews, peer reviews, and readiness reviews, as appropriate;

6. the identification of applicable implementation documents;

7. the identification of field and laboratory testing equipment or other equipment;

8. the identification of required QA records, including provisions and documentation for providing objective evidence of the work performed;

9. the identification of prerequisites, special controls, specific environmental conditions, processes, or skills; and

10. the identification of applicable computer software.

1.1.2.6 Compliance Application Peer Reviews

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

Peer reviews of the following activities shall be conducted in a manner consistent with NUREG-1297, *Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories:*

A. conceptual models selected and developed by the DOE;

B. waste characterization analysis as required in 40 CFR § 194.24(b); and

C. engineered barrier evaluation as required in 40 CFR § 194.44.

1.2 PERSONNEL QUALIFICATION AND TRAINING

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

1.2.1 Additional Qualification Requirements

Qualification requirements for CAO and participant positions or job functions shall be established for activities important to compliance application, nuclear safety, waste characterization or waste isolation. The evaluation shall be documented. These positions include but are not limited to managers, designers, scientists, independent assessment personnel, operators, maintenance personnel, technicians, and inspectors.

The responsible organization shall:

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

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

1.2.2 Additional Training Requirements

CAO and participant personnel performing activities important to compliance application, nuclear safety, waste characterization or waste isolation shall receive related training in accordance with the following requirements. Training shall emphasize the correct performance of work, provide a description of why the applicable quality and nuclear safety requirements exist, and describe the fundamentals of the work and the context. Training shall be subject to ongoing review to determine instruction and training program effectiveness, and shall be upgraded whenever needed improvements or enhancements are identified. Management is expected to:

A. Ensure personnel receive indoctrination and training, including on-the-job and hands-on training, as needed to achieve initial proficiency; maintain proficiency; and

adapt to changes in technology, methods, job responsibilities, and quality assurance implementing procedures, prior to performing any tasks, that are subject to the QAPD.

B. Ensure personnel receive indoctrination in the following:

1. general criteria, including, applicable QA Plans, codes, regulations, and standards; and

2. specific criteria, including applicable QAPjPs and implementing procedures.

C. Records generated during qualification, general indoctrination and training, or specific skill training activities shall be collected and maintained as QA records.

1.3 QUALITY IMPROVEMENT

1.3.1 General Requirements

A. This section defines CAO management responsibility for building a culture in which continuous improvement is a fundamental and integral part of the organization's mission. The CAO and participants shall establish and implement processes to detect and prevent conditions adverse to quality and to ensure continuous improvement. Items and processes that do not meet established requirements shall be identified, controlled, and corrected.

B. Corrective action for significant condition adverse to quality shall include identification of the causes of adverse conditions and provisions to preclude recurrence. Item reliability, process implementation, and other relevant information shall be reviewed and the data analyzed to identify items and processes needing improvement.

C. All personnel shall be responsible for identifying nonconforming items, activities, and processes and shall be encouraged by management to suggest improvements. Management at all levels should foster a "no-fault" attitude to encourage the identification of nonconforming items and processes. Nonconformances shall be documented, evaluated, and dispositioned.

1.3.2 Additional Requirements

The requirements of this section shall apply, in addition to the above requirements, for items, activities, and processes related to compliance application, nuclear safety, waste characterization or waste isolation.

1.3.2.1 Identifying and Classifying Conditions Adverse To Quality

A condition adverse to quality is an all-inclusive term used in reference to failures, malfunctions, deficiencies, and nonconforming items and processes. Conditions adverse to quality shall be identified and documented. Documentation shall clearly identify and describe the characteristics that do not conform to specified criteria.

A. Conditions adverse to quality shall be classified in regard to their significance. Corrective actions shall be developed accordingly.

B. Two categories of classification shall be established:

   1. conditions adverse to quality; and

   2. significant conditions adverse to quality.

Significant conditions adverse to quality are conditions that if not corrected, could have a serious effect on safety, operability, waste isolation, compliance, or the reliability of the QA program.

1.3.2.2 Control of Conditions Adverse to Quality

A. Conditions adverse to quality shall be investigated, including the extent of the condition and the impact on completed work, and documented. Corrective action plans, as appropriate and as discussed in Section 1.3.2.4, shall be developed, documented, and implemented as soon as practical.

B. Significant conditions adverse to quality shall be reported to and evaluated by the cognizant quality assurance organization, other relevant compliance functions (e.g. environmental and safety) and the responsible management to determine if a work suspension order is necessary. Corrective action plans for significant conditions adverse to quality shall address all provisions of Section 1.3.2.4. Management of the cognizant organization shall be notified and provided with the results of the subject evaluations.

   1. The cognizant organization shall issue work suspension order to the responsible management after a work suspension condition has been identified.

   2. The cognizant organization shall take appropriate action to lift and close (in part or total) the work suspension order based on the resolution of the related significant condition adverse to quality. The quality assurance organization shall verify and document the completion of applicable corrective actions prior to any management action releasing the work suspension order.

1.3.2.3 Control and Disposition of Nonconforming Items

Nonconforming items are adverse conditions, or the result of adverse conditions requiring the following additional controls.

A. Nonconforming items shall be identified by marking, tagging, or other methods that do not adversely affect their end use. The identification shall provide traceability to the related adverse condition documentation, and shall be legible and easily recognizable. If marking or tagging of a nonconforming item is not practical then the item, container, package, or segregated storage area shall be clearly identified.

B. Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. If segregation is impractical or impossible due to physical conditions, then other administrative controls and precautions shall be employed to preclude inadvertent use of a nonconforming item.

Nonconforming items shall be controlled to prevent any adverse impact on test, installation, or use. Organizations affected by the nonconformance shall be notified.

C. Responsibility for the control of further processing, delivery, installation, or operation of nonconforming items, systems or equipment shall be designated in writing.

D. The nonconforming characteristics shall be reviewed and recommended. Dispositions of nonconforming items shall be proposed and approved in accordance with documented procedures. The responsibility and authority for the evaluation and disposition of nonconforming items shall be defined in applicable QA plans or implementing procedures. Personnel performing evaluations to determine a disposition 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.

E. The disposition of nonconforming items shall be identified and documented, and have the concurrence of the cognizant quality assurance organization.

1. The disposition, such as "use-as-is," "reject," "repair," "rework," or "scrap" for nonconforming items shall be identified and documented. Further processing, delivery, installation, or use of a nonconforming item shall be controlled, in accordance with approved procedures, pending the evaluation and approval of the disposition.

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

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

1.3.2.4 Corrective Action Planning and Follow-up

Corrective action plans are required for all significant conditions adverse to quality and shall address the following points, as appropriate: the actions to resolve the initial problem (remedial actions);

A. the assessment of the extent and impact of the significant condition adverse to quality (investigative actions);

B. the determination of the root cause of the problem;

C. the actions be taken to preclude recurrence of the problem; and

D. the expected completion dates and responsibilities for the required actions.

A follow-up system shall be established to verify the effective implementation of scheduled corrective actions and to complete the corrective action in a timely manner. The cognizant organization (the organization that documented the condition adverse to quality) shall evaluate the adequacy of corrective actions planned, assign responsibility for follow-up verification, and perform and document the corrective action verification.

1.3.2.5 Improvement Analysis

Quality performance data shall be identified, collected, and routinely analyzed to identify opportunities to improve items, 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 analyses shall be performed by the organization, in a manner and at a frequency that provides for prompt identification of trends adverse to quality. CAO and participants will report trending information to responsible management and to the quality assurance organization of the next higher level participant. Reports of conditions adverse to quality shall be evaluated to identify adverse quality trends, and

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identify root causes, with results reported to the organization responsible for corrective action.

1.3.2.6 Recurring Conditions Adverse to Quality

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

A. determine the events leading to the occurrences;

B. develop an understanding of the technical and work activities associated with the conditions adverse to quality;

C. ascertain any generic implications;

D. determine the extent to which similar quality problems, or precursors to the problem, have been recognized by the responsible organization; determine the effectiveness of any corrective actions that were taken, and identify any generic implications and impacts on completed work;

E. consider suspending work associated with the applicable activity; and

F. suggest actions that can be taken by the responsible organization to preclude recurrence.

1.4 DOCUMENTS

1.4.1 General Requirements

Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design.

1.4.2 Additional Requirements

Documents that specify requirements, prescribe processes, or establish design important to compliance application, nuclear safety, waste characterization, or waste isolation, such as instructions, procedures, drawings, test plans, management plans, technical reports, performance reports, and test reports, shall be controlled according to the requirements listed below, to assure that correct documents are being employed.

1.4.2.1 Document Preparation, Review, Approval, and Issuance

Documents shall be reviewed for adequacy, correctness, and completeness prior to approval and issuance. The CAO and participants shall identify the individuals or

organizations responsible for the preparation, review, approval, and issuance of controlled documents.

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

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

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

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 cognizant quality assurance organization shall review documents that translate CAO QAPD or QAPP requirements.

H. Review comment documentation shall be resolved in accordance with approved procedures. Dispositioned review comment documentation shall be maintained by the originating organization.

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

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

1.4.2.2 Document Distribution and Use

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

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

B. Effective dates shall be established and identified on the 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 or revision of controlled documents and forms.

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

1.4.2.3 Document Changes

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.

A. Document changes shall be:

1. reviewed by the organizations or technical disciplines affected; and

2. clearly indicated in the changed document.

B. Editorial 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 changes:

1. correcting grammar or spelling (the meaning has not changed);

2. renumbering sections or attachments; or

3. updating organizational titles

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

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

1.5 RECORDS

1.5.1 General Requirements

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

1.5.2 Additional Requirements

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

1.5.2.1 Records System

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

This does not prohibit the management of QA records within a general records system, nor does this require a separate records system for QA records, as long as the applicable provisions of Section 1.5.2 are satisfied for the control of QA records.

1.5.2.2 Generating QA Records

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

   1. identify those documents that shall become QA records; and

   2. identify the organization responsible for submitting the QA records to the records system.

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

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

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

E. Once authenticated, QA records shall be submitted to the records system, as described above, for either permanent or temporary storage. 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.

F. QA records may be originals or reproducible copies; unless, otherwise required.

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

1.5.2.3 Indexing QA Records

The records 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, as a minimum, record retention times and the location of the record within the records system. These and other features of the record system shall facilitate the disposition of scheduled QA records and ensure the retrievability of any and all QA records entered.

1.5.2.4 Classifying QA Records

QA records shall be initially classified as either "post closure", "lifetime" or "nonpermanent."

A. Records that fall into one or more of the following categories shall be classified as "post closure" QA records:

1. records that assist in preventing actions that could impair the long-term isolation of the waste;

2. 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;

3. records providing information relevant to post-closure monitoring and assessment of performance of the repository system;

4. records preserving for future generations information regarding the geologic setting relevant to mitigation of releases of radioactive materials; and

5. records that would be of significant value after decommissioning and closure of the repository.

B. Records that do not fall into the above listed categories but do fall into one or more of the following categories shall be classified as "lifetime" QA records:

1. records that may be used for repository permitting or certification;

2. records that may be used to identify and assess the performance capabilities of those engineered and natural barriers important to waste isolation;

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

4. records that would be of significant value in demonstrating the capability for safe operation or in determining the cause of an accident or a malfunction of an item in the WIPP repository;

5. records that would be of significant value in maintaining, reworking, repairing, replacing, or modifying WIPP repository systems, components, or structures;

6. records that would be needed during decommissioning and closure of the repository;

7 records that relate to site characterization samples and data;

8 records that relate to data used in performance assessment of the WIPP facility;

9. records that relate to the mixed transuranic waste form characterization and acceptance of the mixed transuranic waste form; and

10. records that document regulatory compliance.

C. Records that provide objective evidence that the QA program has been properly implemented but do not meet the above criteria shall be classified as "nonpermanent" QA records.

1.5.2.5 Receiving QA Records

Each organization responsible for the receipt of QA records 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. As a minimum, the receipt control system shall include the following:

A. provisions to permit a current and accurate assessment of the status of QA records;

B. a method for identifying the records required to be included in the records system;

C. a method for identifying the records that have been received;

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

E. provisions to control and protect the records from damage or loss during the receiving processes; and

F. a method for submittal of completed records to the storage facility without unnecessary delay.

1.5.2.6 Storage, Preservation, Safekeeping, and Disposition of QA Records

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

1. a description of the storage facility;

2. a description of the filing and indexing systems that are used;

3. a method for ensuring that a receipt acknowledgment is returned to the sender;

4. a description of controls governing QA record access, retrieval, and removal; and

5. a method for filing supplemental information and documenting the authorization for corrections.

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 moisture, temperature, rodent infestation, excessive light, electromagnetic fields, or stacking, as appropriate for the type of record being stored.

C. 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 that the records are useable.

D. Lifetime QA records are required to 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 the particular item while it is installed in the repository or is being stored for future use. Lifetime records shall be evaluated for the need to be upgraded to post closure records prior to their destruction.

E. Design and construction of a single record storage facility shall meet the following criteria:

1. reinforced concrete, concrete block, masonry, or equal construction;

2. floor and roof with drainage control (if a floor drain is provided, a check valve, or equal, shall be included);

3. doors, structure and frames, and hardware shall be designed to comply with the requirements of a minimum 2-hour fire rating;

4. sealant applied over walls as a moisture or condensation barrier;

5. surface sealant on floor providing a hard wear surface to minimize concrete dusting;

6. foundation sealant and provisions for drainage;

7. forced air circulation with filter system;

8. fire protection system; and

9. only those penetrations used exclusively for fire protection, communication, lighting, or temperature/humidity control are allowed; all such penetrations shall be sealed or dampened to comply with the minimum 2-hour fire protection rating.

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

F. The following are acceptable alternatives to the criteria of Section F. above, for a single storage facility:

1. 2-hour fire rated vault meeting the National Fire Protection Association (NFPA) 232-1986, *Standards for the Protection of Records* or NFPA 232AM-1986 or both;

2. 2-hour fire rated Class B file containers meeting the requirements of NFPA 232-1986 or NFPA 232AM-1986 or both; or

3. 2-hr fire rated file room meeting the requirements of NFPA 232-1986 or NFPA 232AM-1986 or both, with the following additional provisions:

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

   b. Records storage in fully enclosed metal cabinets;

   c. Adequate access and aisle ways;

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

   e. Prohibition in the room of smoking, eating, or drinking;

   f. 2-hour fire rated dampers or doors in all boundary penetrations.

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 requirements of either Sections F or G 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, prior to establishing storage at dual facilities, 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 a UL label (or equivalent) certifying one-hour fire protection or be certified by a person competent in fire protection.

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

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

K. 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. operational status permits the disposal of such records; and

4. the related contractual requirements have been satisfied.

1.5.2.7. Correcting Information in QA Records

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

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

C. Corrections to QA records should be made with 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 REQUIREMENTS

2.1 WORK PROCESSES

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

B. The intent of this section is to establish the policy that each person, who performs work, is responsible for the quality of his or her work, and he or she will have the goal of doing work correctly the first time. 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 of this QAPD.

