405

HQO.880212.0003

Department of Energy
Washington, DC 20585

FEB 11 1988

Mr. B. J. Youngblood
Chief, Operations Branch
Division of High-Level Waste Management
Office of Nuclear Material
Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Reference: Letter, R. Stein, HQ/OGR to B. Youngblood, NRC, dated January 8, 1988.

Dear Mr. Youngblood:

The above noted reference committed HQ/OGR to furnish the NRC with a draft copy of the revised HQ/OGR Quality Assurance Plan (OGR/B-3), no later than February 19, 1988.

We are forwarding, under separate cover, marked to your attention, a draft copy of the revised QA Plan, which includes the following documents:

- Quality Assurance Requirements (QAR) for the HLNWR Program, Revision "E", dated February 5, 1988. The QAR defines the QA Program requirements for all participating organizations.

- Quality Assurance Program Description (QAPD) for the HLNWR Program, Revision "C", dated February 5, 1988. This QAPD has been structured to present the QA Program description for OCRWM. A QAPD is to be be prepared and issued by each program participant.

The above noted documents are for information purposes only. We do not expect NRC to submit comments to HQ/OGR on the draft documents. The draft documents will be revised upon completion of the recently announced OCRWM reorganization, at which time they will be formally submitted to NRC for review and comment.

8802240365 880211
PDR WASTE
WM-1 PDR

If you or your staff have any questions, please contact Karl Sommer at (202) 586-1639.

Sincerely,

Ralph Stein

Ralph Stein, Acting Director
Siting, Licensing and Quality
Assurance Division
Office of Civilian Radioactive
Waste Management

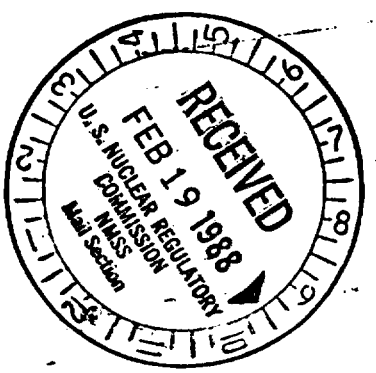
Rec'd 2/19/88

WM Record File 405

WM Project 1
Docket No.
PDR ✓
LPDR

Distribution:
Youngblood Dellgatti
Ridde
Voltura Donnelly
(Return to WM, 623-SS) Duncan
Kennedy Belke

RECEIVED
FEB 19 1988
U.S. NUCLEAR REGULATORY COMMISSION
NMSS
Mail Section



U.S. DEPARTMENT of ENERGY

OFFICE of CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE REQUIREMENTS

for the

HIGH LEVEL NUCLEAR WASTE REPOSITORY PROGRAM

DRAFT

REVISION E, 02/05/88

8804150282

QUALITY ASSURANCE REQUIREMENTS
for the
HIGH LEVEL NUCLEAR WASTE REPOSITORY PROGRAM

INDEX

SECTION		PAGE
Introduction		1
Glossary		ii
I -	Organization	1
	A) QA Responsibilities	1
	B) Stop Work Orders	1
	C) Dispute Resolution	1
II -	Quality Assurance Program	2
	A) Planning	2
	B) Quality Levels	3
	C) Personnel Selection, Indoctrination, Training, and Qualification	5
	D) QA Surveillance	5
	E) QA Program Review	6
	F) QA Program Assessment	6
	G) QA Management Information Reporting and Tracking	7
III -	Design Control	8
	A) Control of Scientific Investigations	8
	B) Design Data Processing Control	8
	C) Peer Reviews	10
	D) Computer Software Control	11
IV -	Procurement Document Control	13
V -	Instructions, Procedures, and Drawings	14

VI - Document Control 15

SECTION PAGE

VII - Control of Purchased Items and Services 16

VIII - Identification and Control of Materials, Parts, Components, and Samples 17

IX - Control of Processes 18

X - Inspection 19

XI - Test Control 20

A) Test Requirements 20

B) Test Procedures 20

C) Test Program Review 20

D) Test Equipment and Media Control 21

E) Test Results 21

F) Test Records 21

XII - Control of Measuring and Test Equipment 22

XIII - Handling, Storage, Transport, and Shipping 23

A) Sample Handling and Transport 23

B) Sample Storage 23

XIV - Inspection, Test, and Operating Status 24

XV - Control of Nonconforming Items 25

A) Resolution of Nonconforming Items 25

XVI - Corrective Action 26

A) Trend Analysis 26

B) Unusual Occurrence Reports (UOR) 26

C) Significant Quality Deficiencies 26

D) Corrective Action 26

SECTION		PAGE
XVII - Quality Assurance Records		28
	A-D) General	28
	E) Record Identification and Cross Referencing	29
	F) Records Management Plan	30
	G) Temporary Record Storage	30
	H) List of Typical Post-Closure Records	30
	I) List of Typical Lifetime Records	30
XVIII - Audits		33
	A) Audit Planning and Scheduling	33
	B) Technical Considerations	33
	C) Audit Preparation	33
	D) Audit Deficiencies	33
	E) Audit Reporting	33
	F) Audit Responses	34
ATTACHMENTS		
	Attachment 3-1: Requirements to Computer Software for High-Level Nuclear Waste Repository Applications	3.1-1
APPENDICES		
	Appendix I: Instructions for Preparation of a QA Program Description	I-1

INTRODUCTION

GENERAL

The assurance of quality achievement is a continuing commitment of managers at all levels in the Office of Civilian Radioactive Waste Management (OCRWM) High-Level Nuclear Waste Repository Program (hereafter referred to as Program). Well-defined quality assurance (QA) programs are to be established and effectively implemented by all participating organizations. Responsibility for QA is not limited to QA personnel at OCRWM or in the Project Office(s). All OCRWM and Project management, technical, and administrative personnel and Program Participants are to participate in QA program planning and implementation and shall comply with the requirements of this QA Requirements document as described in their QA Program Description's and administrative and technical procedures for their respective organizations.

The QA program will be managed and executed in a manner consistent with the requirements of the Office of Civilian Radioactive Waste Management (OCRWM).

PURPOSE AND APPLICABILITY

This document defines OCRWM Quality Assurance (QA) Requirements for: collection of scientific and technical information, planning, site characterization, design, construction, and operation of high-level nuclear waste repositories and associated facilities. This includes exploratory shaft facility design and construction. This document complies with 10 CFR 60, Subpart G, and is to be used in conjunction with ANSI/ASME NQA-1, 1986 Edition.

The application of this document or portions thereof for high-level nuclear waste repositories, shall be specified in written contracts, policies, plans, manuals, procedures, or instructions.

RESPONSIBILITY

The organizations invoking this document shall be responsible for specifying which OCRWM QA Requirements, or portions thereof, apply, and for applying them to specific items, services, and activities as appropriate. The organization upon which this document, or portions thereof, is invoked shall be responsible for complying with the specified requirements.

DEFINITIONS

The terms and definitions of NQA-1, Supplement S-1, apply, with the additional terms and definitions identified in the Glossary of this document. Where differences between this document and other documents exist, the definitions in this document shall take precedence.

GLOSSARY

TERMS AND DEFINITIONS

1. ACTIVITIES THAT AFFECT QUALITY: Activities that have impact on the validity of information or data reported that could cause undue risk to the radiological health or safety of the public, or that could adversely impact the achievement of mission prime objectives.

2. DATA ACCURACY: The degree of agreement of a measurement with an accepted reference or true value. Accuracy is a measure of the bias in a system.

3. DATA COMPARABILITY: A measure of the confidence with which one data set can be compared to another.

4. DATA COMPLETENESS: A measure of the amount of valid data obtained from a measurement system compared to the amount that was planned.

5. DATA PRECISION: A measure of mutual agreement among individual measurements of the same property usually expressed in terms of standard deviation.

6. DATA QUALITY: The totality of features and characteristics of data that bears on its ability to satisfy a given purpose. The characteristics of major importance are accuracy, precision, completeness, representativeness, and comparability.

7. DATA REPRESENTATIVENESS: The degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, or an environmental condition.

8. DATA VALIDATION: A systematic effort to review data to assure acceptable data quality.

9. EXPERIMENTS: Performance of operations that are carried out under controlled conditions to establish characteristics or values not known previously or to verify independently identified conditions.

10. FINDING: A statement of fact regarding noncompliance with established policies, regulations, or other applicable requirements.

11. GEOLOGIC REPOSITORY: A physical containment system that may be used for the disposal of radioactive wastes in geologic formations. A geologic repository includes the engineered systems, the geologic repository operations area and the portion of the geologic setting that provides isolation of the radioactive waste and is located within a controlled area.

12. ITEM: An all-inclusive term commonly used in place of any of the following: structure, system, component, material, and equipment. The term "item" may also include technical data, documents, computer codes, samples and related activities.

13. NONCONFORMANCE: A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate. Examples of nonconformances include: non-conforming items and/or inadequate or incorrect documentation therefor, and/or quality problems such as procedural deficiencies and deviations.

14. OBSERVATION: A recommendation for improvement in, or concern for, a QA program element which meets the minimum requirements but could be improved by adopting the recommendation or heeding the concern.

15. PEER REVIEW: A documented critical review performed by personnel who are independent of those who performed the work but who have technical expertise at least equivalent to those who performed the original work.Peer reviews are in-depth, critical reviews and evaluations of documents, material or data that require interpretation or judgment to verify or validate assumptions, plans, results or conclusions or when the conclusions, material or data contained in a report go beyond the existing state of the art.

16. PROGRAM: For purposes of clarification and uniform understanding and use, Program, when used, shall mean the U.S. Department of Energy Civilian Radioactive Waste Management Program.

17. PROGRAM PARTICIPANTS: All contracted organizations performing activities associated with the Program, including prime and sub-contractors, national laboratories, other government organizations, etc., but excluding OCRWM and the Project Office(s).

18. QA PROGRAM ASSESSMENT: An analysis and determination of management controls and resources performed by an organization's management or that of a higher-level organization for achieving QA Program adequacy and effectiveness. Normally, QA program assessment does not evaluate compliance with QA Program procedures.

19. QUALITY VERIFICATION: A planned and documented set of activities, to be performed by those individuals and organizations that are directly responsible for achieving quality and by those who are independent of the item or activity being verified for quality. Elements of quality verification include: Technical Review, Peer Review, Design, Review, Readiness Review, QA Program Review, QA Program Assessment, QA Audits, and QA Surveillance.

20. Q-LIST: A list of geologic repository structures, systems, components, and activities that have been determined to be important to safety and/or waste isolation and are thereby subject to the highest quality level (Quality Level 1) of the formal QA program.

21. QUALITY: A standard which may be regarded, in the technical sense, as a definable, controllable, measurable, and verifiable property, feature, or characteristic of a study, investigation, design, item, process, or product. Quality is frequently defined, in the physical sense, as the fitness of an item for its intended purpose. Conformance or compliance to established regulations and requirements is a definition of quality in a licensing and contractual sense.

22. QUALITY ACHIEVEMENT: The satisfactory performance of a work activity, such as drilling, designing, constructing, testing, operating, and data acquisition, in accordance with technical criteria, requirements, and procedures which result in a satisfactory end item.

