Department of Energy
Carlsbad Area Office
P. O. Box 3090
Carlsbad, New Mexico 88221

May 26, 1997

Mr. Steve Zappe
New Mexico Environment Department
Hazardous Radioactive Materials Bureau
244 Galasteo St.
Santa Fe, NM 87505

Subject: Draft Revision 2 of the QAPD

Dear Mr. Zappe:

The DOE CAO has drafted its second revision of CAO-97-1012, Quality Assurance Program Document (QAPD).

The revision is for the most part limited to Section 1 - Management Requirements, although some revisions have been made within Section 3 - Assessment Requirements, Section 4 - Sample Control Requirements and Section 6 -Software Requirements. The reason for the revisions contained within Section 1 was to combine CAO and participants organizational requirements. Also, some minor revisions have been made within the Policy Statement, Table I-1, QA Program Source Documents, and the Glossary.

The draft revision is contained within 27 specific pages that are being forwarded to you along with a copy of the Change History for a courtesy review by you. The Change History lists the specific sections that were revised along with the rationale for the revision.

We have scheduled the issuance of this revision for July 1, 1997 and need the results of your review by June 6, 1997 in order to support this schedule.

All changes from Revision 1 are indicated with change bars.

If you have any questions regarding this revision, please call me at (505) 234-7484.

Sincerely,

Samuel Vega FOR R.D. BROWN

R. Dennis Brown
CAO QA Manager

97-1035
UFC 1000.00

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REVIEW PLAN

FOR

CAO QAPD, REVISION 2

REVIEW PLAN CONTENTS

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2 Affected Pages for CAO QAPD, Revision 2

1.0 OBJECTIVE

The objective of this review plan is to establish guidelines for the review of the affected pages of the Carlsbad Area Office (CAO) Quality Assurance Program Document (QAPD), Revision 2.

2.0 PURPOSE OF REVIEW PLAN

The purpose of this review plan is to ensure that the Revision 2 of the QAPD is adequately reviewed in accordance with established review criteria.

3.0 REVIEWERS

Reviewers have been selected based on required expertise and background. Reviewers shall concentrate on those portions of the procedure related to their area of expertise.

A "Document Review/Approval Matrix" (Attachment 1) has been developed to identify each reviewer and the type of review required.

4.0 REVIEW GUIDELINES

The following will be used as the review criteria: DOE Order 5700.6C, 10 CFR Part 830, 10 CFR §§ 71.101- 71.137 (Subpart H), 40 CFR Part 194, ASME NQA-1(1989), ASME NQA-2a-1990 addenda, Part 2.7 to NQA-2 (1989), & ASME NQA-3 (1989).

Please provide specific comments and return to the review chairperson. The resolution of comments will be coordinated by the review chairperson, R. Dennis Brown, Assurance Team Leader.

All mandatory comments (e.g., regulatory requirements, industry standards, or DOE program requirements) must be so noted by placing an asterisk (*) to the left of the comment section location on the Document Review Record (DRR).

Any reviewer questions or concerns with the review plan, forms, or requirements of the review, should be directed to R. Dennis Brown at (505) 234-7484.

5.0 REVIEW SCHEDULE

The review comments must be completed and returned to the review chairperson, on the date indicated on the cover letter. Any deviation from this completion date must be resolved with the review chairperson.

6.0 REVIEW DELIVERABLES

The Document Review Record must be returned to the review chairperson.

If the comments are faxed the originals must follow.

Fax - (505) 887-0292
Mail- U.S. Department of Energy
Carlsbad Area Office
P.O. Box 3090
Carlsbad NM 88221

FedEx- 101 W. Greene Street
Carlsbad NM 88221-3090

7.0 RECORDS

The review chairperson shall ensure that records generated as a result of the review, will be packaged. The package will contain the following:

- Copy of affected pages of the CAO QAPD, Revision 2 (Draft)
- Completed Document Review Record
- Completed Document Review/Approval Matrix.
- Copy of final CAO QAPD, Revision 2

ATTACHMENT 1

DOCUMENT REVIEW RECORD

Instructions for Completing the Document Review Record

To ensure that the review comments can be automatically sorted, please enter your comments onto the Document Review Record form as follows:

1. **Enter the section number in the first column, marked "Sec."**

   For example, enter 4 if your comment is about any item in Section 4, (e.g., section 4.1, 4.11, etc.)