C. This section further establishes management involvement in the work processes through their interactions with personnel performing the work and through their review and verification 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 properly accomplish their tasks.

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 review work and related information to assure 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 and QA standards and implementing procedures commensurate with applicable control levels.

2.1.2 Implementing Procedures

For activities and processes supporting compliance application, or related to nuclear safety, waste characterization or waste isolation, appropriate procedures, shall be developed and followed in accordance with the requirements of this section.

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

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

1. responsibilities of the organizations affected by the document;

2. technical, regulatory, quality assurance, or other program requirements;

3. sequential description of the work to be performed, including any allowance for out-of-sequence processing;

4. quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished;

5. prerequisites, limits, precautions, process parameters, and environmental conditions;

6. special qualification and training requirements;

7. verification points and hold points;

8. 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); and

9. identification and classification of QA records to be generated by the implementing procedure.

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

2.1.3 Item Identification and Control

A. Items and systems supporting compliance application, or related to nuclear safety, waste characterization or waste isolation, shall be identified and controlled in accordance with the requirements of this section.

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

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

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

2. 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 control). When used, physical markings shall:

   a. be applied using materials and methods that provide a clear, permanent, and legible identification;

   b. not be detrimental to the function or service life of the item;

   c. be transferred to each part of an identified item when the item is subdivided; and

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

3. 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 meeting the special requirements.

4. 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.

5. 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.

2.1.4 Special Processes

Special processes supporting compliance application or related to nuclear safety, waste characterization or waste isolation, shall be controlled in accordance with the requirements of this section.

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

   1. the results are highly dependent on the control of the process;

   2. the results are highly dependent on the skill of the operator; or

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

B. Implementing procedures shall be established to ensure special process parameters are controlled and specified environmental conditions are maintained. In addition to the requirements provided in Section 2.1.2, special process implementing procedures shall include or reference:

   1. the requirements for qualification of personnel, processes, and equipment; and

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

2.1.5 Handling, Storage, and Shipping

Items supporting compliance application or related to nuclear safety, waste characterization or waste isolation, shall be controlled in accordance with the requirements of this section.

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

B. 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.

C. 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.

D. 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.

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

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

   3. 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.

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

E. 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:

   1. maintenance or replacement of markings and identification tags damaged during handling or aging;

   2. protection of identification markings that are subject to excessive deterioration resulting from environmental exposure; and

   3. update of related identification records and documentation.

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

2.2 DESIGN CONTROL

2.2.1 General Requirements

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

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

2.2.2 Additional Requirements

The design of items and processes supporting compliance application or related to nuclear safety, waste characterization, or waste isolation, shall be controlled in accordance with the requirements of this and following sections.

This section provides requirements to ensure that designs (from conceptual through final) are 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.

2.2.2.1 Design Input

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

A. design inputs shall 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; and

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

2.2.2.2 Design Process

The design process shall be controlled 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; and

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

2.2.2.3 Design Analyses

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

B. Documentation of design analyses shall include:

1. definition of the objective of the analyses;

2. definition of design inputs and their sources;

3. results of literature searches or other applicable background data;

4. identification of assumptions and designation of those assumptions that shall be verified as the design proceeds;

5. 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; and

6. identification of the reviewer and the 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 Section 6.

2.2.2.4 Design Interface

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

2.2.2.5 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:

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

   1. design review;

   2. alternate calculations; or

   3. qualification testing.

B. The particular design verification method shall be identified.

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 design verification may be performed by the originator's supervisor provided that:

   I. 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

   2. the supervisor is the only individual in the organization competent to perform the verification, and

   3. 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.

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

   2. 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, complexity of design, degree of standardization, state of the art, and similarity with previously proven designs.

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

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

2. known problems affecting standard or previously proven designs and their effects on other features shall be considered;

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

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

2.2.2.6. Design Reviews

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

1. design inputs were correctly selected and incorporated;

2. assumptions necessary to perform the design work were adequately described, reasonable, and reverified as necessary;

3. appropriate design methods were used;

4. design output is reasonable compared to design inputs; and

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

B. Disposition of design review comments shall be documented.

2.2.2.7. Alternative Calculations

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

2.2.2.8. Qualification Testing

When qualification testing is used, the following requirements shall apply:

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 shall 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 modified item 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; and

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

2.2.2.9 Design Change

Design changes shall be controlled in accordance with 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;

   1. 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.

   2. 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. if a significant design change becomes necessary because of an incorrect original design, the design process and design verification methods and implementing procedures shall be reviewed and modified as appropriate. These design deficiencies shall be documented according to the requirements provided in Section 1.3.2;

E. field changes shall be incorporated into the applicable design documents; and

F. design changes that impact related implementing procedures or training programs shall be communicated to the appropriate organizations.

2.3 PROCUREMENT

2.3.1 General Requirements

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

2.3.2 Additional Requirements

The procurement of items and services important to compliance application, nuclear safety, waste characterization, or waste isolation, shall be controlled in accordance with the requirements of this and following sections.

2.3.2.1 Procurement Planning Requirements

Procurement activities shall be planned as early as possible and documented to assure a systematic approach to the procurement process. Procurement planning shall:

A. Identify procurement methods and organizational responsibilities, including the appropriate 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:

1. procurement document preparation, review, and change control;

2. selection of procurement sources;

3. proposal or bid evaluation and award;

4. purchaser evaluation of supplier performance;

5. purchaser verifications including any hold-point and witness-point notifications;

6. control of nonconformances;

7. corrective action;

8. acceptance of the item or service; and

9. identification of QA records.

2.3.2.2 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:

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

2. an evaluation of the supplier's current QA documentation supported by any qualitative and quantitative information; and

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

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

2.3.2.3 Proposal/Bid Evaluation

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

1. technical considerations;

2. QA program applicability;

3. supplier personnel skills;

4. supplier production capabilities;

5. supplier past performance;

6. alternatives proposed by the supplier; and

7. exceptions taken by the supplier.

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

C. Supplier QA provisions shall be accepted by the purchaser QA management before authorizing the supplier to start work.

2.3.2.4 Procurement Document Requirements

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

A. the scope of work;

B. technical requirements, including:

1. design bases shall be identified or referenced;

2. specific documents (such as drawings, codes, standards, regulations, 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; and

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

C. QA provisions specified by the purchaser QA organization, including:

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

2. the pass-down requirements that the supplier shall incorporate into any sub-tier procurement document; and

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

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

E. the requirements of Section 1.5 and provisions for disposition, if the supplier is required to maintain QA records;

F. requirements for the supplier to report nonconformances and obtain purchaser approval of supplier recommended dispositions;

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

H. requirements for the use, control, and calibration of measuring and test equipment in conformance to the requirements of ANSI/NCSL Z540-1, *Calibration Laboratories and Measuring and Testing Equipment - General Requirements.*

2.3.2.5 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 shall meet the prescribed requirements.

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

C. 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.

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

2.3.2.6 Supplier Performance Evaluation Requirements

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

A. establishing an understanding between the purchaser and supplier of the requirements and specifications identified in the procurement documents;

B. requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements;

C. reviewing supplier documents that are prepared or processed during work performed to fulfill procurement requirements;

D. identifying and processing necessary change information;

E. establishing the method to be used to document information exchanges between purchaser and supplier; and

F. establishing the extent of assessment activities and inspection.

2.3.2.7 Acceptance of Items or Services

A. Source Verification

The purchaser 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 the purchaser's QA organization. In addition:

1. 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.

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

3. Source verification shall be performed by qualified personnel.

B. Receiving Inspection

When a receiving inspection is used to accept an item:

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

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

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

4. The inspection shall be planned and executed in accordance with the applicable requirements of Section 2.4.

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

C. 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 the purchaser and supplier.

D. Supplier Certificate of Conformance

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

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

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

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

4. The certificate shall be signed or otherwise authenticated by an official of the supplier organization.

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

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

2.3.2.8. Control of Supplier Nonconformances

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

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

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

1. Failure to meet technical or material requirements.

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

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

4. The item does not conform to the requirement even though the function of the item is apparently unimpaired.

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

D. The purchaser shall verify implementation of the disposition.

2.3.2.9 Commercial Grade Items

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

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

B. Supplier selection shall be in accordance with source selection requirements.

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, the purchaser shall ensure that:

1. Damage was not sustained during shipment.

2. The item received was the item ordered.

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

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

2.4 INSPECTION AND TESTING

2.4.1 General Requirements

Inspections and testing shall be performed in accordance with approved implementing procedures. An essential part of the work planning process is to identify the items and processes to be inspected or tested, the parameters or characteristics to be evaluated, the techniques to be used, the acceptance criteria, any hold points, and the

organizations responsible for performing the tests and inspections. Inspection for acceptance shall be performed by personnel other than those who performed or directly supervised the work being inspected. Inspection and testing of specified items and processes shall be conducted using established acceptance and performance criteria. The acceptance of items and processes shall be made by and documented by qualified and authorized personnel. Equipment used for inspections and tests shall be calibrated and maintained.

2.4.2 Additional Requirements

Inspection and testing activities supporting compliance application or related to nuclear safety, waste characterization, or waste isolation, shall be conducted in accordance with the requirements of this section, as applicable.

2.4.2.1 Qualification of Inspection and Test Personnel

This section provides amplified requirements for the qualification of personnel who perform inspection and testing to verify conformance to specified requirements for the purpose of acceptability.

The requirements of this section do not apply to the qualification of personnel for performance of nondestructive examination. Qualification of personnel for nondestructive examination is addressed in Section 2.4.2.2.

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

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

C. 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.

D. 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.

E. 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.

F. 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.

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

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

1. employer's name;

2. identification of person being certified;

3. activities certified to perform;

4. 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;

5. results of periodic evaluation;

6. results of physical examinations, when required;

7. signature of employer's designated representative who is responsible for such certification; and

8. the date of certification and date of certification expiration.

I. 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.

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

2.4.2.2 Qualification of Nondestructive Examination Personnel

This section identifies the requirements for the qualification of personnel who perform nondestructive examination (NDE) [radiographic (RT), magnetic particle (MT), ultrasonic (UT), liquid penetrant (PT), eddy current (ET), neutron radiographic (NRT), and leak testing (LT], to verify conformance to specified requirements.

A. The American Society of Nondestructive Testing (ASNT) Recommended Practice No. SNT-TC-1A, June 1980 Edition, and its applicable supplements shall apply as requirements for personnel performing the above methods of NDE.

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.

2.4.2.3 Inspection Requirements

A. Inspection Planning

Inspection planning shall be performed and documented and shall include the:

1. identification of work operations where inspections are necessary;

2. identification of the characteristics to be inspected and the identification of when, during the work process, inspections are to be performed;

3. identification of inspection or process monitoring methods to be employed;

4. identification of acceptance criteria;

5. identification of sampling requirements;

6. methods to record inspection results;

7. selection and identification of the measuring and test equipment (M&TE) to be used to perform the inspection; and

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

B. Inspection Hold Points

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

C. In-Process Inspections and Monitoring

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

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

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

D. Final Inspections

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

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

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

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

E. Inservice Inspections

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

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

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

F. Inspection Documentation

Inspection documentation shall identify:

1. the item inspected and the date of the inspection;

2. the name or unique identifier of the inspector that documented, evaluated, and determined acceptability;

3. the method of inspection;

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

5. the results;

6. the measuring and test equipment used during the inspection, including the identification number and the calibration due date; and

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

2.4.2.4 Test Requirements

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

A. Test Planning

Test planning shall include:

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

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

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

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

5. any mandatory hold points;

6. the methods that are to be used to record data and results; and

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

B. Test Documentation

Test documentation shall identify:

1. the applicable test requirements, plans, and procedures, including revisions;

2. the item or work product tested;

3. the date of the test;

4. the name of the tester and data recorders;
5. the type of observation and method of testing;
6. the identification of test criteria or reference documents used to determine acceptance;
7. the results and acceptability of the test;
8. the actions taken in connection with any noted nonconformances;
9. the name of the person evaluating the test results; and
10. the identification of the measuring and test equipment used during the test (including the identification number and calibration due date).

C. Test Results

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

2.4.3 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. Equipment discussed in the following sections includes measuring and test equipment, measuring and data collection equipment, equipment (either hand held or installed) used for data indication, and other equipment used for data indication, collection, or evaluation. These are termed as M&TE.

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

2.4.3.1 Use and Control of M&TE

Each organization using M&TE shall:

A. establish and document a system to control the use and calibration of M&TE;

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

C. establish and maintain documented procedures to evaluate the adequacy of the calibration system and to ensure compliance with the requirements of this QAPD, including the acquisition of calibration services from laboratories meeting the requirements of ANSI/NCSL Z540-1, *Calibration Laboratories and Measuring and Testing Equipment - General Requirements*;

D. 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:

   1. a description or identification of the item;

   2. calibration interval;

   3. date calibrated;

   4. identification of the calibration source;

   5. calibration results (data and status);

   6. calibration action taken (adjusted, repaired, new value assigned, derated, etc.); and

   7. evaluation and corrective action taken in response to out-of-calibration conditions;

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

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

G. handle, store, and transport M&TE in a manner that does not adversely affect the calibration or condition of the equipment; and

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

2.4.3.2 Calibration

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

B. 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.

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

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

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

F. 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.

G. Calibration services shall conform to the requirements of ANSI/NCSL Z540-1, *Calibration Laboratories and Measuring and Testing Equipment - General Requirements.*

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

SECTION 3 – ASSESSMENT REQUIREMENTS

3.1 MANAGEMENT ASSESSMENT

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

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

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

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

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

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

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

3.2 INDEPENDENT ASSESSMENT

3.2.1 General Requirements

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

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

3.2.2 Additional Requirements

The CAO and participant organizations responsible for the performance of activities important to compliance application, nuclear safety, waste characterization or the isolation of waste within the disposal system, shall implement a program of surveillance and audits. The program shall be planned and documented and include both routine surveillance of those activities, and audits to verify compliance with all aspects of the quality assurance program and determine its adequacy and effectiveness. The surveillance and audit program shall be implemented in accordance with the requirements of Sections 3.2.3 and 3.2.4, respectively, in addition to the general requirements above.

3.2.3 Surveillances

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

B. Surveillances shall accomplish the following:

   1. monitor work in progress;

   2. document compliance or non-compliance with established requirements and procedures;

   3. identify actual and potential conditions adverse to quality;

4. obtain timely corrective action commitment from cognizant managers for identified conditions adverse to quality;

5. provide notification to responsible managers of the status and performance of work under surveillance; and

6. verify timely implementation of corrective action.

C. Surveillances of the subject activities, conducted by the responsible organization, may be counted as satisfying the requirement to do surveillances of related activities in the corresponding surveillance schedule period.