23. QUALITY ASSURANCE (QA): Defined classically in regulations, codes, and standards as comprising all those planned and systematic actions necessary to prove that a structure, system, or component will perform satisfactorily in service. When the product is a report of a significant study or investigation, QA also comprises those planned and systematic actions necessary to provide adequate confidence in the validity and integrity of the reported data, methods, and procedures and in the protection, retrievability, and possible replicability of the data. QA includes a multidisciplinary system of management controls backed by quality verification and overview activities that demonstrate completeness and appropriateness of achieved quality.

24. QUALITY ASSURANCE ADMINISTRATIVE PROCEDURES: Procedures that govern the process of QA Planning, Management Controls, and Quality Verification. These procedures provide instructions for the implementation and application of the OCRWM QA Requirements document.

25. QUALITY CLASSIFICATION: An indication of the relative significance of an item or activity to radiological safety, waste isolation or programmatic importance. An item or activity may be designated Quality Level 1, 2, or 3 (QL-1, QL-2, or QL-3).

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

27. TECHNICAL PROCEDURE: Implementing procedures that prescribe the actions required to achieve quality in the performance of work activities on the projects. These procedures contain instructions for the actual performance of technical work, evaluations, investigations, and testing.

28. TECHNICAL REVIEW: A documented traceable review performed by qualified personnel who are independent of those who performed the work but who have technical expertise at least equivalent to those who performed the original work. Technical reviews are in-depth, critical reviews, analyses and evaluations of documents, material or data that are within current state-of-the-art, are based on established standards, and that require technical verification and/or validation for applicability, correctness, adequacy and completeness.

I ORGANIZATION

The provisions of NQA-1, Basic Requirement 1 and Supplement 1S-1 shall apply with the following amplifications:

(A) QA RESPONSIBILITIES

Persons and organizations performing QA functions shall have direct access to management levels which will assure the ability to:

(1) Identify quality problems.

(2) Initiate, recommend, or provide solutions through designated channels.

(3) Verify implementation of solutions.

(4) Stop unsatisfactory work.

Persons and organizations with the authority shall be identified and a description of how those actions shall be carried out is provided.

(B) STOP WORK ORDERS

Procedures for issuing and lifting stop work orders shall be developed and implemented at OCRWM the Project Office(s), and Program Participant levels. The procedures shall include:

(1) criteria for stopping work and for lifting stop work orders;

(2) authorities and responsibilities; and

(3) methodology for verifying and documenting acceptable corrective action prior to lifting stop work orders.

(C) DISPUTE RESOLUTION

Procedures shall be developed for resolution of disputes involving quality arising from a difference of opinion between QA personnel and other Program personnel.

II QUALITY ASSURANCE PROGRAM

The provisions of NQA-1 Basic Requirement 2 and Supplements 2S-1, 2S-2, 2S-3, and 2S-4 apply with the following additions, amplifications, and modifications.

(A) PLANNING

OCRWM, the Project Office(s), and Program Participants shall develop QA Program Descriptions which shall address the OCRWM QA Requirements and which shall be consistent with Appendix 1 to this document. QA Program Descriptions are to be reviewed and approved by the next higher Program organization level. QA programmatic planning shall be coordinated among affecting organizations and shall include the following elements, as a minimum:

(1) Definition of scope and objectives of activities including performance objectives

(2) Assignment of quality levels to items and activities based on their importance to radiological safety, waste isolation, and other Program objectives

(3) Selective application of necessary and appropriate QA requirements and procedural controls within each quality level (i.e., a graded approach) to items and activities covered by the QA program

(4) Assignment of responsibilities

(5) Identification of the specific scientific and technical information to be collected and analyzed

(6) Identification of applicable technical and programmatic quality standards, procedures, and criteria, including provisions for quality assurance organization involvement and concurrence.

(7) Use of technical reviews and peer reviews, as appropriate

(8) Identification of suitable field and laboratory testing equipment

(9) Identification of methods or procedures for field, laboratory and engineering sampling, testing and analysis activities

(10) Definition of required data and quality assurance records.

(11) Use of Readiness Reviews which shall be planned, performed, and documented at critical phases of the design, construction, testing, and operation of high-level nuclear waste repositories and associated facilities, commensurate with their importance or relation to radiological safety, waste isolation, and other programmatic objectives. These Readiness Reviews will be a means of providing line management visible evidence that:

(a) work activities have been completed satisfactorily;

(b) administrative and technical procedures have been reviewed for adequacy and appropriateness. Such procedures shall address the following:

(1) scope of the readiness review;

(2) authorities and responsibilities;

(3) qualification and assignment of personnel;

(4) role of headquarters;

(5) identification of detailed procedures to be used in conducting the review;

(6) resolution of comments and disposition of nonconformances; and

(7) records of the readiness review results.

(c) personnel are qualified and have been suitably trained Readiness Reviews shall be performed in accordance with "DOE Guidelines for Application of Readiness Reviews to Department of Energy Activities" dated January, 1987.

(B) QUALITY LEVELS

All activities within the scope of the OCRWM Program Management System (PMS) are to be "Managed for Quality". Those PMS technical items and activities that are designated to be covered by formal, documented and auditable quality assurance programs are to be assigned Quality Levels. Accordingly, OCRWM has adopted three Quality Levels for the Program which are referred to as QL1, QL2 and QL3. The decision process for assigning Quality Levels is to be guided by the following general criteria which are consistent with and amplify the OCRWM Director's Statement on Quality Assurance. Associate Directors may provide more definitive Program guidance on Quality Levels, as necessary, to further define these general criteria.

(1) Quality Level 3 (QL3)

QL3 is for assignment to selected PMS technical items and activities that are neither important nor related to public or occupational radiological health and safety or waste isolation but are of such special programmatic importance as to be controlled according to good management and work practices and QA requirements. Good practices and QA requirements are to be consistent with applicable governing documents, and are to be applied to QL1 and QL2 as well as to QL3. Consistent with DOE Order 5700.6B Program QA Requirements are to be based on ANSI/AMSE NQA-1. QL3 designations are to be made by or with the approval of the appropriate OCRWM Associate Director. This authority may be delegated by the OCRWM Associate Director to subordinate managers.

For items and activities of special programmatic importance, QL3 designation requires, as a minimum:

(a) Formal, documented, and auditable QA programs, plans, procedures, and good practices;

(b) Compliance with applicable QA requirements of ANSI/AMSE NQA-1;

(c) Assignment of responsibility for assuring quality achievements;

(d) Indoctrination and training of personnel;

(e) Verification of QA program adequacy and effectiveness;

(f) QA reporting separate from QL1 and QL2.

(2) Quality Level 2

QL2 is for assignment to those items and activities that are not assigned QL1 but are designated by the appropriate Associate Director or by authorized subordinate managers as being related to public or occupational radiological health and safety or waste isolation. QL2 is also for assignment of those items and activities whose failure, omission or degradation could challenge but not adversely affect the safety functions of QL-2 designated items at the time they are needed to prevent or mitigate accidents or isolate waste. QL2-designated items and activities may support licensing but are not required to comply with the QA requirements of 10 CFR Parts 60, 71, and 72, and are not Q-listed. The minimum requirements for QL2 are the same as those stated in Paragraph (1) above for QL3.

(3) Quality Level 1

QL1 is reserved for items and activities that are (1) important to public radiological health and safety and waste isolation; (2) subject to compliance with applicable NRC regulatory QA requirements of 10 CFR Part 60, Subpart G; 10 CFR Part 71, Subpart H; or 10 CFR Part 72, Subpart G; and (3) identified by the appropriate Associate Director or by authorized subordinate managers on the Q-list(s). QL1 designation includes items and activities that prevent or mitigate the consequences of postulated accidents that could cause undue risk to public health and safety.

In addition to the requirements for QL3 and QL2 stated in paragraphs (1) and (2) above, QL1 designation requires:

(a) Identification and Q-listing of items and activities; and

(b) Compliance with applicable NRC regulatory QA requirements.

1.28

(C) PERSONNEL SELECTION, INDOCTRINATION, TRAINING, AND QUALIFICATION

Supplement 2S-4 to NQA-1 shall apply, except that Paragraph 2 is amplified as follows:

(1) Quality affecting activities associated with licensing a high-level nuclear waste repository include: sample collection and handling; computer code documentation, verification, validation, and transfer; preparation and review of technical calculations; quality records processing, storage and retrieval activities; technical and peer reviews, management assessments and readiness reviews; and collection of scientific and technical information, planning, site characterization, design, construction, testing, and operation of high-level waste repositories and associated facilities.

(2) The responsible organization shall analyze each job position to determine the quality affecting task responsibilities of the position. The analysis shall identify education and experience prerequisites for each position involved in the performance or verification of activities that affect quality.

(3) Personnel selected to perform or verify activities which affect quality shall have education, experience, and training commensurate with the minimum requirements specified. The capabilities of an individual shall be based upon an evaluation of education and experience and compared to those established for the position. Training requirements shall also be identified.

(D) QA SURVEILLANCE

QA surveillance shall be used to:

(1) monitor work in progress (not completed work);

(2) document compliance or noncompliance with requirements and procedures;

(3) provide continuous management information on the activity under surveillance; and

(4) obtain prompt corrective action commitments.

Surveillance results shall be summarized in a surveillance report which contains a description of the item or activity under surveillance, a listing of the requirements governing the item or activity; identification of deficiencies, nonconformances, or exemplary practice noted during the surveillance; and the commitment of cognizant supervision/management to correct deficiencies, it any, and their causes. QA surveillances for QL1 and QL2 items and activities shall be reported separately from QL3.

(E) QA PROGRAM REVIEW

QA Managers at all organizational levels shall regularly review the scope and status of those portions of the overall OCRWM QA program for which they are responsible for implementation. QA program review results shall be documented and the information disseminated to affected organizations.

QA program reviews shall verify, as a minimum, that:

(1) Quality Levels have been assigned to items and activities that are to be verified for quality;

(2) QA program requirements have been identified and implemented through approved plans/manuals and procedures;

(3) Indoctrination and training have been completed for individuals conducting overviews; and

(4) Existing or potential significant quality problems and issues have been identified, documented and resolved.

Responsibilities, methods, and frequencies for QA program review shall be described in QA administrative procedures.

(F) QA PROGRAM ASSESSMENT

Managers shall continuously assess the effectiveness of QA program, plans and actions to achieve and assure quality. QA program assessments shall provide a basis for continually improving QA program management controls and procedures, for clarifying QA responsibilities and authorities, and for obtaining objective evidence that adverse quality trends or significant problems are prevented or have been corrected by appropriate organizations. Management assessments shall be performed regularly and reported at least annually to the highest management position identified by the organization's QAPD.

QA program assessments shall include an evaluation of:

(1) QA program management, planning and procedural controls;

(2) QA direction (QA program requirements and guidance);

(3) Organizational structure and staffing (interfaces, authorities, staffing levels, and personnel qualifications);

(4) QA indoctrination and training (scope, attendance, and management support) which shall:

- promote the OCRWM-wide QA concept,
- enhance proper attitudes toward QA, and
- improve methodologies;

(5) QA management information and tracking (identification, analysis and resolution of quality problems and dissemination of lessons learned).

Each QA program assessment shall be documented in a report which is to include, as a minimum, a summary statement, comments or observations for each topic of the assessment, and recommendations where appropriate. A recommendation generally necessitates a written response from the assessed organization which is to address actions taken or planned for each recommendation and a schedule for completion. An assessment recommendation is defined as an action needed to strengthen or improve the adequacy or effectiveness of a QA aspect such as the organization structure. A recommendation differs from an audit finding in that is it usually based on the knowledge and experience of the assessor rather than upon a procedural noncompliance.

