MASTER

PROPOSED QUALITY ASSURANCE MANUAL
FOR THE
OFFICE OF WASTE ISOLATION

September 26, 1977
(Published May 22, 1978)

This report was prepared by NUS Corporation under subcontract 89Y-22334 with Union Carbide Corporation, Nuclear Division. The subcontract was administered by the Office of Waste Isolation.

**UNION
CARBIDE**

OFFICE OF WASTE ISOLATION
OAK RIDGE, TENNESSEE

*prepared for the U.S. DEPARTMENT OF ENERGY under
U.S. GOVERNMENT Contract W-7405 eng 26*

DISTRIBUTION OF THIS DOCUMENT IS UNLIMITED

DISCLAIMER

This report was prepared as an account of work sponsored by an agency of the United States Government. Neither the United States Government nor any agency Thereof, nor any of their employees, makes any warranty, express or implied, or assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed, or represents that its use would not infringe privately owned rights. Reference herein to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise does not necessarily constitute or imply its endorsement, recommendation, or favoring by the United States Government or any agency thereof. The views and opinions of authors expressed herein do not necessarily state or reflect those of the United States Government or any agency thereof.

DISCLAIMER

Portions of this document may be illegible in electronic image products. Images are produced from the best available original document.

REFORM

This report was prepared as an account of work sponsored by the United States Government. Neither the United States nor the Energy Research and Development Administration, nor any of their employees, nor any of their contractors, subcontractors, or their employees, makes any warranty, express or implied, or assumes any legal liability or responsibility for the accuracy, completeness or usefulness of any information, apparatus, product or process disclosed, or represents that its use would not infringe privately owned rights.

OFFICE OF WASTE ISOLATION
STATEMENT OF QUALITY ASSURANCE POLICY

The Quality Assurance Program described in this manual has been developed by the Office of Waste Isolation, Nuclear Division of the Union Carbide Corporation to assure safe, and reliable siting, design, procurement and construction, operations and decommissioning of the repository required for the National Waste Terminal Storage Program. This Quality Assurance Program was designed to meet the requirements of the U. S. Code of Federal Regulations, Title 10, Part 50, Appendix B entitled "Quality Assurance Criteria for Nuclear Power Plants". This Quality Assurance Program will be revised to meet other pertinent federal regulations that eventually become a part of the requirement for this repository.

The Quality Assurance Program applies to all activities affecting the quality of safety related functions of the geological, structural, hydrological and mechanical systems and components that prevent or mitigate the consequences of postulated actions that could cause undue risk to the health and safety of the public. The activities that fall under the auspices of this program include the site evaluation, site selection, design, procurement, fabrication, installation and testing of any system or component that is safety related and will eventually have an influence on the construction, operation and decommissioning of the repository.

The Director of the Office of Waste Isolation is responsible for the OWI commitment to meet the quality assurance objectives listed above. The Manager of OWI Quality Assurance is responsible for the preparation of this Quality Assurance Manual and the implementation of its various sections, procedures and instructions which further define the policy stated here with relation to the acceptable quality assurance criteria for the repository. Other department managers with responsibilities for activities that affect quality and who are responsible for implementing procedures and instructions required by this manual will do so by preparing and implementing departmental procedures that delineate their quality related functions and describe the interfaces with the Quality Assurance Department that occur in the process. Implementation of the Office of Waste Isolation Quality Assurance Program is to be audited at least yearly under the direction of the Quality Assurance Manager and the results of those audits reported to the Director of the Office of Waste Isolation. Changes to this manual may be made only with the approval of the OWI Manager of Quality Assurance and the Director of the Office of Waste Isolation.

Since the achievement of the objectives described in this manual require the support of all departments, adherence to this policy and the sections, procedures and instructions contained within this manual is mandatory for all OWI personnel.