3.2.4 Audits

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

3.2.4.1 Scheduling Audits

A. The CAO and participant organizations shall perform an annual evaluation of audit needs (both internal and external) from which to develop and maintain a schedule of audits. The evaluation shall be documented and include justification for the approach used to determine the subjects, scope, and frequency of the audits scheduled, as well as those areas for which audits have not been scheduled. This evaluation shall include:

1. a review of documentation furnished by, or regarding the work of the organization or supplier (such as certificates of conformance, nonconformance notices, and corrective actions);

2. the results of previous assessments (including assessments from other sources), source verifications, and receiving inspections; and

3. a review of experience from identical or similar products or services furnished by the same organization or supplier.

B. Audits shall be scheduled to begin as early in the life of a project or activity as practicable and continue at intervals consistent with the schedule for accomplishing the work and commensurate with the assigned control level.

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

3.2.4.2 Planning and Preparation for Audits

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

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

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

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

D. Audits shall include technical evaluations of the applicable procedures, instructions, activities, and items.

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

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3.2.4.3 Audit Team Selection

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

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

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

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

3.2.4.4 Auditor Qualification

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

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

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

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 actions.

3.2.4.5 Technical Specialist Qualification

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

3.2.4.6 Lead Auditor Qualification

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

A. 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:

1. Education (four credits maximum)

    a. 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.

    b. 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.

2. Experience (nine credits maximum)

The prospective lead auditor shall have participated in a minimum of five QA audits or equivalent verifications (such as management assessments, pre-award surveys, or comprehensive surveillance, as long as the parameters of the audit process are met) within a period of time not to exceed three years prior to the date of certification. One audit of which shall be a nuclear QA audit within the year prior to qualification. In addition, for technical experience in such areas as scientific investigation, site characterization, nuclear waste management, production, transportation, engineering, manufacturing, construction, operation, maintenance, or experience applicable to the auditing organization's area of responsibility scores one credit for each full year, with a maximum of five credits for this aspect of experience.

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

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

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

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

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

3. 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.

4. 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).

B. Lead Auditor Communication Skills

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

C. Lead Auditor Training

Prospective lead auditors shall be trained to the extent necessary to ensure their competence in skills as established by the organization responsible for performing audits. Training in the following areas shall be accomplished and its completion verified based upon a management evaluation of the particular needs of each prospective lead auditor:

1. knowledge and understanding of the participant organization's QA Program and other program related procedures, codes, standards, regulations, and regulatory guides;

2. general structure of QA plans and implementation procedures, as a whole.

3. auditing techniques of examining, questioning, evaluating, reporting, methods of identifying, following up, and closing corrective action items; and

4. audit planning in functional areas of nuclear QA.

D. Lead Auditor Examination

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

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

   a. Maintain the integrity of the examination through confidentiality of files and, where applicable, proctoring of examinations.

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

E. Lead Auditor Certification

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

1. name of the organization performing the certification;

2. name of the lead auditor;

3. date of certification or recertification;

4. basis of certification (such as education, experience, communication skills, and training); and

5. signature of the designated representative of the organization responsible for the certification.

F. Lead Auditor Proficiency Maintenance

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

   a. regular and active participation in the audit process;

   b. review and study of codes, standards, QA implementation procedures, instructions, and other documents related to QA program auditing; and

   c. participation in training programs.

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

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

3.2.4.7 Performing Audits

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

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

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

D. Conditions adverse to quality shall be documented and corrected according to the requirements of Section 1.3.2.

3.2.4.8 Reporting Audit Results

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

A. a description of the audit scope;

B. the identification of the auditors;

C. the identification of persons contacted during the audit;

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

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

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

G. a description of commendable quality practices.

Additionally, audit findings of a common nature shall be grouped in the report whenever possible so that related or systematic breakdowns in the QA program are identified. Findings or deficiencies shall be categorized based on their relative importance, to indicate their degree of impact on compliance assessment, nuclear safety, waste characterization, waste isolation, environmental protection, or the QA program.

3.2.4.9 Audit Response and Follow Up

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

3.2.4.10 Audit Records

The following documents, when developed in fulfillment of the audit requirements of this QAPD, shall be controlled as QA records, in accordance with Section 1.5 of this QAPD: audit plans; audit reports, audit checklists, audit responses, and documentation of corrective action completion and follow-up.

SECTION 4 – SAMPLE CONTROL REQUIREMENTS

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

4.1 GENERAL

The following general requirements apply to sample control:

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

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

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

D. A chain of custody record form shall be maintained. The chain of custody record shall provide a document trail of all persons that have custody of a given sample, including the date and time of its transfer, from the time the sample is taken until its final disposition.

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

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

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

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

4.2 SAMPLE IDENTIFICATION

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

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

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

1. be applied using materials and methods that provide a clear and legible identification;

2. not affect the sample content or form; and

3. be transferrable to each identified sample part when the sample is subdivided.

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

1. the maintenance or replacement of markings and identification tags that have been damaged during handling or aging; and

2. the protection of identification markings from excessive deterioration due to environmental exposure.

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 implementing procedures. Controls shall provide for the maintenance of sample characteristics, sample integrity, and sample identification during storage.

A. 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.

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

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

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

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

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

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

4.4 DISPOSITION OF NONCONFORMING SAMPLES

A. Sample requirements that are not met as specified in work controlling documents (such as job packages, travelers, or work requests) shall be identified, documented, evaluated, and segregated in accordance with Section 1.3.

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.

SECTION 5 – SCIENTIFIC INVESTIGATION REQUIREMENTS

This section applies to all technical investigations and design development data collection activities performed in support of the WIPP Compliance Application. Scientific investigations shall be defined, controlled, verified, and documented. Process variables affecting scientific investigations shall be measured and controlled. Test processes conducted in support of such investigations shall be controlled in accordance with the requirements of Sections 2.4, *Inspection and Testing*, 2.4.2.4, *Test Requirements*, and 2.4.3, *Monitoring, Measuring, Testing, and Data Collection Equipment*, as applicable, and as supplemented by the requirements of this section.

5.1 PLANNING SCIENTIFIC INVESTIGATIONS

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

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

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

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

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

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

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

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

5.2 PERFORMING SCIENTIFIC INVESTIGATIONS

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

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

C. Scientific notebooks shall contain, as a minimum:

1. a statement of the objective and description of work to be performed or reference to an approved plan that describes the work;

2. the method(s) used;

3. identification of the samples;

4. the measuring and test equipment used;

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

6. a description of changes made to methods used, as appropriate; and

7. the potential sources of uncertainty and error in test plans, procedures, and parameters that must be controlled and measured to assure that tests are valid.

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

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

F. Data collection and analysis shall be controlled by procedures of sufficient detail to allow the processes to be repeated. Where appropriate, quality control checks shall be performed, using recognized methods such as replicate, spike, and split samples; control charts; blanks; reagent checks; replication of the methods used to obtain the results; or alternate analysis methods.

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

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

5.3 DATA DOCUMENTATION, CONTROL, AND VALIDATION

5.3.1 Data Identification and Usage

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

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

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

D. Data that are determined to be erroneous, rejected, superseded, or otherwise unsuited for their intended use shall be controlled to prevent their inadvertent use. Controls shall include the identification, segregation, and disposition of inadequate data. The basis for the disposition of erroneous data shall be justified and documented.

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

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

5.3.2 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 is valid.

B. All applicable data collected 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. the results of the data review shall be documented; and

3. the reviewer shall be independent of the collection activities.

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.

5.4 QUALIFICATION OF EXISTING DATA

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

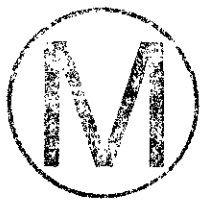
Existing data shall be qualified using one or a combination of the following methods:

A. Determination that the data were collected under a QA program that is equivalent in effect to ASME NQA-1-1989 edition; ASME NQA-2a-1990 addenda, Part 2.7, to ASME NQA-2-1989 edition; and NQA-3-1989.

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

C. Confirmatory testing that is performed and documented.

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



SECTION 6 — SOFTWARE REQUIREMENTS

6.1 GENERAL

This section of the QAPD establishes Software Quality Assurance (SQA) requirements for CAO participants that develop, procure, maintain, or use computer software that is important to compliance application, and waste characterization.

6.2 APPLICABILITY

A. The requirements in this section apply to computer software that manipulates or produces data that are, in turn, used to process, gather or generate information and whose output is relied upon to make design, analytical, operational, or compliance-related decisions with respect to the performance of the waste confinement, waste characterization, waste transportation, or waste acceptance processes. 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 are software that are 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 do not generate data that are used in the formulation of conclusions. However, specific applications supporting Section 6.2A above, written for use within these types of software (e.g. detailed formulas or macros), that can be verified by hand calculations or other means shall meet the following requirements of this section:

1. A listing of the version of the software used, and

2. Documentation that the specific application provides correct results for the specified range of input parameters.

6.2.1 Inventory of Software

An inventory of all software shall be maintained to identify the software name, version, classification, exemption status, operating environment, and the person and organization responsible for the software.

6.2.2 Classification of Software

Software that is not exempt from the provisions of the QAPD shall be classified. The criteria for classification shall be documented in the inventory and shall address the purpose of the software relative to its use in engineering, scientific, testing, data collection, design, analysis, operations activities, and its importance to safety or significance in managing information or augmenting mission-essential decisions.

6.2.3 Software Quality Assurance

Plan(s) for ensuring software quality shall be prepared for each new software project at the start of the software life cycle. For procured software the software quality plan shall be prepared prior to when the software enters the purchaser's organization. Plan(s) may be prepared individually for each software project, or 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. The plan shall identify:

A. the software products to which it applies;

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

C. the organizations responsible for performing the work and achieving software quality and their tasks and responsibilities;

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

E. the standards, conventions, techniques, or methodologies that guide the software development, as well as the methods used to assure implementation of requirements; and

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

6.3 SOFTWARE PROCUREMENT

A. The procurement of software and related services shall be performed in accordance with Section 2.3 of this QAPD. This section of the QAPD identifies responsibilities of the sponsoring organization for procured software upon receipt of the software.

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

C. 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.

6.4 SOFTWARE DEVELOPED UNDER OTHER QA PROGRAMS

Software that has not been developed or approved in accordance with this QAPD shall be evaluated using the criteria of this section. The software shall be uniquely identified and controlled prior to the evaluation, accepted by the sponsoring organization, and placed under configuration control prior to use. This evaluation shall serve as the basis to:

A. Determine the adequacy of existing verification and validation activities, and software documentation to support operation and maintenance; and

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

1. user application requirements;

2. test plans and test cases required to validate the software acceptability; and

3. user documentation per Section 6.8.6.

6.5 SOFTWARE DEVELOPMENT & LIFE CYCLE

A. The activities associated with the evolution of the software shall use an iterative or sequential approach. The approach shall address the analysis of the problem under study, the transformation of the analysis into the design, the implementation of the design into validated computer software, and the development of sufficient documentation to demonstrate that the specified requirements have been successfully implemented in the computer software.

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

1. definition of requirements;
2. design;
3. implementation;
4. testing;
5. installation and checkout;
6. operations and maintenance; and
7. retirement.

C. Following the development of the Software Quality Plan, no strict sequence of performing activities is required (i.e., activities, may be performed serially or recursively) provided that all the specified requirements for each software development phase are met and the intent of the requirements are not subverted.

6.5.1 Requirements

Software requirements shall be specified, documented, and reviewed. These requirements shall pertain to functionality, performance, design constraints, data attributes, and external interfaces (e.g. hardware limitations) as outlined in Section 6.8.2. Each requirement shall be specified in sufficient detail to permit the accomplishment of design and validation activities. Software requirements shall be traceable throughout the software development cycle, and a verification and validation plan shall be prepared at the conclusion of documenting and approving software requirements.

6.5.2 Design

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

6.5.3 Implementation

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

6.5.4 Testing

A. 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, test cases, and test results, is the primary method of software validation.

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

6.5.4.1 Verification Tests

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

A. hand calculations;

B. calculations using comparable proven problems;

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

D. comparison with other validated software of similar purpose; and

E. manual inspections or qualitative checks, not involving numerical manipulation such as visual inspection of table reformatting (or plotting).

6.5.4.2 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 other acceptable means. The results of this evaluation shall be of sufficient scope and depth to prove the capabilities and limitations delineated in the software documentation.

6.5.5 Installation and Checkout

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

1. execution of tests for installation and integration;

2. documented acceptance of the software for operational use; and

3. the placement of the software under configuration control prior to use.

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

6.5.6 Operations and Maintenance

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

B. 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.

6.5.6.1 Post Installation Maintenance

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

6.5.6.2 In-Use Tests

A. 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.

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

6.5.7 Retirement

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

6.6 SOFTWARE VERIFICATION AND VALIDATION

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

1. adequately and correctly performs all intended functions; and

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

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

1. did not specify a singular design approach;

2. did not rule out certain design considerations;

3. did not establish the design inputs used; and

4. is the only individual in the organization competent to perform the verification or validation.

6.6.1 Verification

Verification is a formal checking activity performed throughout the evolution of the software life cycle. Verification activities shall be clearly documented, including the identification of those performing and approving the verification. The reviewed documents shall be updated and placed under configuration control. Documentation of review comments and their disposition shall be retained. Comments and their disposition not incorporated shall be retained in accordance with established procedures.

6.6.1.1 Requirements

Verification review(s) of software requirements shall ensure that the requirements are complete, verifiable through testing, consistent, and technically feasible as described in Section 6.5.1.

6.6.1.2 Design

Verification review(s) of software design shall evaluate the technical adequacy of the design approach and ensure that all the requirements have been addressed and that the design is complete, verifiable, (through testing, using approved test plans and test cases) consistent, technically feasible, and traceable to the software requirements as described in Section 6.5.2.

6.6.1.3 Implementation

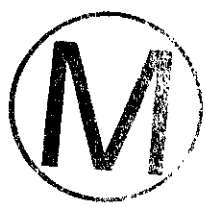
Verification of the implementation of software design shall consist of the examination of software logic and source code to assure adherence to standards and conventions and to assure that the design has been implemented as described in Section 6.5.3.

6.6.1.4 Testing

Verification of software testing shall consist of reviews to assure that the specified test criteria, the expected results, and the software development documentation have been met as described in Section 6.5.4.

6.6.1.5 Installation and Checkout

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



6.6.2 Validation

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

B. 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 assess the adequacy and correctness of the documentation in meeting the requirements of this section of the QAPD, and the overall acceptability of the software for the intended use.

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

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

1. detect errors introduced during the modification of the systems or system components;

2. verify that the modifications have not caused unintended adverse effects; and

3. to verify that the modified system(s) or system component(s) still meets specified requirements.

6.7 SOFTWARE CONFIGURATION MANAGEMENT

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

6.7.1 Configuration Identification

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

1. uniquely identifies each configuration item;

2. identifies changes to configuration items by revision or version identifier; and

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

6.7.2 Configuration Change Control

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

B. 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 assure that the change is appropriately reflected in the software documentation, and to assure that document traceability is maintained. The degree of software validation shall be commensurate with the nature and scope of the change.