(G) QA MANAGEMENT INFORMATION REPORTING AND TRACKING

Participating organizations at all management levels shall establish communication channels which ensure timely reporting, dissemination, and tracking of QA management information, such as:

(1) The status of development and implementation of the OCRWM QA program and its sub-elements;

(2) Status of resolution of significant quality problems, issues, and trends; and

(3) Summary of QA overview results, including both adverse conditions and exemplary practices.

QA management information shall be reported at least quarterly to appropriate levels of management in the Program including the cognizant Associate Director.

III DESIGN CONTROL

The provisions of NQA-1, Basic Requirement 3 and Supplement 3S-1 shall apply to the design of structures, systems and components integral to and associated with high-level nuclear waste repositories.

For the Collection of Scientific and Technical Information for Site Characterization, the design control provisions of NQA-1, Basic Requirement 3 and supplement 3S-1 shall apply with the following additions and amplifications:

(A) CONTROL OF SCIENTIFIC INVESTIGATIONS

Scientific investigations shall be defined, controlled and verified. Process variables affecting scientific investigations shall be measured and controlled. Variables that affect interrelated scientific investigations shall be identified, documented, and controlled appropriately in each investigation to assure comparability. Procedures for conducting scientific investigations and their implementation shall be reviewed for technical adequacy and approved by qualified persons other than those who prepared the procedures. Changes to procedures for conducting scientific investigations shall be reviewed and approved by qualified persons familiar with the original procedure and the purpose of the investigation to ensure that the original purpose of the investigation is fulfilled. Development activities to develop or establish new methods or procedures for conducting scientific investigations shall be documented. The results shall be reviewed for adequacy and approved by qualified persons prior to implementation of the procedures for data collection.

(B) DESIGN DATA PROCESSING CONTROL

(1) Planning

The intended use of the data shall be determined and documented as part of the planning for data gathering and processing. Any alternate use of the data shall be evaluated for appropriateness and the justification documented. Planning shall assure compatibility of data processing with any conceptual or mathematical models used at each applicable stage. Planning shall establish provisions for data quality evaluation to assure data generated are valid, defensible, comparable, complete, representative, and of known precision and accuracy.

(2) Data Collection and Analysis

Practices, techniques, equipment, and both manual and computerized methods used to obtain and analyze data shall be verified to assure they are technically sound and selected properly. Controls shall be established over these processes to assure they are properly used and are free from tampering to maintain data integrity.

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 results, or alternate analysis methods.

Data Transfer and Reduction Controls shall be established to assure data transfer is error free (or within a prescribed permissible error rate), to assure no information is lost in transfer and that the input is completely recoverable from the output. Examples of data transfer include: copying raw data from a notebook into a computerized data form, or covering a written data set to punched cards, or copying from computer tape to disk. 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 which allow for the validation of the conversion process.

(3) Data Traceability and Identification

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 shall be maintained throughout the needed lifetime of the data.

(4) Data Recording, Storage, and Retrievability

The method of data recording (e.g., laboratory and field notebooks, log books, data sheets, computerized instrumentation systems, etc.) shall be controlled to avoid loss and permit retrievability. At appropriate stages of data processing where data is stored, controls shall be established to assure data integrity and security is maintained. Controls shall prescribe how specific types of data will be stored with respect to media, conditions, location, retention time, and access. Data shall be suitably protected from damage and unintentional destruction during their prescribed lifetime and readily retrievable from wherever stored.

(5) Control of Erroneous Data

Data that is found to be erroneous, rejected, superseded, or otherwise unsuited for their intended use shall be controlled by procedures. Controls shall include the identification, segregation, and disposition of inadequate data to avoid their inadvertent use. The basis for the disposition of erroneous data shall be justified.

(6) Evaluating and Reporting Results

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

(7) Qualification of Data With Indeterminate Quality

Data to be used which was not collected under a quality assurance program in accordance with this document shall be qualified for its intended use. This includes data collected from such sources as professional journals, technical reports and symposia proceedings. The organization using the data shall establish procedures for the data qualification process considering both technical and quality assurance programmatic criteria. Factors to be considered include:

(a) Qualifications of personnel or organizations generating the data

(b) Technical adequacy of the equipment and procedures used to collect the data

(c) Environmental conditions (if germane)

(d) Quality and reliability of the measurement control program under which the data were generated.

The data qualification process shall describe how data will be assessed for their quality characteristics such as accuracy, precision, completeness, representativeness and comparability. Acceptable qualification methods include, but are not limited to, any one or a combination of the following: peer reviews, corroborating data, confirmatory testing (either by alternate methods or replication), and demonstration that the data were collected under a quality assurance program equivalent to a QA program meeting the requirements of this document.

(C) PEER REVIEWS

Peer reviews shall be conducted for scientific investigations which involve use of untried or unproven state-of-the-art testing and analysis procedures and methods, or where detailed technical criteria and requirements do not exist or are being developed. Peer reviews shall consider an appropriate spectrum of technical skills in the subject matter to be reviewed. Peer reviewers shall be knowledgeable in the subject matter to be reviewed to a degree at least equivalent to that needed to perform the work to be reviewed. Peer reviewers shall have no direct involvement as a participant, supervisor, technical reviewer or advisor in the work being reviewed. Peer reviewers shall have sufficient freedom from funding considerations to ensure the work is impartially reviewed.

Peer reviewers shall document their findings, which shall address, as a minimum, the suitability of the work being reviewed for its intended purpose and whether the work conforms to specified requirements. Minority positions, if any, must also be documented. The peer review report shall identify the reviewers and document their qualifications and experience in a manner that provides sufficient information to demonstrate that the requirements for technical coverage and independence were met. The investigators performing the work under review shall document their disposition of and justify and departures from, the peer review group's findings and recommendations.

(D) COMPUTER SOFTWARE CONTROL

For a geologic repository, computer software used to perform analysis in support of the design shall be controlled to the same level of requirements as software used to perform direct design analysis. Auxiliary software used to support primary analysis software shall be controlled at a level of control commensurate with the complexity of that software and with the level of commercial support available. Supplemental, detailed requirements for the development, maintenance and security of computer software based on the software life cycle model is contained in Attachment 3-1 to this document.

(1) Each organization participating in any phase of the Program shall prepare a description of their Software Design, Test and Configuration Management System and submit it to the next higher program organizational level for review and approval. The description shall:

(a) Provide criteria for application of the requirements of this document based on the complexity and importance of the software used to perform analysis in support of the design of a geologic repository.

(b) Indicate the methods to be used to develop computer program requirements, to translate those requirements into a detailed design and to implement that design in executable code.

(c) Relate the types of documentation to be prepared, reviewed and maintained during software design, code implementation, test and use.

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

(e) Specify the process to be used for verification and validation of the software developed or applied to geologic repository design analyses.

(f) Identify the procedure for reporting and documenting software discrepancies, including source(s), evaluating impacts of discrepancies on previous calculations, and determining appropriate corrective action.

(2) Software shall be placed under configuration management as each baseline element is approved. Software baseline elements shall be uniquely identified to assure positive control of all revisions; the identification of each code version shall be directly related to the associated documentation.

(3) Changes to software shall be systematically evaluated, coordinated and approved to assure that the impact of a change is carefully assessed prior to updating the baseline, required action is documented, and the information concerning approved changes is transmitted to all affected organizations. Changes to computer software shall be subject to the same level of approval, verification, and validation as the original software.

(4) Computer programs developed and/or modified shall be documented in accordance with the applicable elements of NUREG-0856, Final Technical Position on Documentation of Computer Codes for High-Level Waste Management. This requirement may be met in part by existing documentation if properly referenced and related to the NUREG-0856 requirements.

(5) Testing of software, including new or modified software, shall be performed for those inputs and conditions necessary to exercise the software, identify boundary conditions and to provide a suitable benchmark or sample problem for installation. The goal of testing is to develop a set of test cases that have the highest probability of detecting the most errors in order to identify under what conditions the software does not perform properly.

(6) Verification and Validation activities shall assure that the software adequately and correctly performs all intended functions and that the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system.

(7) Software shall be qualified for use. This qualification shall be based on the ability of the software to provide acceptable results for specific applications and compliance with the requirements of this document. Software that has not been developed in accordance with this document may be qualified for use provided the software is verified and validated, a software baseline established, and applicable documentation prepared to support the software in accordance with the provisions of this document.

IV PROCUREMENT DOCUMENT CONTROL

The provisions of NQA-1 Basic Requirement 4 and Supplement 4S-1 shall apply.

V INSTRUCTIONS, PROCEDURES, AND DRAWINGS

The provisions of NQA-1 Basic Requirement 5 shall apply, with the following additions and amplifications:

(A) Formal QA and attendant work activities are to be prescribed by, and performed in accordance with, documented QA Administrative Procedures (QAAP's) and Technical Procedures, respectively. OCRWM policy is that QAAP's and Technical Procedures are to be reviewed and approved by the next higher Program organizational level.

(B) Specific organizational responsibilities for review, approval, and change of QAPD's, QAAP's, and Technical Procedures are to be defined at OCRWM, the Project Office(s), and Program Participant organizational levels.

VI DOCUMENT CONTROL

The provisions of NQA-1 Basic Requirement 6 and Supplement 6S-1 shall apply.

VII CONTROL OF PURCHASED ITEMS AND SERVICES

The provisions of NQA-1 Basic Requirement 7 and Supplement 7S-1 shall apply, with the following additions and amplifications:

(A) Suppliers' certificates of conformance shall be periodically evaluated, as appropriate, by audits, independent inspections, or tests to assure they are valid and the results documented.

VIII IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, COMPONENTS, AND SAMPLES

The provisions of NQA-1 Basic Requirement 8 and Supplement 8S-1 shall apply with the following additions and amplifications:

(A) SAMPLE MANAGEMENT

Samples shall be identified and controlled in a manner consistent with their intended use. Such controls shall define the responsibilities (including interface between organizations) for collection, identification, traceability of samples (including archival samples); for test allocation; disposition of samples; and generation of associated records.

(1) Sample Identification.

Samples shall be identified by placing the identification directly on the samples when possible, or on their container, or on a label or tag attached to the samples or their container. Sample identification shall be verified and documented prior to release for testing or analysis.

(2) Sample Traceability.

Identification systems shall assure traceability of samples to the appropriate source, requirement or use document. Traceability of samples from initial acquisition through final disposition is required. Measures shall be taken to preclude the use of samples that have lost their identity.

(3) Archival Samples.

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

IX CONTROL OF PROCESSES

The provisions of NQA-1 Basic Requirement 9 and Supplement 9S-1 shall apply with the following additions and amplifications:

(A) QA personnel shall be involved in the qualification activities to help assure satisfactory performance.

(B) Processes that have a significant effect on quality characteristics and that produce results that cannot be readily verified by inspection or testing of the final product are to be identified and controlled by those organizations responsible for performing the work. The controls to be established and implemented on such processes shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.

X INSPECTION

The provisions of NQA-1 Basic Requirement 10 and Supplement 10S-1 shall apply.

XI TEST CONTROL

The provisions of NQA-1, Basic Requirement 11 and Supplement 11S-1, shall apply to tests required to verify conformance of an item to specified requirements (confirmatory testing) and to demonstrate that an item will perform satisfactorily in service (qualification testing).