2. **Enter the page number in the second column, marked "Page." For section-style page numbers (e.g., 1-5, 3-13), it is preferable that you enter only the page number (e.g., 5, 13). (Including the hyphenated number may slow the sorting procedure).**

   For example, enter 7 if your comment is about an item either on page 3-7 or, if the page numbers are sequential, on page 7.

3. **Enter the paragraph number in the third column, marked "Para." If a partial paragraph begins the page, consider that paragraph "0."**

   For example, enter 2 if your comment is about an item in the second, full paragraph on the page.

4. **Enter the line number in the fourth column, marked "Line".**

5. **If your comment requires a response and resolution (i.e., a "mandatory" comment), enter an asterisk "*" at the beginning of the Comment column. Include the section number in the Comment column, if desired.**

6. **The reviewer signs the "Document Reviewer" block after completing the initial review prior to transmitting the comments.**

7. **The reviewer signs the "Comment Resolution Approved" block when satisfied that all review comments have been resolved with the originator.**

WASTE ISOLATION PILOT PLANT (WIPP)
CARLSBAD AREA OFFICE

DOCUMENT REVIEW RECORD

DOCUMENT NAME: CAO Quality Assurance Program Description

REVISION: Revision 2, (Draft)

DOCUMENT DATE: May, 1997

REVIEWER:

REVIEW INSTRUCTIONS/ACCEPTANCE CRITERIA:

1. In accordance with the attached review plan for CAO QAPD, Revision 2.
2.
3.

FORWARD RESULTS TO:

COMMENTS DUE BY: June 6, 1997

COMMENTS THAT ARE ANNOTATED WITH AN (*) ARE MANDATORY AND REQUIRE RESPONSE AND RESOLUTIONS

SEC	PAGE	PARA	LINE	COMMENT	AUTHOR RESPONSE	REVIEWER ACCEPT/ REJECT

WASTE ISOLATION PILOT PLANT (WIPP)
CARLSBAD AREA OFFICE

DOCUMENT REVIEW RECORD

DOCUMENT NAME: CAO Quality Assurance Program Description

REVISION: Revision 2, (Draft)

DOCUMENT DATE: May, 1997

REVIEWER:

COMMENTS THAT ARE ANNOTATED WITH AN (*) ARE MANDATORY AND REQUIRE RESPONSE AND RESOLUTIONS

SEC	PAGE	PARA	LINE	COMMENT	AUTHOR RESPONSE	REVIEWER ACCEPT/ REJECT

REVIEWED BY:	COMMENT RESOLUTION APPROVED:
Signature Date	Signature Date

ATTACHMENT 2

CHANGE HISTORY

Revision:	Changes to the QAPD
2	• Policy Statement - Clarified line organizations responsibility to evaluate quality as opposed to verify quality • Table 1-1, Page 1-2 - Deleted requirements documents 40 CFR Part 261. No specific QA Program Requirements are included in Part 261. Part 268 is no longer applicable to the LWAA. • Section 1 - Management Requirements - redefined application to the CAO and Participants • Section 1.1 - Revised to delete "CAO Organizational Structure" • Section 1.1.1 - Revised this section to reflect applicability of organizational structure to CAO and Participant Organizations. Deleted Figure 1-1, CAO Organization Chart • Rev. 1 Section 1.1.1.1 - Deleted responsibilities of the CAO Manager • Rev. 2 Section 1.1.1. - Formerly Section 1.1.1.2, revised to identify responsibilities for both CAO and Program Participants • Section 1.1.1.2 - Formerly Section 1.1.1.3, revised to address all employees • Section 1.1.1.3 - Formerly Section 1.1.1.4, revised to encompass QA management for CAO and Program Participants • Rev. 1 Section 1.1.1.5 - Deleted Participant Organization. Included requirements in Section 1.1.1.1 and 1.1.1.3 • Section 1.1.1.5 - Formerly Section 1.1.1.6 - Deleted Figure 1-2, CAO Primary Interfaces. Deleted subsections 1.1.1.6.B.2 and 1.1.1.6.B.3 which described CAO Interfaces. Subsection 1.1.1.6.B.1 encompasses interface responsibilities for both CAO and Program Participants. • Section 1.1.1.6 - Formerly Section 1.1.1.7 • Section 1.1.1.7 - Formerly Section 1.1.1.8 • Section 1.1.2.1.A - Revised to encompass CAO and Program Participants for the development of procedures implementing QAPD Requirements • Section 1.1.2.1.B - Deleted • Section 1.1.2.1.C - Deleted • Rev. 1 Section 1.1.2.1.D - Deleted • Rev. 1 Section 1.1.2.1.D.1 - Deleted • Rev. 1 Section 1.1.2.1.D.2 - Deleted • Rev. 2 Section 1.1.2.1.D - Revision to require CAO and Program Participants to develop Procedures incorporating requirements of QAPD, QAPP, QAPjP • Figure 1-3, Document Hierarchy - Deleted