6.7.3 Configuration Status Accounting

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

6.8 DOCUMENTATION

Software shall be described in one or more documents that detail user instructions, technical basis, functional requirements, and maintenance-related information sufficient

to allow independent verification allow maintenance, and provide traceability of the documentation to the software. The documentation shall be reviewed by an individual competent in the technical subject area for which the use of the software is intended. The review shall verify that the documentation adequately and accurately reflects the software that comprise the system and it 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.

6.8.1 Procurement Documentation

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

6.8.2 Requirements Documentation

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

1. Functionality - the functions the software is to perform;

2. Performance - the time-related issues of software operation such as speed, recovery time, response time, etc.;

3. Constraints - those imposed on implementation activities - any elements that will restrict design options;

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

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

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

6.8.3 Design and Implementation Documentation

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

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

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

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

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

6.8.4 Verification and Validation Documentation

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

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

6.8.5 Change Documentation

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

6.8.6 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:

A. the software name and version identifier;

B. statement(s) of functional requirements and system limitations, including hardware;

C. 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;

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

E. a description of any required training necessary to use the software; and

F. user information for obtaining user and maintenance support.

6.8.7 Error Documentation

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

6.9 PROBLEM REPORTING AND CORRECTIVE ACTION

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

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

1. problems are identified, evaluated, documented, and, if required, corrected;

2. problems are assessed for their impact on past and present uses of the software;

3. changes to software are in accordance with the software configuration management requirements of this section of the QAPD; and

4. results are provided to the affected users along with any revised software documentation.

C. Problems that 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 to represent a condition adverse to quality shall be controlled in accordance with Section 1.3 of this QAPD.

6.10 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 of the QAPD.

APPENDIX A – GLOSSARY

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

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

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

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

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

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

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

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

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

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

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

Characteristic: A property of a work product that is distinct, describable, and measurable.

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

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

Condition Adverse to Quality: An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances, and technical inadequacies. A significant condition adverse to quality is one which, if uncorrected, could have a serious effect on safety, operability, waste confinement, compliance demonstration, or the reliability of the QA program.

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

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

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

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

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

Data Comparability: A measure of the confidence with which one data set can be compared to another.

Data Completeness: A measure of the amount of valid data obtained, compared to the amount that was planned.

Data Precision: A measure of the mutual agreement between comparable data gathered or developed under similar conditions, usually expressed in terms of a standard deviation.

Data Representativeness: The degree to which data accurately and precisely represent a characteristic of a population, a parameter, variations at a sampling point or environmental conditions.

Design Basis: Information that identifies the specific functions to be performed by items and the specific values or ranges of values chosen for controlling parameters as reference bounds for design.

Design Input: Those criteria, parameters, bases, or other design requirements upon which the detailed final design is based.

Design Output: Drawings, specifications, and other documents resulting from the translation of design input requirements.

Design Process: The technical process that commences with the identification of design input and ends with the issuance of design output documents.

Design Review: A documented evaluation of design output during the design process to determine the design adequacy and the conformance to specified acceptance criteria.

Disposal System: The disposal system is any combination of engineered and natural barriers that isolate transuranic waste after disposal. For the purposes of the WIPP, this will include the combination of the repository/shaft system and the controlled area.

Document: Written or pictorial information that describes, specifies, reports, or certifies activities, requirements, procedures, or results.

Document Control: The process that provides for document adequacy review, approval for release by authorized personnel, and distribution for use at the prescribed work locations.

Error: A discrepancy between a computed, observed, or measured value or condition and the true, specified, or theoretically correct value or condition.

Fissionable Materials: A nuclide capable of sustaining a neutron-induced fission chain reaction (e.g., uranium-233, uranium-235, plutonium-238, plutonium-239, plutonium-241, neptunium-237, americium-241, and curium-244).

Graded Approach: The process by which the level of analysis, documentation, verification, and other controls necessary to comply with QA program requirements are developed commensurate with specified factors.

Hazard: A source of danger (e.g., material, energy source, or operation) with the potential to cause illness, injury, or death to personnel or damage to a facility or to the environment (without regard to the likelihood or credibility of accident scenarios or consequence mitigation).

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

Item: An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, or support system.

Lead Auditor: An individual trained, qualified, and certified to organize and direct an audit, report audit findings, and evaluate corrective actions.

Lifetime Records: Records required to be maintained for the useful life of the items to which they pertain while the items are installed in the plant or facility (life of the item), or for the lifetime of the equipment, facilities, or programs to which the records apply.

Line Management: Those management positions that are directly responsible for task products and services. Includes CAO supervisors and team leaders; and contractor management within the context of the definition.

Line Organization: The organization directly responsible for task products and services. Includes CAO offices and teams; and contractor organizations within the context of the definition.

Management Assessment: Assessment performed by management that focuses on how well the integrated quality assurance program is working and 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 or qualitative measurements.

Monitoring and Data Collection Equipment (M&DC): A subcategory of M&TE that is used in the collection of measurement data for the establishment of test conditions and general information and the collection of general measurement data not utilized to verify the conformance of an item or equipment to specified criteria.

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

Nonpermanent Records: Records having value for a specific, limited time and authorized by the National Archives and Records Administration to be destroyed after that time.

Nonreactor Nuclear Facility: Those activities or operations that involve radioactive or fissionable materials in such form and quantity that a nuclear hazard potential exists to the employees or the general public. Incidental use and the generation of radioactive materials in a facility operation (e.g., check and calibration sources, radioactive isotopes used in research and experimental and analytical laboratory activities, electron microscopes, and x-ray machines) would not ordinarily require the facility to be included in this definition. The transportation of radioactive materials , accelerators and reactors, and their operations are not included.

Participant: A DOE contractor organization that furnishes items or services in support of CAO sponsored programs, including those TRU waste generator and storage sites participating in the National TRU Waste Program.

Peer: A person having technical expertise in the subject matter to be reviewed to a degree at least equivalent to that needed for the original work.

Peer Review: A documented, critical review performed by peers who are independent of the work being reviewed. A peer review is an in-depth critique of assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of conclusions drawn in the original work. Peer reviews confirm the adequacy of work.

Permanent QA Record: A QA record which is maintained for the life of the Republic.

Permanent Records: Records that have been determined by the National Archives and Records Administration to have historical or other value warranting permanent preservation in the National Archives.

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 quality assurance requirements for the procurement of items or services.

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

Qualification Testing: A test that is intended to provide a desired level of confidence that an item meets specified criteria.

Quality: The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

Quality Assurance: All those planned and systematic actions necessary to provide adequate confidence that an item will perform satisfactorily in service.

Quality Assurance Program: The program established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

Quality Assurance Record: A completed record, or any authenticated portion of a record that provides objective evidence of the quality of items or activities.

Quality System: See *Quality Assurance Program.*

Receipt Inspection: A method of accepting an item or related service from a supplier by examination or testing of the item or related service to verify conformance to specified requirements.

Records: Books, papers, maps, photographs, machine readable materials or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations or other activities of the government or because of the informational value of the data in them.

Records Holding Facility: A CAO records storage facility meeting regulatory requirements for the storage of inactive records pending their final disposition.

Repair: The process of restoring an item to a condition such that the capability of an item to function reliably and safely is unimpaired even though that item still does not conform to the original requirement.

Rework: The process by which an item is restored to original specifications by completion or correction.

Sample: A subset of a population (e. g. wastes, environmental media, materials, cores) whose properties are used to gain information about the population.

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

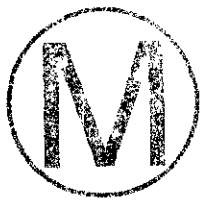
Scientific Investigation: Any research, experiment, test, study, or activity that is performed for the purpose of investigating a natural system or the man-made aspects of a geologic repository, including the investigations that support design of the facilities and the waste package.

Scientific Notebook: A record of the methods and results of scientific investigations that is used when the work involves a high degree of professional judgment or trial and error methods or both.

Service: The performance of work, such as design, construction, fabrication, inspection, nondestructive examination, testing, environmental qualification, equipment qualification, repair, installation, or the like.

Significant Condition Adverse to Quality: See Condition Adverse to Quality.

Site Characterization: The program of exploration and research both in the laboratory and the field that is undertaken to establish the natural conditions and the ranges of parameters of a particular site.



Software: Computer programs, procedures, rules, and associated documentation and data pertaining to the operation of a computer system.

Software Baseline: An item or product that has been formally reviewed and agreed upon, and that serves as the basis for further development and that can be changed only through formal change control procedures.

Software Validation: The process of test and evaluation of the completed software to ensure compliance with software requirements.

Software Verification: The process of determining whether or not the product of a given phase of the software development cycle fulfills the requirements imposed by the previous phase.

Software Verification and Validation (V&V): The process of determining whether the requirements for a system or component are complete and correct, the products of each development phase fulfill the requirements or conditions imposed by the previous phase, and the final system or component complies with specified requirements.

Source Verification: A purchaser method of accepting an item or related service from a supplier by monitoring, auditing, surveillance, witnessing, or observing activities performed by the supplier.

Special Process: A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

Supplier: Any individual or organization who furnishes items or services in accordance with a contract. An all-inclusive term used in place of any of the following: vendor, seller, source, participant, contractor, or subcontractor.

Surveillance: The act of monitoring or observing to verify whether an item, activity, system, or process conforms to specified requirements. Surveillance of a technical work activity is normally done in real time (i.e., the surveillance is accomplished as the work is being performed).

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

Technical Review: A documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of the work but collectively have equivalent technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.

Technical Specialist: An individual assigned to an assessment team when the scope, complexity, or special nature of the work to be examined warrants assessment of the technical adequacy of the work or the effectiveness of the technical process.

Testing: An element of verification for the determination of the capability of an item to meet specified requirements, or processes that facilitate the collection of data in conducting scientific investigations, by subjecting the item or environment to a set of physical, chemical, environmental, or operating conditions.

Traceability: The ability to trace the history, application, and location of an item, data, or sample using recorded documentation. As related to metrology, traceability means, the ability to relate individual measurement results through an unbroken chain of calibrations to one or more of the following:

(a) U.S. national standards maintained by National Institute of Standards and Technology or the U.S. Naval Observatory;

(b) fundamental or natural physical constants with values assigned or accepted by the National Institute of Standards and Technology, or

(c) national standards of other countries which are correlated with NIST.

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.

Verification: See Assessment.

WIPP: The Waste Isolation Pilot Plant, as authorized pursuant to Section 213 of the Department of Energy National Security and Military Applications of Nuclear Energy Authorization Act of 1980 (Pub.L. 96-164; 93 Stat. 1259, 1265) to provide a research and development facility for demonstrating the safe disposal of radioactive wastes produced by national defense activities.

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

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

APPENDIX B – REFERENCES

National Fire Protection Association (NFPA) Standard 232-1986, *Standards for the Protection of Records*

SNT-TC-1A, June 1980, *The American Society of Nondestructive Testing (ASNT) Recommended Practice*

10 CFR Part 71, Subpart H, *Packaging and Transportation of Radioactive Material, Quality Assurance*

10 CFR Part 830, *Nuclear Safety Management*

40 CFR Part 194, *Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance with 40 CFR Part 191 Disposal Regulations*

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

ASME NQA-2a-1990 addenda, Part 2.7, *Quality Assurance Requirements of Computer Software for Nuclear Facility Applications*

ASME NQA-3-1989, *Quality Assurance Program Requirements for the Collection of Scientific and Technical information for Site Characterization of High-Level Nuclear Waste Repositories*

NUREG-1297 (1988), *Peer Review for High-Level Nuclear Waste Repositories*

DOE Order 5700.6C, *Quality Assurance*

DOE Order 5700.6C, *Attachment 1, Quality Assurance Program Implementation Guide*

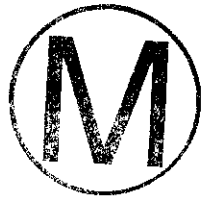
DOE-EM QARD, *U.S. Department of Energy - Office of Environmental and Waste Management (EM) Quality Assurance Requirements and Description Document*

ANSI/NCSL Z540-1, *General Requirements for Calibration Laboratories and Measuring and Test Equipment*

DOE, Division of Nuclear Safety, G-830.120, *Implementation Guide for use with 10 CFR Part 830.120 Quality Assurance*

NUREG/BR-0167 (1993), *Software Quality Assurance Program and Guidelines*

WIPP/CAO-95-1127, *CAO Operational Plan*



Effective Date: May 3, 1996

WP 13-1
Revision 16

WID Quality Assurance Program Description

12/1/95

Manager, Quality and Regulatory Assurance — Date

12/1/95

WID General Manager — Date

4/24/96

Carlsbad Area Office, Quality Assurance Manager — Date

WASTE ISOLATION PILOT PLANT

WIPP

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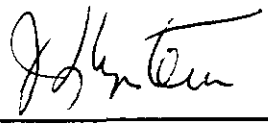
WID Quality Assurance Program Policy Statement

Westinghouse Waste Isolation Division (WID), a division of the Government and Environmental Service Company of Westinghouse Electric Corporation, is the United States Department of Energy's (DOE) Performance-based Management and Operating Contractor (MOC) at the Waste Isolation Pilot Plant (WIPP). The WID 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 WID 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 elements. As a management tool, the graded approach determines the degree of application of controls commensurate with importance and relative risk to worker safety, environmental impact, and protection of the public, among other factors.

The WID's policy is for all WID managers to participate in establishing, implementing, and assessing the WID Quality Assurance Program. Senior management's task is to provide planning and resources to accomplish the WID's objectives. The WID line organization is responsible to achieve the desired level of quality, and to review, evaluate, and improve work processes. Each individual is responsible for the quality of his or her own work.

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



12/6/95

J. L. Epstein
General Manager
Waste Isolation Division
Westinghouse Electric Corp.

Date

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Table of Contents

Table of Contents

Table of Contents

LIST OF ACRONYMS AND ABBREVIATIONS

ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
ASQC	American Society for Quality Control
CAO	Carlsbad Area Office
CFR	Code of Federal Regulations
DOE	Department of Energy
DOE-AL	Department of Energy-Albuquerque
DOE-HQ	Department of Energy-Headquarters
EEG	Environmental Evaluation Group
EPA	U.S. Environmental Protection Agency
M&DC	Monitoring and Data Collection Equipment
M&TE	Measuring and Test Equipment
NAS	National Academy of Sciences
NIST	National Institute of Standards and Technology
NQA	Nuclear Quality Assurance
NUREG	Nuclear Regulatory Commission Report Designation
QAPD	Quality Assurance Program Description
QARD	Quality Assurance Requirements and Description
TRU	Transuranic
TSR	Technical Safety Requirement
WID	Waste Isolation Division
WIPP	Waste Isolation Pilot Plant

INTRODUCTION

The Waste Isolation Division (WID) Quality Assurance Program Description (QAPD) is the quality management document which identifies federal and industry quality requirements applicable to the WID quality assurance program. This document establishes the minimum quality requirements for WID personnel and guidance for the development and implementation of quality assurance programs by all WID departments. Requirements and guidance are based on criteria contained in 10 CFR Part 830.120 and supplemented with additional guidance from such sources as 10 CFR 71, DOE Order 5700.6C, NQA-1 (1989 edition), EPA QAMS-005/80, and the Department of Energy (DOE) Carlsbad Area Office (CAO) QAPD. Table I-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 mixed transuranic wastes in the WIPP repository
- Commitment documents that are imposed by DOE
- Guidance documents that provide additional information useful in developing quality assurance programs

This list of source documents is NOT all inclusive.