Tests required to collect data, such as for siting or design input, shall be controlled in accordance with the requirements of NQA-1, Basic Requirement 11 as amplified below:

(A) TEST REQUIREMENTS

Test requirements shall be provided and approved by the organization(s) for those portions of the Program for which they are responsible. Test requirements shall be defined as an integral part of the technical program planning established to identify information needs and resolve issues related to the particular waste management system mission. Approval requirements and authorizations for test requirements, planning, verification, readiness (including procedures), operations, results analysis, and changes thereto shall be documented.

(B) TEST PROCEDURES

Testing activities shall be performed in accordance with written procedures which implement test plans and incorporate test requirements, test methods, and potential sources of uncertainty and error therein. Test procedures shall include or reference provisions for assuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, that necessary monitoring (including witness or hold points) is performed, and that suitable environmental conditions are maintained. Prerequisites shall include the following, as applicable: calibrated instrumentation; appropriate equipment; trained personnel; readiness of test facilities, equipment, supplies and test items or samples; suitable environmental conditions; provisions for data acquisitions; and disposition of test facilities after completion of testing activities.

Testing shall be performed in accordance with applicable ASTM, API, EPA, or APHA applicable test standards. Test standards used without modification require documentation by reference only. If deviation from test standards or establishment of specially prepared test procedures is deemed appropriate, the modified or new test procedures shall be documented in sufficient detail to be repeatable, and be justified, evaluated and approved by the cognizant technical organization.

(C) TEST PROGRAM REVIEW

Test requirements, test planning, test procedure development, test performance, and analysis of test results shall be reviewed and approved by qualified individual(s) or group(s) other that those who performed the original activity. The extent and type of review

required is a function of the importance of the item or activity to radiological safety or waste isolation, the complexity of the test, the degree of standardization, the state-of-the-art, and the similarity with previously proven testing application.

The organization responsible for the testing activities shall define criteria for selecting the types of review to be performed, including use of peer reviews and readiness reviews, the selection process for the review groups, and the process by which reviews are performed and documented.

(D) TEST EQUIPMENT AND MEDIA CONTROL

The range, accuracy, and precision of test equipment shall be specified in order to be commensurate with test requirements. Test media (e.g., fluids) when used, shall be characterized and controlled in accordance with the test requirements and procedures.

(E) TEST RESULTS

Test results shall be documented, evaluated, and their acceptability determined by the responsible testing and/or design organization, as appropriate, to assure that test requirements and objectives have been satisfied. This evaluation for acceptance of test results shall be documented.

(F) TEST RECORDS

Test records shall, as appropriate identify:

(1) Test requirements, plans, and procedures, including applicable revisions

(2) Item or sample tested

(3) Date of test

(4) Tester or data recorder

(5) Type of observation

(6) Results and acceptability for intended use

(7) Action taken in connection with any deviations noted

(8) Person(s) evaluating test results

(9) Identification of test equipment used.

XII CONTROL OF MEASURING AND TEST EQUIPMENT

The provisions of NQA-1 Basic Requirement 12 and Supplement 12S-1 shall apply.

XIII HANDLING, STORAGE, TRANSPORT, AND SHIPPING

The provisions of NQA-1, Basic Requirement 13 and Supplement 13S-1 shall apply to items during the design, construction, testing and operation of high-level nuclear waste repositories and associated facilities.

For the Collection of Scientific and Technical Information for Site Characterization, the provisions of NQA-1, Basic Requirement 13 and Supplement 13S-1, shall apply with the following additions and amplifications:

(A) SAMPLE HANDLING AND TRANSPORT

Samples shall be controlled during handling, transport, storage and shipment by suitably trained individuals in accordance with predetermined work and inspection instructions or procedures, to preclude damage or loss and minimize deterioration. Controls shall be established for appropriate packaging, containers, handling, modes of transport, time constraints on perishable materials (i.e., shelf life), and any other environmental or safety considerations for the sample(s). Measures shall be taken to avoid sample contamination during handling and storage. Where multiple organizations are involved, appropriate procedures shall describe interface and custody responsibilities. Sample identification shall be verified and maintained when samples are handled, transported, or transferred from one organization's responsibility to another.

(B) SAMPLE STORAGE

Measures shall be taken to maintain sample characteristics and identification capability while in storage. These measures shall be consistent with the planned duration and conditions of storage and shall describe actions to be taken where samples have a maximum life expectancy while in storage. Storage methodology shall be developed and implemented to assure that samples are maintained in predetermined environmental conditions commensurate with their intended purpose. Samples shall be controlled to preclude mixing with like samples. Provisions shall be made for storage of tested samples in areas physically separated or identified from untested sample materials.

XIV INSPECTION, TEST, AND OPERATING STATUS

The provisions of NQA-1 Basic Requirement 14 shall apply.

XV CONTROL OF NONCONFORMING ITEMS

The provisions of NQA-1 Basic Requirement 15 and Supplement 15S-1 shall apply with the following additions and amplifications:

(A) RESOLUTION OF NONCONFORMING ITEMS

The QA organization shall:

(1) document their concurrence with the adequacy of corrective action for nonconformances to assure that OCRWM QA Requirements are satisfied.

(2) take follow-up action to verify proper implementation of corrective action for nonconformances and assure close-out in a timely manner.

XVI CORRECTIVE ACTION

The provisions of NQA-1 Basic Requirement 16 shall apply, with the following additions, modifications, and amplifications:

(A) TREND ANALYSIS

Quality information, such as audit reports, surveillance reports, nonconformance reports, and related documents, is to be analyzed to identify both favorable and adverse quality trends. Trend Analysis shall be performed in a manner and at a frequency that ensures the identification and evaluation of cause, impact, and action required. Trends are to be reported to appropriate levels of management in the Program, including the cognizant Associate Director.

(B) UNUSUAL OCCURRENCE REPORTS (UOR)

Unusual occurrences are to be reported in accordance with DOE Order 5000.3. Project-specific criteria for determining unusual occurrences are to be developed by the Project Manager. Copies of Unusual Occurrence Reports are to be provided to appropriate levels of management in the Program and to the cognizant Associate Director.

(C) SIGNIFICANT QUALITY PROBLEMS

Significant quality problems shall be identified, documented, and corrected at each organizational level and reported to the cognizant Associate Director, and to affected organizational levels. Generic criteria for significant quality deficiencies are:

(1) Failure of an organization to establish and implement appropriate QA and technical requirements, QA Program Descriptions, QA Administrative and Technical procedures for QL1, QL2 and QL3 items and activities.

(2) Significant deficiencies in quality assurance administrative and technical documentation, technical data, and/or computer codes which were not detected and corrected during Technical/QA reviews (i.e., a systematic breakdown).

(3) Identified adverse quality trends and/or the failure of the affected organization(s) to take appropriate and timely corrective actions.

(4) Significant deficiencies in design and construction practices which are detected subsequent to formal Technical or QA organization acceptance.

(D) CORRECTIVE ACTION

Upon discovering or receiving notification that a significant quality problem or unusual occurrence exists, the affected organization shall:

(1) prepare a Corrective Action Report (CAR) to document the condition

(2) take immediate actions to remedy the specific condition(s) and to assure timely resolution and closeout

(3) determine causative factors

(4) assure that managerial and/or procedural controls have been reviewed, implemented, monitored, and revised, as necessary

(5) assure documented QA organization concurrence with the adequacy of corrective action

(6) notify affected managers at all levels of the significant quality deficiency, the corrective actions taken, and of lessons learned to improve conditions or avoid similar occurrences

(7) The QA organization shall take follow-up action to verify proper implementation of corrective action including timely closeout.

XVII QUALITY ASSURANCE RECORDS

The provisions of NQA-1 Basic Requirement 17 and Supplement 17S-1 shall apply, with the following additions, modifications, and amplifications:

(A) A quality assurance record is an individual document or other item that has been executed, completed, and approved and that furnished evidence of the quality and completeness of data (including raw data), items, and activities affecting quality; documents prepared and maintained to demonstrate implementation of quality assurance programs (e.g., audit, surveillance, and inspection reports); procurement documents; other documents such as plans, correspondence, documentation of telecons, specifications, technical data, books, maps, papers, photographs, and data sheets; and items such as magnetic media, physical samples (such as rock, core, and water); and other materials that provide data and document quality regardless of the physical form or characteristic. A completed record is a document or item (and documentation) which will receive no more entries, whose revisions would normally consist of a reissue of the document (or documentation), and that is signed and dated by the originator and, as applicable, by approval personnel.

(B) For a high-level nuclear waste repository, quality assurance records may be of two types:

(1) Documents - Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results, and

(2) Items - Physical samples, magnetic media, and other materials that retain or support data.

(C) One copy of all referenced material cited in final reports shall be retrievable from the Program records system.

(D) In lieu of classifying quality assurance records as defined in Supplement 17S-1 Paragraph 2.7, quality assurance records for nuclear waste repositories shall be classified as Post-Closure, Lifetime, or Nonpermanent in accordance with the criteria specified below.

(1) Post-Closure Records - Post-closure records are those that will be retained for 300-1000 years depending on the lifetime of the specific waste package(s) to be used in the repository at the selected site(s).

(2) Lifetime Records - Lifetime records are those that are required to be retained and preserved in an acceptable condition for the operating life of the repository, i.e., until termination of the repository license. Any records that meet one or more the following criteria shall be maintained as lifetime records until the completion of all activities (siting, site characterization, and repository construction, operation, decommissioning and closure) at a particular site:

(a) Records which may be used for repository licensing.

(b) Records used in support of site selection, site nomination, site characterization, and repository location recommendations.

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

(d) Records of computer programs and mathematical models needed to perform ongoing correlations between performance assessment predictions and actual test results and data collection and analysis.

(e) Records which would be of significant value in demonstrating capability for safe operation or in determining the cause of an accident or malfunction of an item in a repository.

(f) Records which would be of significant value in maintaining, reworking, repairing, replacing, or modifying repository systems, components, or structures.

(g) Records which would be of significant value in exercising of the retrieval option for the waste package.

(h) Records which would be of significant value after decommissioning and closure of a repository.

(3) Nonpermanent Records - Nonpermanent records are those that do not qualify as lifetime records. For a geologic repository, nonpermanent records shall be retained for a least 3 years after initiation of repository operation or until the sites to which they relate are dropped from consideration as a repository site.

(E) RECORD IDENTIFICATION AND CROSS REFERENCING

Records shall be clearly identified by a unique number or other designation which is directly traceable to controlling programmatic information (e.g., project, contract number, task number, WBS number, preparing organization, author, date, title, subject, etc.).

Final reports shall contain a listing, by unique number or other designation that enables prompt retrieval, of all documents used to compile or evaluate the report. This listing shall include, as a minimum, all referenced documents, peer review or other review documents, computer codes, data sheets, procedures, and test plans. All documents referenced by final reports, except readily available references such as encyclopedias, dictionaries, engineers handbook, etc., shall be retrievable from the Records Management System.

(F) RECORDS MANAGEMENT PLAN

Organizations participating in any phase of the geologic repository program shall prepare a records management plan and shall submit it for review and approval to the same authority that approves their QAPD. The Records Management Plan shall:

(1) Identify the types of records to be generated, purchased, and/or maintained, including all records referenced in pertinent final reports and other documents.

(2) Identify the methods to be used to comply with all applicable records requirements including those to be used to control in-process records.

(3) Identify and define the responsibilities of pertinent organizations including the QA organization.