President UCC/ND

Date

NOTICE

This report was prepared as an account of work sponsored by the United States Government. Neither the United States nor the United States Department of Energy, nor any of their employees, nor any of their contractors, subcontractors, or their employees, makes any warranty, express or implied, or assumes any legal liability or responsibility for the accuracy, completeness or usefulness of any information, apparatus, product or process disclosed, or represents that its use would not infringe privately owned rights.

DISTRIBUTION OF THIS DOCUMENT IS UNLIMITED

11/19

OFFICE OF WASTE ISOLATION
QUALITY ASSURANCE MANUAL

Table of Contents

<u>Section</u>	<u>Title</u>	<u>Rev. No.</u>	<u>Date</u>
i	Statement of Policy		
ii	Table of Contents		
iii	Cross Reference Matrix		
iv	Introduction		
1.0	ORGANIZATION		
2.0	QUALITY ASSURANCE PROGRAM		
3.0	DESIGN CONTROL		
4.0	PROCUREMENT DOCUMENT CONTROL		
5.0	INSTRUCTIONS, PROCEDURES AND DRAWINGS		
6.0	DOCUMENT CONTROL		
7.0	CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES		
8.0	IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS		
9.0	CONTROL OF SPECIAL PROCESSES		
10.0	INSPECTION		
11.0	TEST CONTROL		

OFFICE OF WASTE ISOLATION
QUALITY ASSURANCE MANUAL

INDEX (continued)

<u>Section</u>	<u>Title</u>	<u>Rev. No.</u>	<u>Date</u>
12.0	CONTROL OF MEASURING AND TEST EQUIPMENT		
13.0	HANDLING, STORAGE AND SHIPPING		
14.0	INSPECTION, TEST AND OPERATING STATUS		
15.0	NONCONFORMING MATERIALS, PARTS OR COMPONENTS		
16.0	CORRECTIVE ACTION		
17.0	QUALITY ASSURANCE RECORDS		
18.0	AUDITS		

CROSS REFERENCE MATRIX

OWI QUALITY ASSURANCE PLAN - GUIDES/REQUIREMENTS/STANDARDS

Section No.	Title	Chapter 12	10CFR50, App.	ANSI N45.2
		USNRC Reg. Guide 3.39, Para. No.	B - Criterion	Standard Para. No.
1.0	Organization	12.1.1	I	3.0
2.0	QA Program	12.1.2	II	2.0
3.0	Design Control	12.1.3	III	4.0
4.0	Procurement Document Control	12.1.4	IV	5.0
5.0	Instructions, Proc. & Drwgs.	12.1.5	V	6.0
6.0	Document Control	12.1.6	VI	7.0
7.0	Control of Purchased Mat'l., Equip. and Services	12.1.7	VII	8.0
8.0	Identification and Control of Mat'l., Parts, & Components	12.1.8	VIII	9.0
9.0	Control of Special Processes	12.1.9	IX	10.0
10.0	Inspection	12.1.10	X	11.0
11.0	Test Control	12.1.11	XI	12.0
12.0	Control of Measuring and Test Equip.	12.1.12	XII	13.0
13.0	Handling, Storage and Shipping	12.1.13	XIII	14.0
14.0	Inspection, Test, and Operating Status	12.1.14	XIV	15.0
15.0	Nonconforming Materials, Parts or Components	12.1.15	XV	16.0
16.0	Corrective Action	12.1.16	XVI	17.0
17.0	Quality Assurance Records	12.1.17	XVII	18.0
18.0	Audits	12.1.18	XVIII	19.0

OFFICE OF WASTE ISOLATION
QUALITY ASSURANCE MANUAL
INTRODUCTION

The Office of Waste Isolation quality assurance policy for the Repository is established by the President of Union Carbide Corporation, Nuclear Division, in the OWI Statement of Quality Assurance Policy. This policy is implemented by the Director of the Office of Waste Isolation, via the OWI Manager of Quality Assurance.