The 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., Section 5, Scientific Investigation QA Requirements [applicable portions of ASME NQA-3]; and Section 6, Software Quality Assurance [ASME NQA-2, Part 2.7]).

The WID is required to develop a quality assurance program description that describes how we intend to manage our work activities to achieve planned objectives and goals. Quality assurance implementing procedures shall be utilized 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 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 all WID departments 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 the WID's quality objectives.

Table I-1 SOURCE DOCUMENTS

REGULATORY REQUIREMENTS DOCUMENTS	TITLE
10 CFR 830.120	Nuclear Safety Management, Quality Assurance Requirements
10 CFR 71	Subpart H, Quality Assurance (Packaging and Transportation)
40 CFR 194	Criteria to the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance with 40 CFR Part 191 Disposal Regulations
40 CFR 261	Identification and Listing of Hazardous Waste
40 CFR 268.6	Land Disposal Restrictions
COMMITMENT DOCUMENTS	**TITLE**
DOE Order 5700.6C	Quality Assurance
CAO QAPD CA0-95-1012	Quality Assurance Program Description
ANSI/NCSL Z540-1-1994	Standards and Calibration Program
ASME NQA-1 (1989, with 1992 Addenda) and Supplementary Requirements	Quality Assurance Program Requirements for Nuclear Facilities
GUIDANCE DOCUMENTS	**TITLE**
EPA QAMS-005/80	EPA Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans
ASME NQA-2- Part 2.7 (1989)	Quality Assurance Requirements of Computer Software for Nuclear Facility Applications
ASME NQA-3 (1989), Parts 2.2, 2.3, 2.4,3.1, 3.2, 3.3, 17.3, 18 and 3SW-1	Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories
NUREG-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

NOTE: List is NOT all inclusive.

SECTION 1 MANAGEMENT QUALITY ASSURANCE REQUIREMENTS

1.1 Quality Assurance Program and Organization

This section defines the requirements for the development of the WID quality assurance program. It also describes the WID organizational structure, interfaces, functional responsibilities, and levels of authority for performing, managing, and assessing the adequacy of work. The WID is required to develop, implement, maintain, and document its quality assurance programs in accordance with 10 CFR Part 830.120, 10 CFR Part 71, Subpart H, and DOE Order 5700.6C, and includes the guidance provided in the DOE CAO QAPD.

The quality assurance (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 quality assurance program is to ensure that the WID develops and implements an effective management system. The management system shall ensure that items, processes, and services meet or exceed the requirements of the WIPP Quality Assurance Program.

Effective implementation of the WID QA program is dependent on the efforts of all levels of the WID organization. The organization is structured such that the individual performing the work is responsible for achieving and maintaining quality; line management is responsible for verifying the quality; and an independent assessor is responsible for independently assessing the quality of the work. The Quality and Regulatory Assurance (Q&RA) Department is responsible for defining, integrating and ensuring effective implementation of quality assurance activities. The WID has applied a graded approach to the application of quality assurance requirements to the WID Quality-affecting activities. The items identified on Attachment 2 are the quality-affecting activities the WID performs and will be subjected to the Quality Assurance requirements specified in the QAPD. 6/13/96

An organization chart is shown in Figure 1-1.

1.1.1 WID General Manager

The General Manager has overall responsibility for the development and implementation of the quality assurance program. The General Manager is responsible for approving this document. Authority for execution of the QA function, which includes ensuring effective implementation, is delegated to the Q&RA manager. The Q&RA manager is authorized to establish QA policy and ensure its effective implementation.

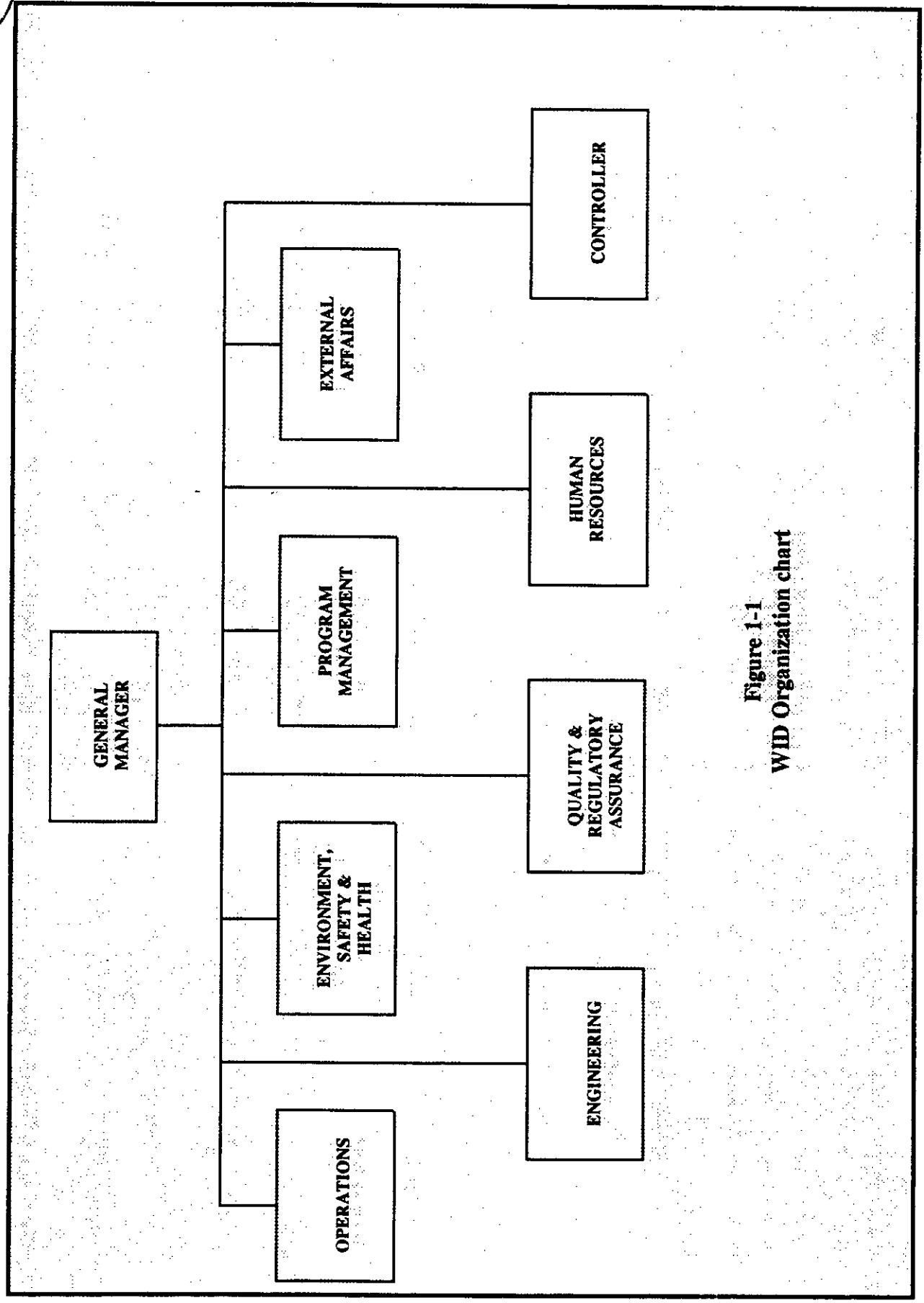

Figure 1-1
WID Organization chart

1.1.2 Department Managers

The department managers represent the following functional organizations:

- Operations Department
- Controllers Department
- Engineering Department
- Program Management Department
- External Affairs Department
- Human Resources Department
- Quality and Regulatory Assurance Department
- Environment, Safety, and Health Department

Department managers are responsible for implementing this QAPD. Department managers are required to establish and implement policies and procedures that control the quality of work in accordance with this QAPD. Department managers report directly to the General Manager.

Department managers have various quality related responsibilities which include:

- 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 federal regulations, DOE Orders and requirements applicable to WIPP, and applicable state and local laws

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

- Having the responsibility to halt 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 implement applicable portions of the QA program

1.1.3 Line Management

Quality achievement is the responsibility of those performing the work. The line management is responsible for the achievement and verification of quality in their area. Management shall identify the responsibilities and authorities of those organizational line management positions responsible for achieving and verifying 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, the process of receiving, handling, moving, monitoring, and disposal of TRU Waste, and for ensuring that suitable proficiency is achieved and maintained.

1.1.4 Employee

Each WID employee is responsible for the quality of his or her work. The requirements of this QAPD are binding on all personnel through the use of implementing documents.

1.1.5 Quality and Regulatory Assurance Manager

The Q&RA Manager has the overall responsibility to independently assess the effective implementation of the QA program. Additional responsibilities of the Q&RA manager include the following:

- Establish and assess effective implementation of the overall WID QA policy
- Prepare and maintain the WID QAPD
- Interface with the staff on quality assurance matters
- Schedule and conduct QA independent oversight
- Maintain liaison with QA organizations from other WIPP participants and other affected organizations
- Review WID procedures:
  - that implement the QAPD
  - for quality affecting activities

6/18/96

- Evaluate the adequacy of supplier QA Programs (as required)
- Participate in the disposition of conditions adverse to quality
- Participate in the disposition of supplier-related nonconformances
- Assist other departments and sections with quality planning, problem identification, and the development of problem solutions
- Tracking and analysis of quality problem areas
- Ensure Q&RA department involvement in decisions or commitments which directly affect nuclear safety or waste isolation at the WIPP

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The Q&RA 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, yet maintain a sensitivity to cost effectiveness and schedule considerations.
- Have the organizational freedom to effectively communicate with other senior management positions.
- Have no other assigned responsibilities unrelated to the quality assurance program that would prevent full attention to quality assurance matters.

Management shall grant the Q&RA Department 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 quality assurance program requirements will be brought to the attention of the responsible 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

The WID Quality Assurance Program Description and all changes to the QAPD shall be reviewed and approved by the CAO.

1.1.8.1 Quality Assurance Project Plans

- Each quality assurance project plan (QAPjP), when required by other regulatory drivers, shall include the information required by the governing regulatory driver.
- The Q&RA manager shall review and approve all WID 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 Q&RA manager and the cognizant department 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 level of rigor to be applied to each. The grading process provides the flexibility to design controls that best suit the facility or activity. The graded approach process should determine the appropriate level of effort necessary in the performance of work important to safety and waste isolation at the WIPP facility.

The level of quality assurance controls shall be commensurate with, but not limited to, the Design Class of the item, service, or process and its end use with regard to the following criteria:

- Probability of failure
    - Complexity or uniqueness of design or fabrication of the item or design or implementation of the activity
    - Special process controls
    - Reproducibility of the result
    - History of the item or service quality
    - Necessity for special processes controls
- Consequence of failure
    - Function or end use of the item
    - Importance and end use of the data generated
    - Ability to demonstrate functional compliance
    - Impact on the environment, safety, and health
    - Impact on cost and schedule

1.1.9 Interfaces

The CAO is the approval authority for all external QA interface agreements and subsequent revisions between WIPP participants (Generator Sites, Sandia National Laboratories, DOE, and WID).

1.1.9.1 External Interfaces

Interface agreements between the WID and DOE-HQ, EPA, DOE-AL, DOE-CAO, and others are considered external interfaces.

The extent of the QA program with respect to external interface organizations is bounded by WID involvement in the activities and is limited in applicability to WID personnel.

1.1.9.2 Internal Interfaces

WID internal interfaces associated with work activities affecting safety and waste isolation include all WID departments.

1.1.10 Planning Work

Planning shall be performed and documented to ensure that work is accomplished under suitably controlled conditions. Appropriate, nationally recognized standards 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 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

1.2 Personnel Qualification and Training

Personnel performing work will be qualified and capable of performing their assigned tasks. 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 the WID 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 WID hiring authority. The evaluation will be documented for positions that are directly related to environmental compliance and waste isolation. These positions include but are not limited to managers, designers, scientists, independent assessment personnel, operators, maintenance personnel, technicians, auditors, and inspectors. The department managers shall:

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

- Ensure that qualifications, including minimum education and experience are met or, when education and experience can NOT be specifically verified, provide a statement of justification for the personnel assignment.

1.2.2 Training

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 to determine instruction and program effectiveness, and shall be upgraded whenever needed improvements or other enhancements are identified. Department 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 technology, methods, job responsibilities and quality assurance 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

1.3 Quality Improvement

This section defines management's responsibility for building a culture in which continuous improvement is a fundamental and integral part of the organization's mission. The WID shall establish and implement processes to detect and prevent adverse quality conditions and to promote quality improvement. Items and processes that do NOT meet established requirements shall be identified, controlled, and corrected.

Correction shall include identifying the causes of adverse conditions and actions to prevent recurrence. Item reliability, process implementation, and other relevant information shall be reviewed and the data analyzed to identify items and processes needing improvement.

All personnel are responsible for identifying nonconforming items, activities, and processes and are encouraged by management to suggest improvements. Management at all levels should encourage the identification of nonconforming items and processes by:

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

Nonconformances shall be documented, evaluated, and dispositioned.

1.3.1 Conditions Adverse To Quality

1.3.1.1 Identifying Nonconformances

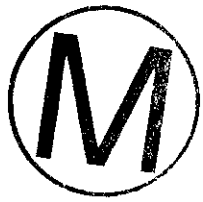
Nonconforming activities, items, and processes shall be identified and documented. Nonconformance documentation shall clearly identify and describe the characteristics that do NOT conform to documented specifications and requirements.

1.3.1.2 Identifying and Classifying Conditions Adverse to Quality

Conditions adverse to quality is an all-inclusive term used in reference to deficiencies, failures and malfunctions caused by defective items, and nonconformances to documented specifications and requirements. Conditions adverse to quality shall be documented. Malfunctions and failures due to normal wear and deterioration, as determined by the maintenance engineer, are NOT considered to be conditions adverse to quality.

A. Conditions adverse to quality shall be classified in regard to their significance, and corrective actions shall be taken accordingly.

B. Two categories of classification shall be established:



- Conditions adverse to quality
- Significant conditions adverse to quality

Significant conditions adverse to quality are conditions that, if not corrected, could have a serious effect on safety, operability, or compliance.

1.3.2 Control and Disposition/Correction of Conditions Adverse to Quality

1.3.2.1 Nonconformances

Nonconforming items shall be identified and segregated to prevent their use prior to the proper disposition of the nonconformance.

The nonconforming item shall be identified by marking, tagging, or other methods that do NOT adversely affect their end use. The identification shall be legible and easily recognizable.

The nonconforming item shall be moved to a segregated storage area. The segregated storage area shall be clearly identified and designated. The segregation area shall be access controlled. If segregation is impractical or impossible due to physical conditions, then other administrative controls and precautions shall be employed to preclude inadvertent use.