(4) Specify the methods and schedule for periodic purges of nonpermanent records.

(G) TEMPORARY RECORD STORAGE

Records shall be controlled from the time they are complete until the time they are stored in a permanent storage facility. Temporary storage, preservation, safe keeping, and retrievability of completed records shall be in accordance with the requirements applicable to the permanent storage of records. The use of dual storage facilities is an acceptable alternative to a single fire-rated, environmentally controlled facility.

(H) LIST OF TYPICAL POST-CLOSURE RECORDS

Listed below are typical post-closure records:

Maps which identify site boundaries
Location of site markers
Underground facility configuration
Stored waste inventory and location
Repository environment monitoring records
Waste package design, fabrication, testing and inspection records
Other records having long term archival and historical interest
Safety analysis reports
Site Characterization Reports
Licensing Reports
Long Term Performance Assessment Records

(I) LIST OF TYPICAL LIFETIME RECORDS

Listed below are typical types of lifetime records for the geologic repositories program. These lists are not intended to be all inclusive or exclusive. Records initially identified as nonpermanent, and still available, may at any time be reclassified as lifetime.

(1) Siting and Site Characterization Records

Drill hole testing procedures
Drill hole drilling procedures
Drill hole location surveys or maps
Drill hole logs and samples
Drill hole test results (including evaluations and interpretations.
Geophysical logs and data
Geophysical test results
Self-potential (electrical) logs and data
Caliper logs and data
Radioactive logs and data (gamma, spectral-gamma, neutron-gamma)
Lithologic logs and data
Seismic and resistivity survey procedures
Seismic and resistivity location surveys or location maps
Seismic and resistivity logs and data
Seismic and resistivity test results (including evaluations)
Laboratory testing procedures
Laboratory record books
Laboratory testing data and data processing
Geologic maps and supporting data
Geologic library samples
Geologic and soil sampling procedures
Geologic test results
In-situ test results
Logs, maps, and geophysical data in support of subsurface correlation
Trench logs and data (including location surveys, maps, and results)
Aerial mapping records (photographs and interpreted overlays)
Microseismic records (paper or magnetic tape)
Remote imagery reports and results
Groundwater and hydrologic regime maps and data (including results)
Seismicity maps and supporting data
Fault maps and supporting data
Epicenter maps and supporting data
Isopach maps and supporting data
Model definition and development reports
Model acceptance criteria reports
Model verification reports
Model exercise reports and results
Hydrogeologic test procedures
Hydrogeologic test results and data
Atmospheric test procedures
Atmospheric Test results and data
Environmental study evaluations and results
Site characteristics reference documents
Test deviation records
Unusual occurrence reports

(2) Design Records

Procedures and reports
Peer review reports and comment resolution
Design criteria change records
Configuration control records
Design classification system
Conceptual design reports
Baseline document index
Technical computer codes and models photographs of repository systems, components, and structures
Summary design data and/or records reflecting significant findings or containing significant findings or containing significant scientific data not duplicated elsewhere which serve as backup for notebook entries and/or reports.

(3) Procurement Records

Contract requisitions
Statements of work with amendments
Acceptance records
Equipment manuals
Operating manuals
Maintenance manuals

(4) Installation Construction Records

Grout design mix reports
Material property reports on liner and seal materials
Material property reports on waste package material
Material property reports on rock bolt materials
Rock bolt installation test reports
Seal installation records and test reports
Shaft alignment measurements

XVIII AUDITS

The provisions of NQA-1, Basic Requirement 18 and Supplement 18S-1, shall apply, with the following additions and amplifications:

(A) AUDIT PLANNING AND SCHEDULING

Audits shall be planned and scheduled consistent with Program and Project milestones and major activities. As a minimum, audits shall be performed annually. Initial QA audits of newly implemented or substantially modified QA programs shall focus on programmatic adequacy and completeness. Such audits are to verify procedural adequacy and compliance, and identify existing or potential deficiencies. Later, as the Program matures, the QA audit focus shall be on the adequacy and effectiveness of QA and technical controls.

(B) TECHNICAL CONSIDERATIONS

The QA Audit program shall include audits which address the quality of the products and of the work being performed as well as QA programmatic compliance. Audit team members selected to participate in audits for technical consideration purposes shall have appropriate technical expertise or experience in the work being audited. Multidisciplinary audit teams shall be employed when activities to be audited involve more than a single technical area.

(C) AUDIT PREPARATION

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.

Audit planning shall include a review of past audit 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 action addressed the root cause of the quality problem and whether effective tracking and follow-up of quality problems occurred.

(D) AUDIT DEFICIENCIES

Audit deficiencies of a common nature shall be combined whenever possible so that related or systematic breakdowns in the quality programs are identified. Deficiencies shall be classified whenever possible based on their importance to safety and to repository performance. QA Audit deficiencies shall be documented as FINDINGS and OBSERVATIONS (see glossary for definitions).

(E) AUDIT REPORTING

Audit results are to be summarized in a report which shall:

(1) contain an Executive Summary describing unsatisfactory results as well as exemplary practices;

(2) be transmitted to the senior line manager for response by the audited organization;

(3) QA audits of QL1 and QL2 items and activities are to be reported separately from audits of QL3.

(F) AUDIT RESPONSES

Audited organizations are to provide responses to identified audit deficiencies which address the following items:

(1) actions taken or to be taken to correct the condition and to prevent recurrence;

(2) root cause for each deficiency or noncompliance;

(3) schedule for completion of actions; and

(4) evaluation of impact of findings on completed work.

Observations are to be considered and appropriate actions taken on the recommendations or concerns.

17.1 QUALITY ASSURANCE PROGRAM DESCRIPTION

17.1.1 ORGANIZATION

17.1.1.1 The QAPD shall describe clearly the authority and duties of persons and organizations performing the quality assurance functions of assuring that the quality assurance program is established and executed and of verifying that an activity has been correctly performed. The QAPD shall provide organization charts and functional responsibility descriptions that denote the lines of responsibility and areas of authority within the Program including OCRWM, the Project Office(s), and Program Participants. These charts and descriptions shall present the structure of quality assurance organizations as well as other functional organizations performing activities affecting quality with clear delineation of their responsibility, authority, internal relationship and external interfaces with the next higher and lower Program organizational levels.

17.1.1.2 The QAPD shall describe the level of management responsible for establishing the quality assurance policies, goals, and objectives and shall describe the continuing involvement of this management level in quality assurance matters. The QAPD shall tell what position has overall authority and responsibility for the quality assurance program and tell what position is responsible for final review and approval of the quality assurance program and related documentation. The qualification requirements of the principal quality assurance and quality control positions shall be described.

17.1.1.3 The QAPD shall describe those measures which assure that persons and organizations performing quality assurance functions have sufficient authority and organizational freedom to (1) identify quality problems, (2) initiate, recommend, or provide solutions, and (3) verify implementation of solutions. The QAPD shall describe the measures which assure that persons and organizations assigned the responsibility for checking, auditing, inspecting or otherwise verifying that an activity has been correctly performed, report to a management level such that this required authority and organizational freedom, including sufficient independence from the pressures of production, are provided. Irrespective of the organizational structure, the QAPD shall describe how the individual or individuals with primary responsibility for assuring effective implementation of the quality assurance program at any location where activities subject to the control of the quality assurance program are being performed will have direct access to such levels of management as may be necessary to carry out this responsibility. The QAPD shall indicate from whom the persons performing quality assurance functions receive technical direction for performing quality assurance tasks and administrative control (salary review, hire/fire, position assignment). The QAPD shall identify those positions or organizations which have written delegated responsibility and authority to stop work or control further processing, delivery, installation, or use of nonconforming items until proper disposition of the deficiency has been approved.

The QAPD shall describe how requirements will be imposed on OCRWM, the Project Office(s), and Program Participants to assure that individuals or groups within their organizations performing quality assurance functions

have sufficient authority and organizational freedom to effectively implement their respective quality assurance programs.

17.1.1.4 The QAPD shall describe the extent to which OCRWM will delegate to other organizations the work of establishing and executing the quality assurance program or any part thereof. A clear delineation of those quality assurance functions which are implemented within the OCRWM quality assurance organization and those which are delegated to other organizations shall be provided in the QAPD. The QAPD shall describe the method by which the OCRWM will retain responsibility for and maintain control over those portions of the quality assurance program delegated to other organizations and should identify the organization responsible for verifying that delegated quality assurance functions are properly carried out. The QAPD shall identify major work interfaces for activities affecting quality and describe how clear and effective lines of communication exist between the OCRWM, the Project Office(s) and Program Participants to assure necessary coordination and control of the quality assurance program.

17.1.2 QUALITY ASSURANCE PROGRAM

17.1.2.1 The QAPD shall cover each of the requirements in the QAR in sufficient detail to permit a determination as to whether and how all of the requirements will be satisfied. The QAPD shall (1) describe the extent to which the quality assurance program will conform to various provisions of the QAR; and (2) identify the organizational element responsible for implementing these provisions.

17.1.2.2 The QAPD shall identify the items and activities to be controlled by the quality assurance program.

17.1.2.3 The QAPD shall describe the measures which assure that the quality assurance program is being established at the earliest practicable time consistent with the schedule for accomplishing activities affecting quality in production operations. That is, the QAPD shall describe how the quality assurance program is being established in advance of the activity to be controlled and how it will be implemented as the activity proceeds. Those activities affecting quality initiated prior to the development of the OCRWM, Project Office(s), and Program Participants' quality assurance program. such as establishing information required to be included in the QAPD, design, procurement, testing and evaluation, audits, and other preparation activities shall be identified in the QAPD. The QAPD shall describe how these activities are controlled by a quality assurance program which complies with the QAR.

17.1.2.4 The QAPD shall describe how the quality assurance program is documented by written policies, procedures, or instructions and how it will be implemented in accordance with these policies, procedures, or instructions that will be used to implement the quality assurance program for each major activity. The procedure list shall identify which requirements of the QAR are implemented by each procedure. In the event certain required procedures are not yet established, a schedule for their preparation shall be provided in the QAPD.

17.1.2.5 The QAPD shall summarize the Program quality assurance policies, goals, and objectives; and describe how disputes involving quality are resolved.

17.1.2.6 The QAPD shall describe the program that provides adequate indoctrination and training of personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained. The QAPD shall describe how the indoctrination and training program will assure that:

1. Personnel performing activities affecting quality are appropriately trained in the principles and techniques of the activity being performed.

2. Personnel performing activities affecting quality are instructed as to purpose, scope, and implementation of governing manuals, policies, and procedures,

3. Appropriate training procedures are established, and

4. Proficiency of personnel performing activities affecting quality is maintained.

17.1.2.7 The QAPD shall describe the qualification requirements for the position or positions responsible for assuring effective implementation of the quality assurance program of OCRWM, Project Office(s), and Program Participants.

17.1.2.8 The QAPD shall describe the measures that assure that activities affecting quality will be accomplished under suitable controlled conditions, including (1) the use of appropriate equipment, (2) a suitable environment for accomplishing the activity, e.g., adequate cleanliness, and (3) compliance with necessary prerequisites for the given activity.