CHANGE HISTORY

- Section 1.1.2.4.A.1 - Deleted reference to cost and schedules
- Section 1.1.2.4.B - Revised to include examples of activities to be included in the Grading Process
- Section1.3.2.1.B.2 - Redefined significant conditions adverse to quality
- Section 1.3.2.2.B - Revised to include notification by TRU Waste sites to CAO of significant conditions adverse to quality
- Section 1.4.2.1.H - Revised to clarify requirements for documentation of resolution of review comments
- Section 1.4.2.3.B - Revised to include additional examples of editorial changes
- Section 1.5.2.6.G - Revised to reference Sections E or F
- Section 1.5.2.6.H - Revised to address storage of uncopied records
- Section 3.2.3.C - revised to include audits or independent assessments as substitutes for surveillances
- Section 4.4.A - Revised to clarify samples that are nonconforming
- Section 6.2.A - Revised to align with Section 6.1
- Section 6.2.B - Revised to address SEIS Software
- Appendix A Glossary - Added definition of "Post-closure QA Records".

Table I-1 QA PROGRAM SOURCE DOCUMENTS

REGULATORY REQUIREMENTS DOCUMENTS	TITLE
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 the 40 CFR Part 191 Disposal Regulations
40 CFR Part 268.6	Land Disposal Restrictions
ASME NQA-1-1989 (incorporated by reference in 40 CFR Part 194)	Quality Assurance Program Requirements for Nuclear Facilities
ASME NQA-2a-1990 addenda, Part 2.7 (incorporated by reference in 40 CFR Part 194)	Quality Assurance Requirements of Computer Software for Nuclear Facility Applications
ASME NQA-3-1989 excluding Section 2.1 (b) and © and Section 17.1 (incorporated by reference in 40 CFR Part 194)	Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories
NUREG-1297(1988) (incorporated by reference in 40 CFR Part 194)	Peer Review for High-Level Nuclear Waste Repositories
COMMITMENT DOCUMENTS	**TITLE**
DOE Order 5700.6C	Quality Assurance
DOE-EM QARD	U. S. Department of Energy - Office of Environmental Management (EM) Quality Assurance Requirements and Description Document
ANSI/NCSL Z540-1	General Requirements for Calibration Laboratories and Measuring and Test Equipment
GUIDANCE DOCUMENTS	**TITLE**
DOE Order 5700.6C, Attachment 1	Quality Assurance Program Implementation Guide
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

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 evaluate 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.

Manager, CAO _____ Date _____

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 and its participants.

1.1 ORGANIZATION AND QUALITY ASSURANCE PROGRAM

This section describes the organizational structure, primary interfaces, functional responsibilities, and levels of authority required to 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 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. QA Managers of the CAO and participant organizations are responsible for defining, integrating, and ensuring effective implementation of the CAO QA Program.

1.1.1.1 Management

A. Management has overall responsibility for the successful accomplishment of activities subject to this QAPD. Management provides the necessary planning, organization, direction, control, resources, and support to achieve their defined objectives. Management is responsible for planning, performing, assessing, and improving the work.

B. 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. Management has various QA responsibilities that include:

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

2. ensuring compliance with all applicable regulations, DOE orders and requirements, 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 Management are responsible for the achievement and evaluation of quality in their area. Management shall identify the responsibilities and authorities of those organizational line management positions responsible for achieving and evaluating quality.