Nonconforming items and processes shall be controlled to prevent any adverse impact on test, installation, or use. Nonconformance documentation shall include recommended dispositions of nonconforming items. The nonconformance shall be reviewed by the organization that originally reviewed and approved the item or by a designated organization that is qualified and knowledgeable. Organizations affected by the nonconformance shall be notified.

Reworked, repaired, and replaced items shall be inspected and tested in accordance with original requirements or specified alternatives. Personnel responsible for analyzing and dispositioning nonconformances will have an adequate technical understanding of the item function and have access to pertinent background information relative to the nonconformance. The disposition of nonconforming items will have the concurrence of the Q&RA Department.

A. The disposition of "use as is," "reject," "repair," or "rework" for nonconforming items shall be identified and documented. Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending the evaluation and approval of the disposition.

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

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

D. The responsibility and authority for reviewing, evaluating, approving the disposition, and closing nonconformances shall be specified.

1.3.2.2 Conditions Adverse to Quality and Significant Conditions Adverse to Quality

A. Conditions adverse to quality shall be investigated and documented by responsible management. Corrective action shall be determined, documented, and completed in a timely manner.

B. Line management shall investigate the cause and the extent of the condition and document the results; determine, document, and complete remedial action and take prompt corrective action to prevent recurrence. These may not all apply for conditions adverse to quality. In the case of significant conditions adverse to quality the root cause shall be determined. The Q&RA Department shall evaluate and concur, as appropriate, with the proposed corrective action, including remedial action, the root/probable cause, and actions taken to prevent recurrence to ensure that quality assurance program requirements are satisfied.

C. Significant conditions adverse to quality will be reported to and evaluated by the Q&RA Department and the appropriate management responsible for the condition. Work may be suspended pending the evaluation of the condition.

- Department managers may suspend work after a significant condition adverse to quality has been identified pending evaluation. All WID employees have the responsibility and authority to request that any activity that appears to be unsafe be suspended until the unsafe condition is resolved.

- Department management will take appropriate action to evaluate and correct (in part or total) the unsafe condition(s) that caused the suspension of work.

- The ES&H and the Q&RA department managers may issue a formal "Stop Work Order" pending the resolution of the related significant condition adverse to quality.

D. Significant conditions adverse to quality will be documented and reported to line management, department managers, and to the Q&RA Department.

1.3.3 Corrective Actions

Corrective actions are required to address the following points, as appropriate:

- Determination of the root or probable cause(s) of the condition
- Action to resolve the initial condition
- Action to preclude recurrence of the condition
- Assessment of impact of the condition on affected items or activities
- Schedule completion dates for the required actions, and organizations/individuals responsible for follow-up

A follow-up system shall be established to verify:

- proper implementation of scheduled corrective actions in a timely manner
- the effectiveness of the corrective actions to prevent the condition from reoccurring

1.3.4 Improvement Analysis

Quality performance data shall be identified, collected, and analyzed to identify opportunities to improve items, activities, and processes. This analysis should consider information from external sources and not be limited to one type of work or to one organization.

The analysis shall be performed in a manner and at a frequency that provides for prompt identification of trends adverse to quality. Conditions adverse to quality identified through independent oversight shall be evaluated to identify adverse quality trends and report the results of the evaluation to the organization responsible for corrective action. Trending information will be provided to the CAO.

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, and approval of controlled documents. This is to ensure that documents are accurate, adequate, and approved.

Documents that specify quality requirements or prescribe work activities important to nuclear safety or waste isolation, 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, 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. Changes to the document shall be reviewed by those organizations or technical disciplines affected by the change.

G. The Q&RA Department shall review documents that translate QAPD requirements into implementing documents. Changes to such documents that do NOT change the quality requirements do NOT require review by the Q&RA Department. (See Attachment 1, WID QUALITY REQUIREMENTS IMPLEMENTING DOCUMENT MATRIX)

H. Review comments shall be resolved by the originating organization unless otherwise delegated by management, and the resolutions documented and signed by the reviewer(s) to signify concurrence. Dispositioned review comments shall be maintained as part of the document package.

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.

1.4.2 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 defining the distribution of controlled documents.

1.4.2.1 Major and Minor Changes to Documents

1.4.2.1.1 Major Changes

Changes to documents, other than those defined as minor changes in paragraph 1.4.2.1.2 below, are considered as major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization shall have access to pertinent background data or information upon which to base their approval.

1.4.2.1.2 Minor changes

Minor changes to documents, such as inconsequential editorial corrections, shall NOT require that the revised documents receive the same review and approval as the original documents. To avoid possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated. All minor changes will be reviewed by all affected groups at the minimum and approved in writing by the responsible organization.

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 record" is a completed document that furnishes evidence of the quality of items and/or activities affecting nuclear safety or waste isolation.

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 quality records system. Preparers of such reports shall ensure the entry of such documents into a quality records system.

1.5.1 Generating Quality Records

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

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

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

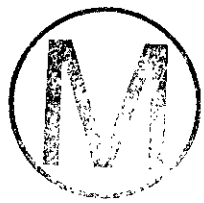
- Records that relate to site characterization samples and data
- Records that relate to data used in the Performance Assessment of the WIPP Facility
- Records that relate to the mixed transuranic waste form characterization and acceptance of the mixed transuranic waste form
- Records that document regulatory 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 post-closure 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 will create quality records that are legible, accurate, and complete.

D. Individuals handling quality records will 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).

E. Records shall become quality records when stamped, initialed or signed, and dated as complete. 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.

F. Quality records may be originals or copies; however, original documents are preferred.



1.5.2 Classifying Quality Records

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

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

- 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 an item
- Records that would be of significant value in determining the cause of an accident or malfunction of an item
- Records that provide required baseline data for in-service inspections.

B. Records that provide objective evidence that the quality assurance program has been properly implemented but do NOT meet the above criteria shall be classified as "nonpermanent" quality records

1.5.3 Indexing Quality Records

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

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

B. Quality records shall be indexed to ensure retrievability.

1.5.4 Receiving Quality Records

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

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

C. Quality records shall be submitted to storage after the receipt process has been completed.

1.5.5 Storing, Preserving, and Dispositioning Quality Records

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

- Description of the storage facility
- Description of the indexing system to be used
- Method for verifying that the quality records received are in agreement with the transmittal document
- Method for ensuring a receipt acknowledgment identifying index number/record location is returned to the sender
- Description of controls governing quality record access, retrieval, and removal
- Method for filing supplemental information
- Method for disposition of superseded quality records

B. The records storage arrangements shall provide adequate protection of records (such as radiographs, photographs, negatives, microfilm, and magnetic media) to preclude damage from moisture, temperature, rodent infestation, excessive light, electromagnetic fields, or stacking as appropriate for the type of record being stored.

C. 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.

D. Retention times of quality records depend upon their classification as "permanent" or "nonpermanent." The WID manager or designee will retain and preserve permanent quality records. Nonpermanent quality records shall be retained for

three years or as otherwise specified. Nonpermanent quality records shall NOT be dispositioned until the following conditions are met:

1. Regulatory requirements are satisfied.

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

3. Purchaser's requirements are satisfied.

E. Design and construction of a single record storage facility shall meet the criteria of the 1989 edition of ASME NQA-1 Supplemental Requirement 17S-1 Section 4.4.1 or Section 4.4.2.

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

G. Records submitted to a temporary storage area shall be stored in a container certified by a person competent in fire protection, or in a UL one-hour fire-rated container, prior to dual storage or submittal to the WIPP Central Records Facility.

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

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

1.5.6 Retrieval of Quality Records

A. The records management system shall provide for retrieval of quality records based upon record type (Nonpermanent and Lifetime).

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

1.5.7 Correcting Information in Quality 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 quality records shall be approved by the originating organization.

C. Quality 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 and administrative controls. 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 each person who performs work is responsible for the quality of his or her work, and he or she will have the goal of doing work correctly the first time. 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 verification 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 assess 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, quality, and implementing procedures commensurate with the complexity and risk of the work.

2.1.2 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
- 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)
- Identify the records generated

D. 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. 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, and prevent the use of incorrect or defective items.

2.1.3.1 Waste Isolation Items

The following additional controls shall be established:

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 control). When used, physical markings shall:

- Be applied using materials and methods that provide a 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 meeting the special requirements.

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 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 WID activities are examples of special processes:

- Nondestructive examination/testing (NDE/NDT) in accordance with SNT-TC-1A (June 1980 Edition)
- 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 section entitled "Implementing Procedure," 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

2.1.5 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.

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

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

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

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

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

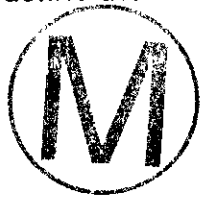
If storage of items is required, then methods shall be established for the control of item identification records that are commensurate with the planned duration and conditions of storage. These methods shall provide for, as applicable:

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

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 by individuals or groups other than those who performed the work. Verification work shall be completed before approval and implementation of the design.

This section provides requirements to ensure that designs (from conceptual through final) are 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.

2.2.2 Design Process

The design process shall be controlled by Design Class, as defined in the Safety Analysis Report (SAR), 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 section entitled "Software Quality Assurance Requirements."

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.

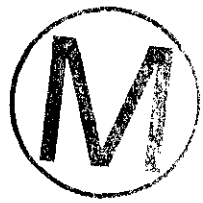
C. The status of the design information or issued design documents shall be identified in transmittals. Where necessary, incomplete designs that require further evaluation, review, or approval shall be identified.

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 design class, as defined in the Safety Analysis Report (SAR), the complexity, and 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.

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.

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

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 shall 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. 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 section entitled "Conditions Adverse to Quality and Significant Conditions Adverse to Quality."

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

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

2.3 Procurement

The WID shall ensure that procured items and services meet established technical and quality assurance requirements and that they perform as specified. Prospective suppliers shall be evaluated and selected on the basis of documented criteria.

2.3.1 Procurement Planning Requirements

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

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. Procurement planning shall be performed for the following items and activities:

- Design Class, as defined in the Safety Analysis Report (SAR), I, II, IIIA, and selected IIIB (Essential Equipment) facilities, systems structures, components and spare parts.

NOTE: There are currently NO Design Class I items or activities at WIPP.

- Design, design validation or computer-code activities (procured or delegated) required for support of Design Class II, IIIA, and selected IIIB (Essential Equipment) facility systems, structures, components, or spare parts.

- Services and operations associated with receipt, installation, maintenance, repair, modification, testing, handling, storage, or special processes of items in Design Class II, IIIA, and selected IIIB (Essential Equipment) facility systems, structures, components, and spare parts.

- Spare parts or equipment purchased to support a Design Class II, IIIA, or selected IIIB (Essential Equipment) system that is NOT the same Design Class as the system or component they are to be installed in shall require a written justification.

- Type "B" (TRUPACT II) packaging and Type "B" packaging spare parts that are classified as Quality Category "A" and spare parts for Type "B" (TRUPACT II) packaging that are classified as Quality Category "B" by the NRC-approved SARP drawings.

- Equipment, components, or activities associated with other radioactive or hazardous waste transport, packaging including the receipt, storage, handling, emplacement, disposal, and retrieval operations.

- Analytical or laboratory services required for acquisition of data necessary to support or substantiate site validation, activities or monitoring for off-site radiological dose rates.

- Operations associated with the acquisition of environmental samples where such samples are used for design validation or monitoring for off-site radiological doses.

    1. Geological programs and associated instrumentation, software, and equipment to collect data relative to assessment and confirmation of the underground geological conditions, and

    2. Programs to collect data relative to long term performance assessments, hydrology programs, etc.

- Technical Safety Requirement (TSR) activities, including operations, records management, documentation, procurement, and testing.

- Environmental data operations (EDOs), including sample collection, analysis, and data handling, reporting, and record management. EDOs include, but are not limited to, RCRA sampling and analyses, monitoring and data collection for the no-migration demonstration (VOC monitoring), mixed waste characterization, groundwater monitoring, and NESHAPS monitoring.

- Mining operations that require adherence to specified dimensions, configurations, or orientations that are critical to operational or experimental activities.

- Procurement of calibration services.

- Monitoring of variables to determine on-site radiological dose.

NOTE: As a minimum ALL service contracts that are related to the activities identified above will require Q&RA review.

Procurement Planning for the above identified items and services shall include 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 quality assurance 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 quality 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. Procurement documents shall identify the organizational responsibilities for determining the source selection based on the design class, as defined in the Safety Analysis Report (SAR), and the risks associated with the end use of the product/service.

B. Measures for selecting procurement sources shall include the following elements:

- Evaluation of the supplier's history for providing an identical or similar product that performs satisfactorily in actual use
- Evaluation of supplier's current quality records supported by any documented qualitative and quantitative information
- Evaluation of the supplier's technical and quality assurance capability based on an evaluation of the supplier's facilities, personnel, and quality program implementation

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

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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 and shall include, as required, the following:

- Technical considerations
- Quality assurance program
- Supplier personnel
- Supplier production capability
- Supplier past performance
- Alternatives
- Exceptions

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

C. When required, supplier quality assurance programs shall be evaluated by the Q&RA Department 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 quality assurance 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, 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 the purchaser shall use to monitor and evaluate the performance of the supplier shall be specified.

C. Quality assurance program requirements shall be specified, including:

- The supplier shall have a documented quality assurance program or program requirements that implements the requirements of this QAPD or equivalent requirements from other recognized sources as required. The level of detail of the quality assurance program plan and subsequent implementing procedures shall depend on the scope, nature, or complexity of the item or service being procured.

- The supplier shall incorporate the appropriate technical and quality assurance program requirements into any subtier supplier-issued procurement document.

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

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

E. If the purchaser requires the supplier to maintain documentation that will become quality records, the retention classification and disposition requirements shall be identified.

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

G. Spare and replacement parts or assemblies and the appropriate technical and quality assurance data required for ordering 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 shall meet the prescribed requirements. 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 organizations and quality assurance organization, as required based on the design class, as defined in the Safety Analysis Report (SAR), and the risks associated with the end use of the product/service.

D. Procurement documents shall be approved by appropriate management.

2.3.3 Supplier Performance Evaluation Requirements

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

- Establishing an understanding between the purchaser and 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 purchaser and supplier
- Establishing the extent of assessment activities and inspection

2.3.3.1 Source Verification

The purchaser may accept an item or service by monitoring, auditing, surveillance, witnessing, or observing activities performed by the supplier or through receipt inspection. 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 the purchaser's quality assurance organization. In addition:

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

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

C. Source verification shall be performed by cognizant Q&RA personnel.

2.3.3.2 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 section entitled "Inspection Planning."

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

C. Receiving inspections shall be performed by qualified personnel.

2.3.3.3 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 the purchaser and supplier.

2.3.3.4 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.

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 quality assurance function and whose function and position are described in the purchaser's or supplier's quality assurance 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 quality assurance 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 Q&RA Department at intervals commensurate with the supplier's past quality performance.