17.1.2.9 The QAPD shall describe the measures that assure that there is regular management review of the quality assurance program to assess its effectiveness and the adequacy of its scope, and implementation. The QAPD shall describe the provisions for reviews by management above or outside the quality assurance organization to assure achieving an objective program assessment. The QAPD shall describe the measures that assure that the quality assurance organization of the OCRWM, the Project Office(s), and Program participants will (1) review and document agreement with the quality assurance programs of the next lower Program organizational level, and (2) conduct or have conducted audits of the next lower Program organizational level.

17.1.2.10 The QAPD shall provide a summary description of an advanced planning that demonstrates control of quality-related activities including management and technical interfaces between OCRWM, the Project Office(s), and Program Participants during site characterization, design, construction, operation and closure of high-level nuclear waste repositories.

17.1.2.11 The QAPD shall describe provisions for maintaining the QAPD current.

17.1.3 DESIGN CONTROL

17.1.3.1 The QAPD shall describe the design control measures that assure that (1) applicable regulatory requirements and design bases for important items and activities are correctly translated into specifications, drawings, procedures, and instructions, for any modifications that become necessary, (2) appropriate quality standards are specified in design documents, and (3) deviations from such standards are controlled.

17.1.3.2 The QAPD shall describe measures to assure that adequate review and selection for application suitability is conducted for materials, parts, equipments, and processes that affect safety-related features of the repository. The QAPD shall describe provisions that assure that standard commercial or so-called "off-the-shelf" materials, parts, and equipment also receive adequate application review and selection before use.

17.1.3.3 The QAPD shall describe the program for applying design control measures to such aspects of design as process development and qualification; materials compatibility; and accessibility for maintenance, in process inspection, and repair and should describe measures for delineation of acceptance criteria for inspections and tests.

17.1.3.4 The QAPD shall describe measures that assure verification or checking of design adequacy, such as by design reviews, use of alternative calculational methods, or performance of a qualification testing program under the most adverse design conditions. The QAPD shall identify the positions or organizations and shall describe measures which assure that the verification or checking process is performed by individuals or groups other than those who performed the original design, but who may be from the same organization.

17.1.3.5 The QAPD shall describe measures for identifying and controlling design interfaces, both internal and external, and for coordination between participating design organizations. The QAPD shall describe measures in effect between participating design organizations for review, approval, release, distribution, collection, and storage of documents involving design interfaces and changes thereto. The QAPD shall describe how these measures will assure that these design documents are controlled in a timely manner to prevent inadvertent use of superseded design information.

17.1.3.6 The QAPD shall describe the measures that will be employed to assure that design changes, including field changes, are subject to the same design controls that were applied to the original design and are reviewed and approved by the organization that performed the original design unless the originating organization designates another responsible organization.

17.1.3.7 The QAPD shall describe measures that will be employed to assure that computer codes and models and revisions thereto are documented, verified, and validated and controlled in accordance with detailed procedures.

17.1.4 PROCUREMENT DOCUMENT CONTROL

17.1.4.1 The QAPD shall describe measures that assure that documents, and changes thereto, for procurement of material, equipment, and services, whether purchased by OCRWM, the Project Office(s), or Program Participants, correctly include or reference the following as necessary to achieve required quality:

1. Applicable regulatory, code, and design requirements,
2. Quality assurance program requirements,
3. Requirements for supplier documents such as instructions, procedures, drawings, specifications, inspection and test records, and supplier QA records to be prepared, submitted, or made available for purchaser review or approval,
4. Requirements for the retention, control, and maintenance of supplier quality assurance records,
5. Provision for purchaser's right of access to supplier's facilities and work documents for inspection and audit, and
6. Provision for supplier reporting and disposition of nonconformances from procurement requirements.

17.1.4.2 The QAPD shall describe (1) measures that clearly delineate the control responsibilities and action sequence to be taken in the preparation, review, approval, and issuance by competent personnel of procurement documents and (2) measures that assure that changes or revisions of procurement documents are subject to the same review and approval requirements as the original documents.

17.1.4.3 The QAPD shall describe measures that assure (1) that procurement documents require suppliers to have and implement a documented quality assurance program for purchased materials, equipment, and services to an extent consistent with their importance, (2) that the purchaser has evaluated the supplier before the award of the procurement order or contract to assure that the supplier can meet the procurement requirements, and (3) that procurement documents for spare or replacement items will be subject to controls at least equivalent to those used for the original supplies or equipment.

17.1.5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

17.1.5.1 The QAPD shall describe measures that assure that activities affecting quality such as site characterization, design, construction, operations, maintenance, modifications, repair, testing, inspection, and auditing are prescribed by appropriately documented instructions, procedures, or drawings and that these activities will be conducted in accordance with these documents.

17.1.5.2 The QAPD shall describe the system whereby the documented instructions, procedures, and drawings will include appropriate quantitative (such as dimensions, tolerance, and operating limits) and qualitative (such as workmanship samples and weld radiographic acceptance standards) acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.

17.1.6 DOCUMENT CONTROL

17.1.6.1 The QAPD shall describe those measures established to control the issuance of documents such as instructions, procedures, and drawings, including changes thereto, that prescribe all activities affecting quality. The description should cover control measures that assure that:

1. Documents are reviewed for adequacy (i.e., information is clearly and accurately stated) and are approved by authorized personnel for issuance and use at locations where the prescribed activity will be performed before the activity is started,

2. Means such as use of updated master document lists exist to assure that obsolete or superseded documents are replaced in a timely manner by updated applicable document revisions, and

3. Document changes are reviewed and approved by the same organizations that performed the original review and approval unless delegated by the originating organization to another responsible organization.

17.1.6.2 The QAPD shall identify the types of documents to be controlled and the group responsible for review, approval, and issuance of documents and changes thereto.

17.1.7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

17.1.7.1 The QAPD shall describe those measures that assure that material, equipment, and services purchased directly by OCRWM, the Project Office(s), or Program Participants will conform to procurement document requirements. The QAPD shall describe the measures that provide, as appropriate for:

1. Evaluation and selection of sources of supply before the award of the procurement order or contract,

2. Surveillance at the supplier's facility by the purchaser or his representative in accordance with written procedures during design, manufacture, inspection, and test of the procured item or service to verify compliance with quality requirements,

3. Source and/or receipt inspection in accordance with written procedures and acceptance criteria of procured items furnished by the supplier,

4. Documentary evidence at the site from the supplier that procured items meet procurement quality requirements such as codes, standards, or specifications. The Program Description should describe measures established by the waste form producer to (a) examine and indicate acceptance of this documented evidence during source or receipt inspection and (b) assure that this documented evidence is available at the production site prior to installation or use of the procured item and that the documentation will be retained at the site, and

5. Periodic verification of supplier's certificates of conformance to assure that they are meaningful.

17.1.7.2 The QAPD shall describe measures whereby OCRWM, the Project Office(s), and Program Participants, or their designated representative will audit and evaluate the effectiveness of the control of quality related activities of contractors and subcontractors at a frequency and extent consistent with the importance to safety, complexity, and quantity of the item or service being furnished.

17.1.8 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

The QAPD shall describe measures established to identify and control items such as materials, parts, and components, including partially fabricated assemblies to prevent use of incorrect or defective items. The QAPD shall describe measures that assure (1) that identification of the item (i.e., heat number, part number, serial number, or other appropriate marking) is maintained either on the item or on records traceable to the item and verified, as required, throughout production, processing and (2) that the method and location of the identification does not affect the function or quality of the item being identified.

17.1.9 CONTROL OF SPECIAL PROCESSES

The QAPD shall describe measures established to control special processes to assure that they are accomplished by qualified personnel using written procedures qualified in accordance with applicable codes, standards, specifications, or other special requirements. The QAPD shall describe those measures that assure that qualifications of special processes, personnel performing special processes, and equipment are kept current and that record files thereof are maintained.

17.1.10 INSPECTION

17.1.10.1 The QAPD shall describe the measures that assure that a program for inspection is established and implemented by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. The Program Description should describe measures that assure that (1) inspection personnel are appropriately qualified and are independent of the individual or group performing the activity being inspected, (2) inspections or tests are performed for each work operation as necessary to verify quality, (3) indirect control by monitoring processing methods, equipment, and personnel is used if direct inspection of processed material or products is impossible

or disadvantageous, and (4) both inspection and process monitoring are used when control is inadequate without both. The QAPD shall describe measures that assure that (1) inspection procedures and instructions are made available with necessary drawings and specifications for use prior to performing the inspections, (2) inspectors' qualifications or certifications are kept current, (3) replaced or reworked items are inspected in accordance with original inspection requirements, and (4) modified or repaired items are inspected by methods that are equivalent to the original inspection method.

17.1.10.2 The QAPD shall describe the system whereby appropriate documents will identify any mandatory sampling or inspection holdpoints that require witnessing or inspecting by the waste form producer or his designated representative and beyond which work may not proceed without the consent of his designated representative.

17.1.11 TEST CONTROL

17.1.11.1 The QAPD shall describe the measures that establish a test program that (1) identifies all testing required to demonstrate that items and services will conform to specified requirements, (2) is conducted by trained and appropriately qualified personnel in accordance with written test procedures that incorporate or reference the requirements and acceptance limits contained in applicable design documents, and (3) includes testing that will be performed in the Product and Process Qualification Phases.

17.1.11.2 The QAPD shall describe the measures that assure test procedures have provisions for assuring that:

1. All prerequisites for the given test have been met,
2. Adequate instrumentation and equipment are available, and
3. The test is performed under suitable environmental conditions and with adequate test methods.

17.1.11.3 The Program Description shall describe the system whereby test results are documented and evaluated to assure that test requirements have been satisfied.

17.1.12 CONTROL OF MEASURING AND TEST EQUIPMENT

The QAPD shall describe the measures established to assure that tools, gauges, instruments, and other measuring and testing devices used in activities affecting quality are properly identified, controlled, adjusted, and calibrated at specified periods to maintain accuracy within necessary limits. The Program Description shall describe measures that assure (1) that these devices are adjusted and calibrated against certified equipment or reference transfer standards having known valid relationships to nationally recognized standards or (2) that if no national standards exist, the basis for calibration is documented. The Program Description shall describe the measures that assure that the error of calibration standards is less than the error of production measuring and test equipment. The Program

Description shall describe provisions that will apply if measuring and test equipment is found out of calibration (1) for evaluating the validity of previous inspection or test results and the acceptability of items inspected or tested since the last calibration check and (2) for repeating original inspections or tests using calibrated equipment where necessary to establish acceptability of suspect items. The QAPD shall describe measures that assure the maintenance of records that indicate the calibration status of all items under the calibration system and that identify the measuring and test equipment.

17.1.13 HANDLING, STORAGE, AND SHIPPING

The QAPD shall describe the measures established to control the handling, storage, shipping, cleaning, and preservation of processing material and equipment and samples in accordance with work and inspection instructions to prevent damage or deterioration. The QAPD shall describe the measures for specifying and providing, when necessary for particular process steps, special protective environments such as inert gas atmosphere, specific moisture content levels, and temperature levels.

17.1.14 INSPECTION, TEST, AND OPERATING STATUS

The QAPD shall describe measures established to indicate by the use of markings such as stamps, tags, labels, routing cards, or other suitable means the status of inspections and tests performed on individual items or activities associated with site characterization, design, construction, and operation of the geologic repository system. The Program Description shall describe measures that provide for the identification of items and services that have satisfactorily passed required inspections and tests where necessary to preclude inadvertent bypassing of such inspections and tests. The Program Description shall describe the measures established for indicating the operating status of structures, systems, and components of the processing equipment and its support facilities and equipment. Such measures shall include, for example, tagging valves and switches to prevent inadvertent operation.