The program is governed by this OWI Quality Assurance Manual which contains the requirements and the assignment of responsibilities for implementation of the program. This manual is developed and maintained by the Manager of Quality Assurance and reviewed and approved by the Director of OWI.

This quality assurance program is unique with regard to two aspects:

1. the requirement to treat the activities related to site evaluation and selection as safety related, and
2. the requirement for OWI to develop and implement the Quality Assurance Program for the repository, although USERDA will be the licensee and may contract directly for major portions of the repository activity.

In order to treat aspect (1), this manual has been written so that repository site evaluation and selection activities are governed by the provisions contained herein.

In order to treat aspect (2), this manual has been written as though OWI was the licensee and assumes that OWI has quality assurance responsibilities for ERDA placed procurements as well as its own. These responsibilities include the establishment of quality requirements for ERDA contractors and final review and approval of ERDA procurement documentation. This assumption is consistent with OWI's present responsibilities for the preparation of the Safety Analysis Report (SAR) and other licensing activities.

The manual contains 18 sections, each section corresponding to its numerical counterpart in the XVIII Criteria of 10CFR50, Appendix B. In addition, each section complies with a corresponding requirement of ANSI N45.2 and Chapter 12 of USNRC Regulatory Guide 3.39 entitled "Standard Format and Content of License Applications for Plutonium Processing and Fuel Fabrication Plants", as indicated in the Cross Reference Matrix contained herein. If and when these criteria are changed or new criteria are developed by the USNRC for the OWI Quality Assurance Program, this manual will be revised for compliance.

QUALITY ASSURANCE MANUAL OFFICE OF WASTE ISOLATION OPERATED BY: UNION CARBIDE CORPORATION NUCLEAR DIVISION OAK RIDGE, TENNESSEE	SECTION NO. 1.0		PAGE 1 OF 4	
	REVISION NO. 0		EFFECTIVE DATE	
	DATE	APPROVED	ORGANIZATION	
			Q.A.	
TITLE ORGANIZATION			T.P.	
			F.P.	
			R.A.	
			PROC	
			DIRECTOR	

1.1.0 Purpose

This section of the Quality Assurance Manual describes the organizations responsible for establishment and execution of the quality assurance program and their relationship to the company organization. This section also delineates the authority and duties of these organizations.

1.2.0 Responsibilities

1.2.1 The Director of the Office of Waste Isolation (OWI) has the overall UCC/ND responsibility for the siting, design, construction, operation and decommissioning of the repository in accordance with applicable regulatory requirements. He is responsible for establishing the policies and requirements necessary to assure the safe and reliable accomplishment of these activities.

1.2.2 The OWI Quality Assurance Manager, hereafter referred to as the QA Manager, is responsible for establishing and executing the Quality Assurance Program described herein. He is responsible for assuring that the program satisfies the requirements of 10CFR50, Appendix B, that applicable regulatory guides have been considered and for keeping the program updated. He is also responsible for establishing a system that will ensure that all the planned actions necessary to provide adequate confidence that the repository will be sited, designed, constructed, operated and decommissioned safely and reliably, are documented and accomplished.

He will provide management with objective information concerning quality, independent of the individual or group directly responsible for performing the activity. He has the authority and organizational freedom to assure that all necessary activities affecting quality are performed properly and correctly. He is responsible for assembling and maintaining a quality assurance staff and directing its activities. He is responsible for establishing and implementing a comprehensive audit program.

1.2.3 The Technical Projects Manager is responsible for establishing and implementing a documented system, conforming to the requirements established herein, that will create, control, and disseminate the geologic criteria required to ensure the safe and reliable evaluation and selection of a site for the repository.

QUALITY ASSURANCE MANUAL	TITLE:	SECTION NO. 1.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION	ORGANIZATION	PAGE 2	OF 4

1.2.4 The Facility Projects Manager is responsible for establishing and implementing a documented system, conforming to the requirements contained herein, that will create, control and disseminate the criteria required to ensure the safe and reliable design, construction, operation and decommissioning of the repository.