2.3.3.5 Control of Supplier Nonconformances

The purchaser and 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 the purchaser that includes supplier-recommended disposition (for example, "use as is" or "repair") and provide technical justification for such disposition.

   Reports of nonconformances to procurement document requirements or documents approved by the purchaser shall be submitted to the Q&RA Department 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 the purchaser 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.

B. The purchaser shall disposition the supplier's recommendation.

C. The purchaser shall verify implementation of the disposition.

2.3.4 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 selection shall be in accordance with source selection requirements.

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, the purchasing organization 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 the purchaser, to ensure conformance with the manufacturer's published requirements.
- Documentation, as applicable to the item, was received and is acceptable.

2.4 Inspection and Testing

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 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. 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 Selecting Inspection Personnel

The individual who performs an inspection to verify conformance of an item to specified acceptance criteria shall be qualified. Personnel who are directly supervised by a qualified inspector are NOT required to be qualified inspectors.

The job performance of inspection personnel will be reevaluated for capability at periodic intervals NOT to exceed three years. The person who has NOT performed inspection or testing activities in his or her qualified area for a period of one year will be reevaluated for required capability.

The inspection shall be performed by personnel other than those who performed or directly supervised the work being performed.

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 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 measuring and test equipment to be used to perform the inspection to ensure that the equipment being utilized for inspection or testing is calibrated and is of the proper type, range, accuracy, and tolerance to accomplish the intended function

2.4.2.2 Inspection Hold Points

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

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 points during successive stages of the process.

D. 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.

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 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

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.

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 ASTM 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.
- Test prerequisites that address calibrated instrumentation, 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.

2.4.3.2 Test Documentation

Test documentation shall identify:

- 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 measuring and test equipment 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.

2.4.4 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 measuring and test equipment, measuring and data collection equipment, equipment (either hand-held or installed) used for data indication, and other equipment used for data indication and/or collection.

2.4.4.1 Calibration

Monitoring, measuring, testing, and data collection equipment shall be calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration shall be documented.

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 department 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% of the acceptable tolerance (e.g., manufacturer's specification) for each characteristic of the measuring and test equipment 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 calibrations performed shall be traceable, through auditable documentation, to NIST standards, international standards or intrinsic standards.

F. When applicable, all calibrations shall be performed in controlled environmental conditions.

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

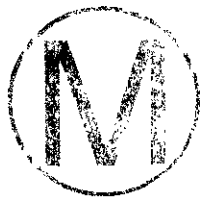
2.4.4.1.1 Control of Out-of-Calibration Equipment

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 measuring and test equipment 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.
    - Take corrective actions, 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.

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

Equipment monitoring, measuring, testing, and data collection equipment calibration documentation shall include the following information:

- Description and unambiguous identification of the item calibrated
- Physical condition of the calibrated item
- Date(s) of performance of calibration, where appropriate
- Identification of the calibration procedure used, or unambiguous description of any non-standard method used
- "As found" and "as left" data
- A signature and title, or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue
- Special limitations of use

SECTION 3 QUALITY ASSURANCE ASSESSMENT REQUIREMENTS

Planned and periodic assessments shall be conducted to measure management effectiveness, item quality and process effectiveness, and to promote improvement. The organization performing independent assessments shall have sufficient authority and freedom from the line organization to carry out its responsibilities. 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 organization to determine the effectiveness of leadership that enables the organization to meet customer requirements and expectations. 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. Strengths and weaknesses affecting the achievement of organizational objectives should be identified so that meaningful action can be taken to improve quality.

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 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 focus on improving items 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 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. Independent assessments 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; and
- Verify timely implementation of corrective action(s).

Organizations responsible for the performance of quality affecting activities related to collection of scientific and technical information for site characterization shall conduct surveillances of those activities.

3.2.1 Planning Independent Assessments

The organization performing the independent assessment shall develop and document an assessment plan for each independent assessment. This plan shall include the scope, purpose, assessment personnel, work to be assessed, organizations to be notified, and schedule. Assessments shall include technical evaluations of the applicable procedures, instructions, activities and items. The scope shall include the work to be assessed and corrective actions taken since the previous assessment.

3.2.2 Scheduling Independent Assessments

A. The Q&RA department will maintain a schedule of independent assessments. The assessment schedule shall be developed annually and revised as necessary.

B. 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 quality assurance compliance shall be performed on a risk based prioritization.

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

3.2.3 Independent Assessment Team Selection

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.

A. An assessment team leader shall be appointed to indoctrinate and supervise the team, organize and direct the assessment and coordinate the preparation and issuance of the assessment report.

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. Technical specialists may 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 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 communication skills, training, audit participation, and passing the lead auditor examination.

3.2.4.1.1 Communication Skills

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

3.2.4.1.2 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, and regulatory guides

- General structure of quality assurance plans and implementation procedures, as a whole, and as related to specific elements of this QAPD

- Auditing or assessment techniques of examining, questioning, evaluating, reporting, methods of identifying, following up, and closing corrective action items

- Audit planning in functional areas of quality assurance

- On-the-job training to include applicable elements of the assessment program

3.2.4.1.3 Audit Participation

The prospective lead auditor shall have participated in a minimum of five (5) quality assurance audits within a period of time NOT to exceed three (3) years prior to the date of the qualification. At least one of the five (5) quality assurance audits shall be a nuclear audit and shall have been performed within the last year .

3.2.4.1.4 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 Q&RA department. The Q&RA department 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.

3.2.4.1.5 Lead Auditor Certification

The lead auditors will be certified by the Q&RA department 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

3.2.4.1.6 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, quality assurance implementation procedures, instructions, and other documents related to quality assurance program auditing or assessment
- Participation in training programs

B. Q&RA 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.

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 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 quality assurance 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 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. All independent assessments shall be performed in accordance with written procedures or checklists.

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 management having responsibility for the area assessed. Conditions requiring prompt corrective action shall be reported immediately to management of the assessed organization.

D. Conditions adverse to quality shall be documented and corrected according to the requirements of the sections entitled "Conditions Adverse to Quality and Significant Conditions Adverse to Quality."

3.2.6 Reporting Independent Assessment Results

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

- 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)
- Statement of the quality assurance program effectiveness
- 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

3.2.7 Assessment Response and Follow Up

A. Management of the assessed organization will investigate conditions adverse to quality in accordance with section 1.3.3 of this QAPD.

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.

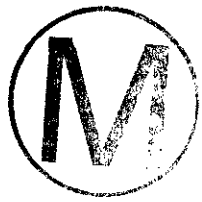
SECTION 4 SAMPLE CONTROL AND QUALITY ASSURANCE REQUIREMENTS

This section defines the requirements for the control of material samples, including identification, handling and shipping, and archiving. This section also defines requirements for the disposition of 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 that the sample was collected.



4.1 Sample Control

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

A. Chain of custody

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

4.2 Sample Identification

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

B. 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.

C. At a minimum samples should be clearly and legibly identified with a label, tag, or other marker to denote the sample number, the sample date, the name of the sampler, and the sample location.

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

E. If samples are to be split or subdivided then sample identification and documentation should 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.

F. Sample traceability shall ensure that the sample can be traced at all times from its collection through final disposition.

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

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. These measures include:

A. 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.

B. 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 special environments or the need for special controls if necessary.

C. If required for particular samples, special protective equipment (such as containers) and special protective environments (such as inert gas, and moisture and temperature limits) shall be specified and provided.

4.4 Disposition of Nonconforming Samples

A. Samples taken 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 section entitled "Identifying and Classifying Conditions Adverse to Quality."

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

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4.5 Environmental Data Operation (EDO) Samples

Guidance for EDO sample planning must address the following items as a minimum. Additional information is contained in EPA QAMS-005/80 Interim Guidance 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 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.

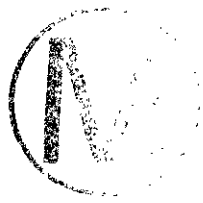
F. Data reproducibility, i.e., a measure of the variability among measurements of the same sample at different laboratories.

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 generated by one source against a body of data generated by another source.

SECTION 5 SCIENTIFIC INVESTIGATION QUALITY ASSURANCE REQUIREMENTS

This section of the WID QAPD is included as a contingency should the WID become responsible for Scientific Investigations. When and if the WID 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 WID responsibilities by the appropriate departments.



SECTION 6 SOFTWARE REQUIREMENTS

6.1 General

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

The application of specific requirements shall be prescribed in written plan(s), policies, procedures and instructions, when and to the extent specified by the organization invoking this section.

6.2 General Requirements

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

6.2.1 Applicability

The requirements set forth in this section of the QAPD apply to computer software which manipulates or produces data that are, in turn, used to process, gather or generate information and whose output is of sufficient importance that it can be relied upon to make design, analytical, operational or compliance-related decisions affecting the performance of the WIPP.

Exempt from the requirements of this section of the QAPD are software that are:

A. Used to prepare intermediate results (e.g., computational aids) where assurance of engineering or scientific conclusions is derived solely from formal verification without reliance on the validity or use of the software outputs; or

B. Considered to be "systems software", providing that the performance history is acceptable and the basis of acceptability is documented.

6.2.2 Inventory of Software

Each organization invoking this section of the QAPD shall inventory software for which it maintains responsibility. This inventory shall identify the software's name, version, and operating environment, and the person and organization responsible for the software.

6.2.3 Classification of Software

Each organization invoking this section of the QAPD shall classify software identified in the inventory. This classification shall be documented in the inventory and address the purpose of the software relative to its use in engineering, design, analysis, and operations activities and its importance to safety or significance in managing information or augmenting mission-essential decisions.

6.2.4 Gradation of Quality Measures

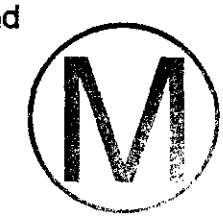
The extent of control measures applied to software will vary as a function of the degree of confidence needed regarding the quality of the software. Quality assurance measures shall be applied to software commensurate with the following:

- Importance of Results to Compliance Demonstration
- Complexity and Uniqueness
- Quality History/Degree of Standardization

Each organization shall make a determination concerning the gradation of quality measures; this determination shall be documented and shall include an evaluation of the software in order to identify the activities to be performed and the documentation that is needed to meet the requirements of this section of the QAPD.

6.2.5 Plans (or Procedures)

The WID 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 Q&RA manager for review and concurrence.



6.2.5.1 Software Quality Assurance

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 prior to when it enters the purchaser's organization. Plan(s) may be prepared to address each software project as a generic document to be applied to categories of software. Plans shall:

A. 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;

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

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

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

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

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

6.2.5.2 Verification and Validation

Plans for software verification and validation shall be prepared at the conclusion of documenting and approving software requirements.

6.3 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 of the QAPD shall become the responsibility of the sponsoring organization upon receipt of the software.

Once the software has been installed and prior to its use, the department 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, documentary results of pre-delivery vendor testing, etc.).

6.4 Software Developed Under Other QA Programs

Software that has NOT been developed in accordance with this section of the QAPD and has NOT been previously approved in accordance with a quality assurance program that is consistent with this QAPD shall be evaluated using this section of the QAPD as the review criteria. This software shall be uniquely identified and controlled prior to evaluation, accepted by the department and placed under configuration control prior to use. This evaluation 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.

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

6.5 Software Development & Maintenance

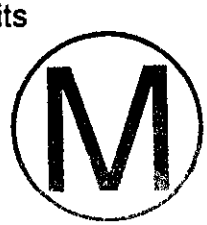
The activities associated with the software's evolution shall use a systematic approach. This approach shall address the analysis of the problem under study, the transformation of the analysis into design, the implementation of the design into validated computer software, and the development of sufficient 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.

6.5.1 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 Section 6.8.2, "Requirements Documentation". 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.



6.5.2 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).

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

6.5.3 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.

6.5.4 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.

6.5.4.1 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; and

D. Comparison to other validated software of similar purpose.

6.5.4.2 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 other acceptable means. The results of this evaluation shall be of sufficient scope and depth to prove the capabilities and limitations delineated in the software documentation.

6.5.5 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, initializing 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.

6.5.6 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. Sustaining activities shall be performed 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.

6.5.6.1 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 controlled to ensure that all changes are documented and are approved by authorized personnel.

6.5.6.2 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 those software where computer failure or electronic drift can affect required outcomes.

6.5.7 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.

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

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. This means it may be performed by the designer's supervisor, provided the supervisor did NOT specify a singular design approach or rule out certain design considerations and did NOT establish the design inputs used, provided the supervisor is the only individual in the organization competent to perform the verification or validation.

6.6.1 Verification

Verification is primarily a checking activity performed throughout the evolution of the software. It shall be clearly documented, including the identification of those who performed the verification, and approved. Documentation of review comments and their disposition shall be retained until they are incorporated into the updated software. Comments and their disposition NOT incorporated shall be retained in accordance with established procedures.

6.6.1.1 Requirements

Verification of software requirements shall ensure that the requirements are complete, verifiable through testing, consistent, and technically feasible.

6.6.1.2 Design

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, technically feasible, and traceable to the software's requirements.

6.6.1.3 Implementation

Verification of the implementation of software design shall consist of the examination of software logic to ensure adherence to standards and conventions and that the design has been implemented according to specification.

6.6.1.4 Testing

Verification of software testing shall consist of reviews to ensure that specified test criteria and expected results have been met.

6.6.1.5 Installation and Checkout

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

6.6.2 Validation

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

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 by a competent individual; this review shall assess the adequacy and correctness of the documentation in meeting the requirements of this section of the QAPD, and overall acceptability of the software for its intended use.

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.

6.7 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.

6.7.1 Configuration Identification

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.

6.7.2 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 document traceability is maintained. The degree of software validation shall be commensurate with the nature and scope of the change.

6.7.3 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.

6.8 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 comprise 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.

6.8.1 Procurement Documentation

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

6.8.2 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, etc.;

C. Constraints - those 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, etc.; and

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

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

6.8.3 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, 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.

6.8.4 Verification and Validation Documentation

Software verification and validation documentation shall consist of associated plans that describe the activities, including the results of reviews and tests, and criteria for accomplishing the verification of the software throughout the systematic activities of the software's evolution. 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 to the validated capabilities of the software.

6.8.5 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.

6.8.6 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;
- 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;
- User instructions that describe the user's interaction with the software, user messages initiated as a result of improper input and how the user can respond, the identification and description of input and output specifications and formats, input parameters; and
- A description of any required training necessary to use the software.

6.8.7 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).

6.9 Problem Reporting and Corrective Action

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 affect on previous use(s) 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 of the QAPD; and

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 Nonconformances section of this QAPD.

6.10 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 of the QAPD.

APPENDIX A – GLOSSARY

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, as used in 10 CFR 830.120 and DOE 5700.6C, 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 quality assurance program assessment performed to determine by investigation of objective evidence the adequacy of and compliance with established quality assurance 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 of a work product that is distinct, describable, and measurable.

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

APPENDIX A – GLOSSARY

Condition Adverse to Quality: An all inclusive term used in reference to deficiencies, failures and malfunctions caused by defective items, and nonconformances to documented specifications. Malfunctions and failures due to normal wear and deterioration are NOT considered to be conditions adverse to quality.