17.1.15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

The QAPD shall describe the measures established to control materials, parts, components, or documents that do not conform to requirements in order to prevent their inadvertent use or delivery. The QAPD shall describe measures that provide for, as appropriate, identification, documentation, segregation, disposition, and notification to affected organizations. The QAPD shall describe measures that assure that nonconforming items are reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures. The QAPD shall describe measures that control further processing or delivery pending proper disposition of the deficiency. The QAPD shall describe measures established by OCRWM and the Project Office(s): (1) for Program Participants to report to them those nonconformances concerning departures from procurement requirements that are dispositioned "use as is" or "repair" and (2) to make such nonconformance reports part of the documentation required at the repository site or to include description of the nonconformance and its disposition on certificates of conformance that are provided to the site prior to use of

material or equipment. The QAPD shall state whether periodic analyses of nonconformance reports are performed to show quality trends and whether such analyses are forwarded to management.

17.1.16 CORRECTIVE ACTION

17.1.16.1 The QAPD shall describe the measures that assure that conditions adverse to quality such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconforming in process and completed products are promptly identified and corrected.

17.1.16.2 The QAPD shall describe how, in the case of significant conditions adverse to quality, the cause of the condition is determined, corrective action is taken to preclude repetition, and the problem with its determined cause(s) and corrective action is documented and reported to appropriate levels of management.

17.1.17 QUALITY ASSURANCE RECORDS

17.1.17.1 The QAPD shall describe the measures that assure that sufficient records are maintained to furnish evidence of activities affecting quality. The QAPD shall describe how the content of such records (1) includes at least the following: test logs, results of reviews, drawings, inspections, tests, audits, monitoring of work performance, and materials and product analyses; and such data as qualifications of personnel, procedures, and equipment; (2) identifies the type of operation, and inspector or data recorder, the results, the acceptability, and action taken to correct any deficiencies noted; and (3) provides sufficient information to permit identification of the record with the item or activity to which it applies.

17.1.17.2 The QAPD shall describe the measures that assure that records will be identifiable and retrievable.

17.1.17.3 The QAPD shall describe the measures that establish requirements (consistent with OGR/B-XX concerning record submittal and retention, security, and storage facilities) for protecting records from destruction by fire, flooding, tornadoes, insects, and rodents and from deterioration by extremes in temperature and humidity.

17.1.18 AUDITS

The QAPD shall describe the program of OCRWM, the Project office(s), and Program Participants for conducting comprehensive planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.

The QAPD shall describe the program features that cover the functions listed below and should identify the positions or organizations that perform these functions.

1. External audits to be performed by OCRWM, the Project Office(s), and Program Participants,

2. Internal audits to be performed by OCRWM, the Project Office(s), and Program Participants,

3. The planning and scheduling of audits to assure that they are regularly scheduled on the basis of the status and safety importance of the activities being performed and are initiated early enough to assure effective quality assurance during production processing, maintenance, modification, repair, inspection, and testing,

4. Conduct of audits in accordance with written procedures or checklists by appropriately trained and qualified personnel not having direct responsibility in the area being audited, and

5. Documentation of audit results with review by management responsible for the area audited and, where indicated, follow-up action taken, including re-audit of the deficient areas.

ATTACHMENT 3-1

REQUIREMENTS FOR COMPUTER SOFTWARE FOR HIGH-LEVEL NUCLEAR WASTE REPOSITORY APPLICATIONS

1.0 GENERAL

This attachment provides detailed requirements for the development, maintenance, and security of computer software. It supplements Section 3 of this document and shall be used in conjunction with that section.

The attainment of software quality is dependent on the control of the entire software development process, and is not assured solely by inspection and test of the end product. This document prescribes appropriate systematic practices that shall:

(A) Reduce the likelihood of defects entering executable code during development

(B) Ensure that the end product answers the requirements of its intended application

(C) Reduce the likelihood that defects will be introduced into executable code during later maintenance and modification.

2.0 APPLICABILITY AND PREREQUISITES

The detailed requirements set forth in this attachment apply to computer software used to produce or manipulate data which is used directly in the design, analysis, and operation of repository structures, systems and components. The extent to which these requirements apply is related to the nature, complexity, and importance of the software application. Individuals or organizations involved in the development and maintenance of computer software shall have in place written policies and procedures that shall assure that the requirements of this part are implemented in a consistent and systematic manner.

3.0 TERMS AND DEFINITIONS

1. AUXILIARY SOFTWARE: (1) Software that may be easily and exactly verified, and that performs a simple function such as conversion of units, change in data format, or plotting of data in support of primary analysis software. (2) A stream of commands or sequence of streams of commands executed to utilize system maintained software, in which the system maintained software generates reportable results. Auxiliary software does not generate primary data.

2. BASELINE: As used for computer software: (1) the stage of computer software at a completed and reviewed phase of the software lifecycle; (2) approved documentation generated within or as a result of completing a phase of the software life cycle.

3. COMPUTER CODE VALIDATION: Assurance that a model as embodied in a computer code is a correct representation of the process or system for which it is intended (NUREG-0856). Usually accomplished by comparing code results to (1) physical data, or (2) a verified or validated code designed to perform the same type of analysis (e.g., benchmarking with a validated code). Peer review may be used for code validation if it is the only available means for validating a code.

4. COMPUTER CODE VERIFICATION: Assurance that a computer code correctly performs the operations specified in a numerical model (NUREG-0856). Usually accomplished by comparing code results to (1) a hand calculation, (2) an analytical solution or approximation, or (3) a verified code designed to perform the same type of analysis (benchmarking).

5. CONFIGURATION MANAGEMENT: (1) A system for orderly control of software, including methods used for labeling, changing, and storing software and its associated documentation. (2) The systematic evaluation, coordination, approval or disapproval, and implementation of all approved changes in an item of software after establishment of its configuration management.

6. CONVERSION REPORT: A written description of all modifications made to the original code or an externally available code after it was brought in-house.

4.0 SOFTWARE LIFE CYCLE

Individuals or organizations implementing software development activities shall adhere to a software life cycle model that requires that software development proceed in a traceable, planned, and orderly manner. The relative emphasis placed on each phase of the software development cycle will depend on the nature and complexity of the software being developed. Verification and/or validation of computer software is performed in two stages:

(1) by the individual generating or modifying the software

(2) by an independent individual or organization, one who did not work on the original software.

The first stage involves activities (i.e., iterations of tests and runs) to arrive at a final product. It is not required to document all of these activities performed to satisfy the software developer. The results of this stage shall, however, form the input to a verification and/or validation plan that shall be documented, reviewed and approved prior to independent tests. Each phase of the software development cycle shall provide specific attributes that shall be incorporated into verification and validation activities. The documentation for each phase of the software development cycle shall be reviewed and approved before succeeding phases can begin. An example of one such model is described below:

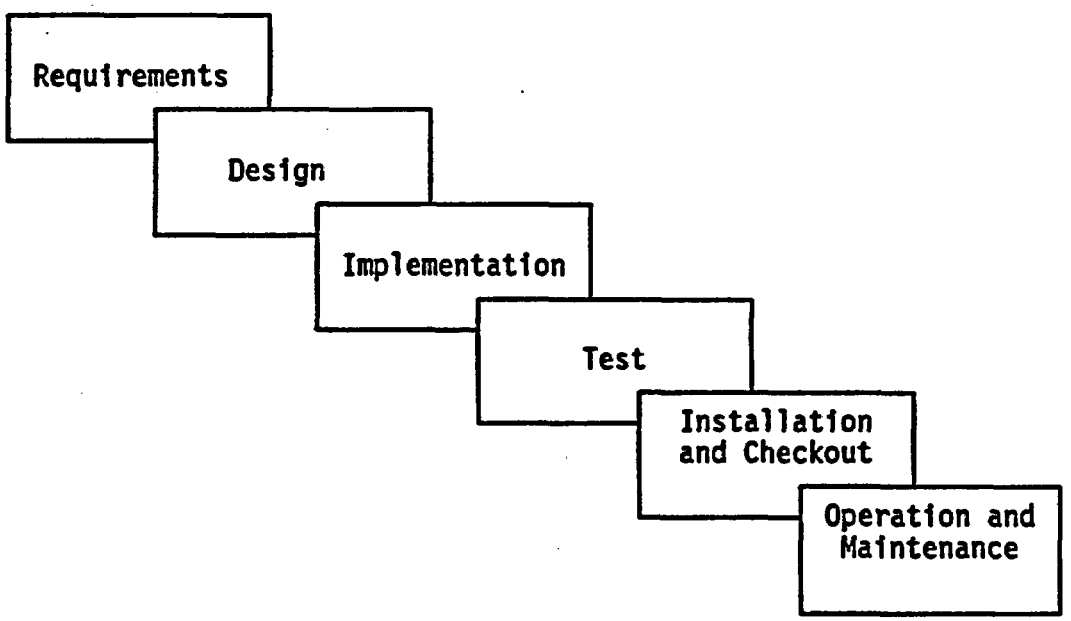


Figure 1. Representative Software Life Cycle Phases Model

The application of the software life cycle to the development and/or use of the software shall be as described in the Software Quality Assurance plan.

(A) A Software Quality Assurance plan shall be prepared for each software development/application effort at the start of the software life cycle. This plan may be prepared individually for each piece of software or may exist as a generic document to be applied to all software prepared within an organization.

The Software Quality Assurance plan shall identify:

(1) the software products to which it applies;

(2) the organizations responsible for software quality and their tasks and responsibilities;

(3) required documentation;

(4) standards, conventions, techniques, or methodologies which shall guide the software development, as well as methods to assure compliance to the same; and

(5) the required software reviews.

(B) Regardless of the life cycle model used, the following requirements shall apply as interpreted and defined by the organizations Software Quality Assurance plan.

(1) Requirements Phase

During this phase requirements that pertain to functionality, performance, design constraints, attributes, and external interfaces of the completed software shall be specified, documented, and reviewed. These requirements shall possess the following characteristics:

(a) A format and language that is understood by the programming organization and the user;

(b) Enough detail to allow for objective verification;

(c) Adequate definition to provide for the response of the software to all realizable classes of input data; and

(d) The information necessary to design the software without prescribing the software design itself.

(2) Design Phase

During the design phase a software design based on the requirements shall be specified, documented, and systematically 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.

Design phase verification and validation activities during this phase shall consist of:

(a) The generation of design-based test cases;

(b) The review and analysis of the software design and

(c) The verification of the software design.

(3) Implementation Phase

During this phase the design shall be translated into a programming language, and the implemented software shall be debugged. Only minor, if any design issues shall be resolved at this phase.

Verification and validation activities during this phase shall consist of:

(a) The possible modification of test cases necessary due to design changes made during coding; and

(b) The examination of source code listings to assure adherence to coding standards and conventions.

(4) Testing Phase

During the testing phase the design as implemented in code shall be exercised by executing the test cases. Failure to successfully execute the test cases may require the modification of the requirements, the design, the implementation, or the test plans and test cases.

Verification and validation activities during this phase shall consist of:

(a) The evaluation of the completed software to assure adherence to the requirements;

(b) The preparation of a report on the results of software verification and validation.

(5) Installation and Checkout Phase

During this phase the software becomes part of a system incorporating other software components, the hardware, and production data. The process of integrating the software with other components may consist of installing hardware, installing the program, reformatting or creating databases, and verifying that all components have been included.