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

1.1.1.2 Employees

Each CAO and 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.

1.1.1.3 QA Management

QA Management has the authority and overall responsibility to independently assess the effective implementation of the QA Program.

A. QA Management shall:

1 schedule and conduct~~ing~~ QA assessments;

2 maintain~~ing~~ liaison with participant QA organizations and other affected organizations;

3 prepare, as appropriate, and review internal procedures that implement the provisions of this QAPD;

4 review and approve, supplier and subcontractor QA plans;

5 track, perform trend analysis, and reporting quality problem areas;

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

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

8 be sufficiently independent from cost and schedule considerations;

9 have the organizational freedom to communicate with management;

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

11 develop, establish, interpret QA policy and ensure effective implementation.

12 prepare, review and issue implementing procedures;

13 interface, as appropriate, with the CAO staff, participants, and other stakeholders, on quality assurance matters;

14 assist subordinate organizations with quality planning, documentation, quality measurement, and problem identification and resolution; and

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

B. The QA organization shall have 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.

1.1.1.5 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

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 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.

1.1.1.6 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.

1.1.1.7 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 WIPP. Examples of implementing documents include the TRU Waste QAPP and site specific QAPjPs.

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

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 matrix shall identify specific reference to the applicable portion of the procedure or document. 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".

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, and waste isolation and other mission objectives.

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. Organizations should design test cases to ensure that grading procedures can be effectively implemented. These test cases should ensure that appropriate controls are applied. Examples may include provisions to determine requirements for auditing of suppliers of drums used to contain TRU Waste; auditing of suppliers of standard laboratory glassware; technical review of procedures for Waste Characterization data; and inclusion of quality requirements in procurement documents for analysis equipment. These are only examples of possible test cases. Each organization should develop their own method to determine that the defined grading process is effective. The graded approach process is not intended to reduce or in any way

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, and waste isolation and other mission objectives.

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. Organizations should design test cases to ensure that grading procedures can be effectively implemented. These test cases should ensure that appropriate controls are applied. Examples may include provisions to determine requirements for auditing of suppliers of drums used to contain TRU Waste; auditing of suppliers of standard laboratory glassware; technical review of procedures for Waste Characterization data; and inclusion of quality requirements in procurement documents for analysis equipment. These are only examples of possible test cases. Each organization should develop their own method to determine that the defined grading process is

effective. 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 level of 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:

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 the result of a breakdown of the QA Program and are conditions that if not corrected, could have a serious effect on safety, operability, waste isolation, TRU Waste site certification or compliance.

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. TRU Waste sites shall notify CAO of all significant conditions adverse to quality. 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

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. A reviewers signature for approval or concurrence on a document is considered to be adequate evidence of resolution of review comments. This signature cannot be delegated. Retention of the review comment documentation generated by a signatory of the document is not required.

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;

3. updating organizational titles;

4. changes to documented schedules;

5. revised or reformatted forms providing the original intent of the form has not been altered; or

6. attachments marked "Example", "Sample", or exhibits that are clearly intended to be representative only.

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.

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 E or F above, but shall meet all other records storage requirements prescribed in this QAPD.

H. When temporary storage of uncopied records (such as for processing, review, or use) is required by an organization's procedures, the records shall be stored in a one-hour fire-rated container. The procedures shall specify the maximum allowable time limit for temporary storage. The container shall bear 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.

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

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.

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. Samples that are nonconforming with respect to requirements specified in work controlling documents (such as job packages, travelers, or work requests) shall be identified, documented, evaluated, and segregated in accordance with Section 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 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. 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. Software utilized in conjunction with the Supplemental Environmental Impact Statement (SEIS) is also excluded from the requirements of this section since it does not generate data used in the formulation of conclusions related to Regulatory Compliance. 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.

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, TRU Waste Site Certification, 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.

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.

Post-Closure QA Records: QA records required to be maintained beyond the operating life of the WIPP repository, for periods of several hundreds of years, and in a manner that would permit future generations to maintain them longer, if desired, using present reasonably available technology.

Procedure: A document that specifies or describes how an activity is to be performed. The term "procedure" 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.