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 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.

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.

APPENDIX A – GLOSSARY

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.

Lead Auditor: An individual trained, qualified, and certified to organize and direct an audit, report audit findings, and evaluate corrective actions.

Line Management: Those management positions below senior management that are directly responsible for work task products and services.

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.

Metrology: The science of precision measurement.

Monitoring and Data Collection Equipment (M&DC): A subcategory of M&TE that is used in the collection of measurement data for the establishment of test conditions and general information and the collection of general measurement data NOT utilized to verify the conformance of an item or equipment to specified criteria.

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

Peer: A person having technical expertise in the subject matter to be reviewed to a degree at least equivalent to that needed for the original work.

Peer Review: A documented, critical review performed by peers who are independent of the work being reviewed. A peer review is an in-depth critique of assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed an of 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.

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 quality assurance requirements for the procurement of items or services.

APPENDIX A – GLOSSARY

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.

Qualification Testing: A test that is intended to provide a desired level of confidence that an item meets specified criteria.

Quality: The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

Quality Assurance: All those 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 the WID 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 Record: A completed document (regardless of medium) that furnishes evidence of the quality of items and/or activities affecting safety or waste isolation.

Quality System: See *Quality Assurance Program.*

Record: A completed document or other media that provide objective evidence of an item, service, or process.

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.

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

APPENDIX A – GLOSSARY

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

Service: The performance of work, such as design, construction, fabrication, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like.

Significant Condition Adverse to Quality: A significant condition adverse to quality is one that, if uncorrected, could lead to a serious affect on safety/operability or the ability to isolate waste.

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.

Software Verification and Validation (V&V): 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.

Stop 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.

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, 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.

APPENDIX A – GLOSSARY

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.

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

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.*

APPENDIX A – GLOSSARY

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.

Work: The process of performing a defined task or activity, for example, 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

Quality Assurance Requirements Cross Reference Matrix

	10 CFR 830.120 CRITERIA	DOE Order 5700.6C CRITERIA	ASME NQA-1 (1989) REQUIREMENTS	EPA QAMS 005/80 ELEMENTS
MANAGEMENT	1.1 PROGRAM	1. PROGRAM	1. ORGANIZATION 2. QUALITY ASSURANCE PROGRAM	
	1.2 PERSONNEL QUALIFICATION & TRAINING	2. PERSONNEL QUALIFICATION & TRAINING	2. QUALITY ASSURANCE PROGRAM	3. PROJECT DESCRIPTION 16. QUALITY ASSURANCE REPORTS to MANAGEMENT
	1.3 QUALITY IMPROVEMENT	3. QUALITY IMPROVEMENT	15. CONTROL OF NONCONFORMING ITEMS 16. CORRECTIVE ACTIONS	15. CORRECTIVE ACTION
	1.4 DOCUMENTS & RECORDS	4. DOCUMENTS & RECORDS	6. DOCUMENT CONTROL 17. QUALITY RECORDS	1. TITLE PAGE 2. TABLE of CONTENTS
PERFORMANCE	2.1 WORK PROCESS	5. WORK PROCESS	5. INSTRUCTIONS, PROCEDURES, DRAWINGS 8. IDENTIFICATION & CONTROL of ITEMS 9. CONTROL of PROCESSES 12. CONTROL of MEASURING & TEST EQUIPMENT 13. HANDLING, STORAGE, & SHIPPING	6. SAMPLING PROCEDURES 7. SAMPLE CUSTODY 8. CALIBRATION 9. ANALYTICAL PROCEDURES 13. PREVENTIVE MAINTENANCE
	2.2 DESIGN	6. DESIGN	3. DESIGN CONTROL	5. DATA QUALITY OBJECTIVES 6. SAMPLING PROCEDURES 10. DATA REDUCTION 11. INTERNAL QUALITY CONTROL 14. ROUTINE PROCEDURES to ASSESS DATA QUALITY
	2.3 PROCUREMENT	7. PROCUREMENT	4. PROCUREMENT DOCUMENT CONTROL 7. CONTROL of PURCHASED ITEMS & SERVICES	N/A
	2.4 INSPECTION & ACCEPTANCE TESTING	8. INSPECTION & ACCEPTANCE TESTING	10. INSPECTION 11. TEST CONTROL 12. CONTROL of MEASURING & TEST EQUIPMENT 14. INSPECTION, TEST, & OPERATING STATUS	8. CALIBRATION 13. PREVENTIVE MAINTENANCE
ASSESSMENTS	3.1 MANAGEMENT ASSESSMENT	9. MANAGEMENT ASSESSMENT	2. QUALITY ASSURANCE PROGRAM	3. PROJECT DESCRIPTION 14. ROUTINE PROCEDURES to ASSESS DATA QUALITY 16. QUALITY ASSURANCE REPORTS to MANAGEMENT
	3.2 INDEPENDENT ASSESSMENT	10. INDEPENDENT ASSESSMENT	18. AUDITS	12. AUDITS 14. ROUTINE PROCEDURES to ASSESS DATA QUALITY

Attachment 1 - WID QUALITY REQUIREMENT IMPLEMENTING DOCUMENTS

WID QUALITY REQUIREMENTS IMPLEMENTING DOCUMENT MATRIX			
WP 13-1 REQUIREMENTS		Document Number	IMPLEMENTING DOCUMENT Title
SECTION 1	Program 1.1	WP 02-EM1010	Quality Assurance/Quality Control, and Sampling Tracking
		WP 03-1	WIPP Startup and Acceptance Program
		WP 07-1	WIPP Geotechnical Engineering Quality Assurance Program
		WP 09	Engineering Conduct of Operations and Procedures Manual
		WP 09-9	Configuration Management Plan
		WP 12-13	Quality Assurance Plan, Analytical Laboratory
		WP 13-1	WID Quality Assurance Program Description
		WP 13-QA3501	Graded Approach
	Personnel Qualification and Training 1.2	QAI 2-2	Indoctrination and Training of Q&RA Personnel
		QAI 2-5	Qualification and Certification of Inspection Personnel
		QAI 9-1	Training, Qualification, and Certification of Personnel in Nondestructive Examination
		WP 03-1	WIPP Startup and Acceptance Program
		WP 03-006	Qualification and Certification of Startup Testing Personnel
		WP 12-919	WIPP Master Drill/Exercise Procedure
		WP 14-TR3001	WIPP Training Model
		WP 14-TR3002	Analysis of Training
		WP 14-TR3003	Design of Training
		WP 14-TR3004	Training Program Development
		WP 14-TR3101	Training Impact System
		WP 14-TR3102	Requesting and Scheduling Training
		WP 14-TR3305	Instructor Certification
		WP 14-TR3306	Certification Programs
		WP 14-TR3307	Qualification Programs
		WP 14-TR3308	On-the-Job Training
		WP 14-TR3401	WIPP Training Records
		WP 14-TR3402	Training Policies
		WP 14-TR3501	General Employee Training
		WP 14-TR3502	Training Requirements for Subcontractor Personnel
		TP 011	Access to Training Records Information
		TP 027	Personnel Qualification and Certification Program
		TP 033	Certification and Qualification Card Development

Attachment 1 - WID QUALITY REQUIREMENT IMPLEMENTING DOCUMENTS

WID QUALITY REQUIREMENTS IMPLEMENTING DOCUMENT MATRIX			
WP 13-1 REQUIREMENTS		Document Number	IMPLEMENTING DOCUMENT Title
Quality Improvement 1.3		WP 10-WC3100	Predictive Maintenance Program
		WP 12-135	Root Cause Analysis Investigation Procedure
		WP 12-ES3918	Reporting of Occurrences in Accordance with DOE Order 232.1
		WP 13-QA3003	Corrective Actions Program
		WP 15-RA3003	External Oversight Agency Reviews
		QAI 15-1	Quality Assurance Trend Analysis
Documents and Records 1.4		QAI 2-1	Control of Quality Assurance Instructions
		WP 03-001	Preparation, Release, and Cancellation of Startup Test Procedures
		WP 03-005	Startup Testing Documents/Records Control
		WP 04-MD3003	Control of Operator Aids
		WP 09-CN3022	Engineering Document Control and Distribution
		WP 09-9	Configuration Management Plan
		WP 09-10	WIPP Preparation Guide for Plant and System Design Description Documents
		WP 10-3	The Writer's Guide for WIPP Maintenance Procedures
		WP 14-TR3401	WIPP Training Records
		WP 15-PR	Records Management Plan
		WP 15-PR3001	Generation, Storage, and Control of Active WIPP Records
		WP 15-PR3002	Development and Implementation of RIDS
		WP 15-PR3003	Disposal of Nonpermanent Records
		WP 15-PR3005	Records Transfer and Retrieval
		WP 15-PS.1	Management Control Procedures Writer's Guide
		WP 15-PS.2	Technical Procedures Writer's Guide
		WP 15-PS3002	Review, Approval, and Cancellation of WID Procedures
		WP 15-PS3003	Procedure Change Process
		WP 15-PS3004	Guidelines for WID Desktop Instructions
		WP 15-PS3005	Inactivation of WID Controlled Documents
		WP 15-PS3103	Document Distribution
		WP 15-102	Preparation, Revision, and Cancellation of WID Manuals and Plans
		WP 15-105	Administration of Controlled Forms
		WP 15-10	Transport Packaging Fleet Management Plan for the WIPP

Changes to Attachment 1 are minor changes

Attachment 1 - WID QUALITY REQUIREMENT IMPLEMENTING DOCUMENTS

WID QUALITY REQUIREMENTS IMPLEMENTING DOCUMENT MATRIX			
	WP 13-1 REQUIREMENTS	Document Number	IMPLEMENTING DOCUMENT Title
SECTION 2		WP 09-CN3021	Component Numbering
		WP 09-9	Configuration Management Plan
		WP 10-WC3002	Work Control Administration
		WP 10-WC3006	Control and Calibration of Monitoring and Data Collection Equipment
		WP 10-WC3008	Facility Inspection
	Design 2.2	WP 09-CN3007	Engineering and Design Document Preparation and Change Control
		WP 09-009	Location and Control of Underground Drilling Holes
		WP 09-010	Design Development Testing
		WP 09-CN3003	As Built Drawings: Process and Control
		WP 09-CN3018	Design Verification
		WP 09-CN3031	Engineering Calculations
		WP 09-CN3034	Configuration Management Determination
		WP 09-033	Construction Labor Services
		WP 09-035	Site Development Planning and Project Authorization Process
		WP 09-CN3022	Engineering Document Control and Distribution
		WP 09-CN3023	Design Class Determination
		WP 09-CN3024	Configuration Control Board/Engineering Change Proposals
		WP 09-CN3025	Engineering Data Transmittal/Design Input
		WP 09-10	WIPP Preparation Guide for Plant & Systems Design Description Documents
	Procurement 2.3	WP 13-QA3009	Procurement Control Procedure
		WP 13-012	Supplier Evaluation/Qualification
		WP 15-609	Planning, Preparation, and Processing of Purchase Requisitions and Purchase Requisition Change Notices
		WP 15-041	Approval/Variation Request Processing
	Inspection and Acceptance Testing 2.4	WP 03-1	WIPP Startup and Acceptance Program
		WP 03-002	Performance, Approval, and Closeout of Startup Tests
		WP 03-004	Preparation and Use of Startup Acceptance Tests
		WP 09-010	Design Development Testing
		WP 10-WC3008	Facility Inspection
		WP 13-007	Hold Tag Issuance
		WP 13-011	Quality Assurance Surveillance
		WP 13-013	Inspection Points

Attachment 1 - WID QUALITY REQUIREMENT IMPLEMENTING DOCUMENTS

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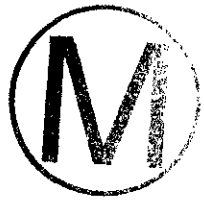
WID QUALITY REQUIREMENTS IMPLEMENTING DOCUMENT MATRIX			
WP 13-1 REQUIREMENTS		Document Number	IMPLEMENTING DOCUMENT Title
SECTION 3	Management Assessment 3.1	WP 15-RA3002	Regulatory Requirements Impact Assessments and Comments
		MP 1.20	Assessments
	Independent Assessment 3.2	WP 13-005	Internal and Supplier Quality Assurance Audits
		WP 13-011	Quality Assurance Surveillance
		WP 15-RA3003	External Oversight Agency Reviews

WID QUALITY REQUIREMENTS IMPLEMENTING DOCUMENT MATRIX			
WP 13-1 REQUIREMENTS		Document Number	IMPLEMENTING DOCUMENT Title
SECTION 4	SAMPLE CONTROL	WP 02-1	WIPP Ground Water Monitoring QA Plan
		WP 02-EM1	Quality Assurance Project Plan for WIPP Site Effluent and Hazardous Material Sampling
		WP 02-EM1001	Sewage System Discharge Monitoring and Compliance
		WP 12-5	WIPP Radiological Controls Manual
		WP 12-6	WIPP VOC Monitoring Plan
		WP 12-7	WIPP VOC Monitoring Quality Assurance Program Plan
		WP 12-13	Quality Assurance Plan Analytical Laboratory Manual
		WP 02-368	Meteorological Station Strip Chart, Data Logging, and Maintenance Procedure
		DOE/WIPP 93-042	Quality Assurance Project Plan for Sampling of Emissions of Radionuclides to the Ambient Air at the WIPP

Attachment 1 - WID QUALITY REQUIREMENT IMPLEMENTING DOCUMENTS

WID QUALITY REQUIREMENTS IMPLEMENTING DOCUMENT MATRIX			
WP 13-1 REQUIREMENTS		Document Number	IMPLEMENTING DOCUMENT Title
SECTION 6	SOFTWARE	WP 16-107	Risk Analysis for Computer Security
		WP 16-117	WIPP Computer Software Quality Assurance
		WP 16-118	Software Development Life Cycle



Attachment 2 - WID QUALITY AFFECTING ACTIVITIES

Quality Affecting Processes or Equipment Categories		
Waste Isolation Processes	Environmental Processes & Permitting	Design Class 2 & 3A Equipment
• Waste Receipt • Waste Handling • Waste In placement • Waste Monitoring	• Radiation / Contamination Control • Radiation / Environmental Monitoring • Environmental Management • Geotechnical Measurements in support of the Performance Assessment	• Operation of Systems and Equipment • Maintenance of Systems / Equipment • [1] U/G Ventilation / Waste Hoist

The requirements of the QAPD will apply to the activities identified above as Waste Isolation Processes, Environmental Processes and Permitting, and Design Class 2 and 3A with the exception of section 4.0. The requirements contained in Section 4.0 Sample Control Quality Assurance Requirements will only apply to the Environmental Processes and Permitting activities unless specifically called out for other activities. 4/18/96

Design class 3B equipment will be subjected to the Quality Assurance requirements that are appropriate for their end use and the risks associated with the end use.

[1] The Waste Hoist and the Underground Ventilation system will be subjected to the same QA requirements as Design Class 2 and 3A equipment.