1.2.5 The Regulatory Affairs Manager is responsible for establishing and implementing a documented system, conforming to the requirements established herein, that will create, control and disseminate the environmental criteria and the regulatory information and approvals required to ensure the safe and reliable siting, design, construction, operation and decommissioning of the repository.

1.2.6 The Procurement Manager is responsible for establishing and implementing a documented system, conforming to the requirements contained herein, that will create, control and disseminate the information required for the procurement of materials, services and components, from qualified suppliers, in accordance with applicable commercial, technical and quality requirements to ensure the safe and reliable evaluation and selection of a repository site and the safe and reliable design, construction, operation and decommissioning of the repository.

1.3.0 Organization

1.3.1 The organizations participating in this Quality Assurance Program are Quality Assurance, Technical Projects, Facility Projects, Regulatory Affairs, and Procurement. The Office of Waste Isolation organization is as shown in Figure 1.3.1-1 and depicts both a functional (supervisory and administrative) responsibility and an interface (quality related) responsibility.

1.3.2 Overall responsibility for the execution of the quality assurance program is assigned to the Quality Assurance Manager. He reports directly to the Director of OWI as shown in Figure 1.3.1-1. The Quality Assurance functional organization is shown in Figure 1.3.2-1.

FIGURE 1.3.1-1
OFFICE OF WASTE ISOLATION
MANAGEMENT ORGANIZATION

FIGURE 1.3.2-1
OFFICE OF WASTE ISOLATION
QUALITY ASSURANCE ORGANIZATION

QUALITY ASSURANCE MANUAL OFFICE OF WASTE ISOLATION OPERATED BY UNION CARBIDE CORPORATION NUCLEAR DIVISION OAK RIDGE, TENNESSEE	SECTION NO. 2.0		PAGE 1 OF 4
	REVISION NO. 0		EFFECTIVE DATE
	DATE	APPROVED	ORGANIZATION
TITLE QUALITY ASSURANCE PROGRAM			Q.A.
			T.P.
			F.P.
			R.A.
			PROC
			DIRECTOR

2.1.0 Purpose

This section of the Quality Assurance Manual defines the Quality Assurance Program and identifies the structures, systems, components and items to be covered by this program. It also describes the requirements for training of personnel who will perform activities affecting quality and for the review of the status and adequacy of the quality assurance program.

2.2.0 Responsibilities

2.2.1 The Quality Assurance Manager is responsible for the preparation of this manual and the establishment of procedures to implement the requirements contained herein.

2.2.2 Quality Assurance is responsible for:

- o establishing written procedures to control the performance of quality assurance activities,
- o reviewing and approving the list of structures, systems, components and items to which this program pertains,
- o establishing requirements for indoctrination and training in quality assurance matters,
- o providing indoctrination in quality assurance functions to quality assurance personnel,
- o providing assistance to other departments in indoctrination of their personnel,
- o training quality assurance personnel to perform quality assurance activities,
- o reviewing the quality assurance procedures on a scheduled basis at least once every two years.

QUALITY ASSURANCE MANUAL	TITLE: QUALITY ASSURANCE PROGRAM	SECTION NO. 2.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION		PAGE 2	OF 4

2.2.3 Technical Projects is responsible for:

- o preparing and maintaining a listing of those items related to repository geologic site evaluation and selection that are covered by the quality assurance program,
- o establishing written procedures to control the performance of quality affecting activities,
- o indoctrinating and training Technical Projects personnel to perform their assigned functions,
- o reviewing the procedures in the Technical Projects Procedures Manual on a scheduled basis at least once every two years.

2.2.4 Facility Projects is responsible for:

- o preparing and maintaining a listing of the structures, systems and components covered by the quality assurance program,
- o establishing written procedures to control the performance of quality affecting activities,
- o indoctrinating and training Facility Projects personnel to perform their assigned functions,
- o reviewing the procedures in the Facility Projects Procedures Manual on a scheduled basis at least once every two years.