Testing activities during this phase shall consist of the execution of test cases for installation and integration. Test cases from earlier phases shall be enhanced and used for installation testing.

(6) Operations and Maintenance Phase

During the operations and maintenance phase the software has been approved for operational use. Further activity shall consist of maintenance of the software to remove latent errors (corrective maintenance), to respond to new or revised requirements (perfective maintenance), or to adapt the software to changes in the software environment (adaptive maintenance). Software modifications shall be approved, documented, tested (including regression testing as appropriate), and controlled in accordance with the following section (Section 5.0, para. B).

5.0 SOFTWARE VERIFICATION AND VALIDATION

Verification and Validation activities by the responsible project organization shall employ methods such as inspection analysis, demonstration, and test to assure that the software adequately and correctly performs all intended functions; and that the software does not perform any function that either by itself or in combination with other functions can degrade the entire system.

Verification and validation activities shall be planned and performed relative to specific hardware configurations. The ratio of verification to validation activity shall be determined by the nature and complexity of the software. The results of all verification and validation activities shall be documented.

(A) VERIFICATION

Verification activities shall be integrated into all phases of the software life cycle and shall be performed to an extent proportional to the criticality of the software. Software verification shall be performed to assure that the software requirements are implemented in the software design, and the software design is implemented in code. Appropriate methods such as inspection, analysis, test, or demonstration shall be applied to accomplish verification objectives.

(B) VALIDATION

Validation activities are performed at the end of the software development cycle to demonstrate that the model as embodied in the computer software is a correct representation of the process or system for which it is intended. This is accomplished by comparing software results against verified and traceable data obtained from laboratory experiments, field experiments or observations, or in situ testing. Specific sets of data used in the validation process shall be identified and justification shall be made for their use.

When data are not available from the sources mentioned above, alternative approaches used shall be documented, including an evaluation of the degree of validity of the model. Alternative approaches may include peer review and comparisons with the results of similar analysis performed with verified software. The results of the validation shall be reported in the verification and validation documentation.

6.0 SOFTWARE CONFIGURATION MANAGEMENT

A software configuration management system shall be established to assure positive identification of software and control of all software baseline changes.

(A) CONFIGURATION IDENTIFICATION

A configuration baseline shall be identified at the completion of each major phase of the software development cycle. Approved changes to a baseline shall be added periodically to the baseline as updates. A baseline plus updates shall specify the most recent software configuration. Updates shall be incorporated into subsequent baselines. Both baselines and updates shall be defined by their composition of software configuration items.

A labeling system for configuration items shall be implemented that:

(1) uniquely identifies each configuration item;

(2) identifies changes to configuration items by revision;

(3) places the configuration item in a relationship with other configuration items and within project baselines;

(4) provides the ability to reconstruct the configuration of the software for any data from the requirements phase up to the present time.

(B) CONFIGURATION CHANGE CONTROL

The proposal for changes to baseline software shall be formally documented. This documentation shall contain a description of the proposed change, the identification of the originating organization, the rationale for the change, and the identification of affected baselines and software configuration items. The proposal shall be formally evaluated by a qualified individual or organization with the ability to approve or disapprove the proposed change. Assurance shall be provided that only authorized changes are made to software baselines.

(C) CONFIGURATION STATUS ACCOUNTING

The information that is needed to manage configuration control of software shall be recorded and reported. This information shall include a listing of the approved configuration identification, the status of proposed changes to the configuration, the implementation status of approved changes, and all information to support the functions of configuration identification, and configuration control.

7.0 DOCUMENTATION

The following is the minimum acceptable documentation of computer software developed or modified for any project. It follows the phases of the software life cycle. Additional required documentation may also be identified in the software quality assurance plan.

(A) SOFTWARE REQUIREMENTS DOCUMENTATION

A specific capability of software can be called a requirement only if its achievement can be verified by a prescribed method. Software requirements documentation shall outline the requirements that the proposed software must fulfill. The requirements shall address the following:

(1) functionality - the functions the software are to perform;

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

(3) design constraints imposed on implementation - any elements that will restrict design options;

(4) attributes - non-time-related issues of software operation such as portability, correctness, security, maintainability, etc.; and

(5) external interfaces - interactions with people, hardware, and other software.

(B) SOFTWARE DESIGN DOCUMENTATION

Software design documentation is a document or series of documents that shall contain:

(1) a description of the major components of the software design as they relate to the requirements of the software requirements specification;

(2) a technical description of the software with respect to control flow, data flow, control logic, and data structure;

(3) a description of the allowable and tolerable ranges for inputs and outputs; and

(4) the design described in a manner that is easily traceable to the software requirements.

(C) SOFTWARE IMPLEMENTATION DOCUMENTATION

Any design changes made to the Requirement and Design phase document(s) shall be assessed as to the impact on the design. The revised Requirement and Design phase documents shall be reviewed to the same level of review as the original documents. The results of this phase shall be the basis for the software verification and/or validation plan.

(D) SOFTWARE VERIFICATION AND VALIDATION DOCUMENTATION (TEST)

Software verification and validation documentation shall include a plan that describes the tasks, and criteria for accomplishing the verification of the software in each phase, and the validation of the software at the end of the development cycle. The documentation shall also specify the hardware and system software configuration pertinent to the software. The documentation shall be organized in a manner that allows traceability to both the software requirements and the software design. This documentation will also include a report on the results of the execution of the software verification and validation activities. This report shall include the results of all reviews, audits, and tests, and a summary of the status of the software.

(E) USER DOCUMENTATION

User documentation shall be prepared in accordance with NUREG-0856 and shall include a description of:

(1) program considerations, options, and initialization procedures;

(2) anticipated error situations and how the user can correct them;

(3) internal and external data files, their input sequence, structures, units and ranges;

(4) input and output options, defaults, and formats;

(5) system interface features and limitations;

(6) information for obtaining user and maintenance support; and

(7) sample problems.

8.0 REVIEWS

Reviews of software development activity shall be performed as each life cycle phase is completed to assure the completeness and integrity of each phase of development prior to proceeding to the next development phase. The procedures used for reviews shall identify the participants and their specific responsibilities during the review and in the preparation and distribution of the review report.

The documentation for all reviews shall contain a record of review comments, a plan and timetable for the resolution of the review comments, and the personnel responsible for this resolution.

After review comments are resolved, the reviewed documents shall be updated and placed under configuration management.

(A) SOFTWARE REQUIREMENTS REVIEW

The review of software requirements shall be performed at the completion of the software requirements documentation. This review shall assure that the requirements are complete, verifiable, consistent, and formatted to provide traceability of requirements throughout the development cycle. The review shall also assure that there is sufficient detail available to complete the software design.

(B) SOFTWARE DESIGN REVIEW

The software design review will be held at the completion of the software design documentation. This review shall evaluate the technical adequacy of the design approach, and assure that the design answers all the requirements in the requirements documentation. The complexity of the software design may require the performance of two design reviews; one at the completion of the overall software architecture, and the second at the completion of the total design.

(C) SOFTWARE IMPLEMENTATION REVIEW

The Software Implementation Review is an evaluation of the completed Requirements, Design, and Implementation process prior to independent Verification and/or Validation and concludes in review and approval of the Verification and/or Validation Plan.

(D) SOFTWARE VERIFICATION AND VALIDATION REVIEW

The software verification and validation review is an evaluation of the adequacy of completed software verification and validation activities and concludes in review and approval of the verification and/or validation report.

9.0 DISCREPANCY REPORTING AND CORRECTIVE ACTION

A formal procedure of software discrepancy reporting and corrective action shall be established. This discrepancy reporting system shall interface with the configuration management system to assure formal processing of discrepancy resolutions.

(A) Software discrepancy reporting and corrective action shall assure that, as a minimum;

(1) defects are documented and corrected;

(2) defects are assessed for criticality and impact as previous applications;

(3) corrections are reviewed and approved before changes to the software configuration are made; and

(4) preventive and corrective actions provide for appropriate notification of affected organizations.

10.0 MEDIA CONTROL AND SECURITY

The physical media containing the images of software shall be physically protected to prevent their inadvertent damage or degradation.

11.0 ACQUIRED SOFTWARE

(A) Requirements shall be established for controlling the transfer of computer software from an outside source to a user organization and from a user organization to an outside requesting organization. Software Transfer requests of the organization (or purchases) from an outside source shall include appropriate criteria to enable the software received to comply, as much as possible, with the requirements of this document and the needs of the organization's computer system. Those requirements not met by the software received shall be completed by the organization in the relative phase of the software life cycle that is incomplete or, if that is not possible, the reason shall be documented and maintained with the software and distributed to the users. The software shall be used only for those applications for which the documentation is complete.

(B) Configuration Management change controls shall be established for documenting the conversion of software to be used on a computer system, and/or peripheral hardware, other than that for which it was designed. Conversion includes all modifications and tests made to input/output or the source code or additional software written to run the original software on the new system. Software conversion shall be documented and maintained in the user's manual for the specific version of the software and the computer system on which it is installed. Software conversion changes shall be evaluated and activities performed in accordance with the appropriate Configuration Management system element(s).

12.0 COMPUTER SOFTWARE APPLICATION

(A) Organizations shall establish requirements for controlling the application of verified and/or validated computer software to technical calculations in support of design, analysis, and operation of repository structures, systems, and components.

(B) Organizations shall specify requirements for documenting and reviewing software applications and analyses and assuring that all results are accurate and reproducible. Requirements shall be established for identifying or otherwise marking record copies of all analyses and supporting documentation. Supporting documentation includes computer output (results), code input data including data bases and original sources/references of and assumptions used to obtain such data, code design, user's and/or operation manuals, verification/validation test results and/or hand calculations.

(C) Technical calculations using software shall be performed with applicable computer codes and with software operating procedures defined sufficiently to allow independent repetition of the entire computation.

(1) Controls shall be established for generating and documenting software used to perform technical calculations. All auxiliary software used shall be included in documentation of technical calculations performed and shall be included in independent review as part of the calculation.

(D) All application of computer software shall be independently reviewed and approved to assure that the software selected is applicable to the problem being solved and that all input data and assumptions are valid and traceable.

APPENDIX I

INSTRUCTIONS
FOR PREPARATION OF A
QUALITY ASSURANCE PROGRAM DESCRIPTION

17.0 QUALITY ASSURANCE

In order to provide assurance that the activities and items associated with site characterization, design, construction and operation of the geologic repository system are in conformance with applicable regulatory requirements, it is necessary that a quality assurance (QA) program be established by OCRWM, the Project Office(s), and Program Participants. The QA program must be established commensurate with the schedule for accomplishing the activity. Where some portions of the QA program have not yet been established at the time the QA Program Description (QAPD) is prepared because the activity will be performed in the future, the QAPD shall provide a schedule for implementation. The QA program shall meet the requirements of OCRWM/B-XX, "Quality Assurance Requirements for the High-Level Nuclear Waste Repository Program" (QAR).

In order to facilitate the presentation of the information, OCRWM, the Project Office(s) and Program Participants involved in executing the OCRWM QA Program shall prepare a QAPD in accordance with the outline presented below. It is not intended to dictate the format of any QAPD. It is required, however, that the QAPD address as a minimum, each of the QA Requirements contained in the QAR in sufficient detail to enable the reviewer to determine whether and how all of the requirements of the QAR are/will be satisfied.