2.2.5 Regulatory Affairs is responsible for:

- o preparing and maintaining a listing of those regulatory requirements related to repository site evaluation and selection and safety related structure systems and components that are covered by the quality assurance program,
- o establishing written procedures to control the performance of quality affecting activities,
- o indoctrinating and training Regulatory Affairs personnel to perform their assigned functions,
- o reviewing the procedures in the Regulatory Affairs Procedures Manual on a scheduled basis at least once every two years.

QUALITY ASSURANCE MANUAL	TITLE: QUALITY ASSURANCE	SECTION NO. 2.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION	PROGRAM	PAGE 3	OF 4

- 2.2.6 Procurement is responsible for:
- o establishing written procedures to control the performance of quality affecting activities,
 - o indoctrinating and training Procurement personnel to perform their assigned functions,
 - o reviewing the procedures in the Procurement Procedures Manual on a scheduled basis at least once every two years.
- 2.2.7 The Director of OWI is responsible for reviewing the status and adequacy of the Quality Assurance Program.
- 2.3.0 Requirements
- 2.3.1 Applicable Structures, Systems, Components and Items
- 2.3.1.1 The quality assurance program shall cover all existing safety related structures, systems, and components, including their foundations and supports. The designation of these structures, systems, and components shall be as stated in the repository SAR.
- 2.3.1.2 The Quality Assurance Program shall also cover all items relating to the safe and reliable evaluation and selection of a site for the repository. The designation of these items shall be as stated in the repository SAR.
- 2.3.1.3 Activities affecting the quality of these structures, systems, components and items shall be controlled to an extent consistent with their importance to safety.
- 2.3.1.4 These structures, systems, components, and items shall be designated as "safety related" and shall be identified in enough detail to assure they are easily recognized by all persons performing quality affecting activities.
- 2.3.2 Non-applicable Structures, Systems, Components and Items
- 2.3.2.1 Structures, systems, components and items other than those contained in paragraph 2.3.1 are designated as "non-safety related". While it is not mandatory they be treated as a part of this Quality Assurance Program, "non-safety related" technical work on the repository project the work so the quality of the work can be readily assured.
- 2.3.2.2 The method of establishing and implementing controls for the purpose of performing "non-safety related" technical work is the prerogative of the OWI Quality Assurance Manager but requires the approval of the Director of OWI.

QUALITY ASSURANCE MANUAL	TITLE: QUALITY ASSURANCE	SECTION NO. 2.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION	PROGRAM	PAGE 4	OF 4

2.3.3 Documentation

2.3.3.1 The Quality Assurance Program shall be documented in this Quality Assurance Manual and implementing quality procedures manuals.

2.3.3.2 The Quality Assurance Manual shall contain the policies, requirements, and assignment of responsibilities which govern the Quality Assurance Program.

2.3.3.3 Detailed instructions for implementation of the Quality Assurance Program shall be contained in Quality Procedures. Each of the organizations participating in the Quality Assurance Program is responsible for developing and implementing the procedures it requires to carry out its assigned responsibilities in the Quality Assurance Manual.

2.3.3.4 The Quality Assurance Manual and Quality Assurance Procedures Manual shall be contained in one binder maintained by Quality Assurance.

2.3.3.5 The Procedures developed by the other organizations shall be contained in separate binders and maintained by Technical Projects, Facility Projects, Regulatory Affairs, and Procurement.

2.3.4 Training

2.3.4.1 Indoctrination and training of personnel performing activities affecting quality shall be provided as necessary to assure that suitable proficiency is achieved and maintained.

2.3.4.2 The indoctrination and training shall include familiarity with the requirements of the Quality Assurance Manual and applicable quality assurance procedures as well as knowledge of the procedures for performing the specific activity.

2.3.4.3 Indoctrination and training shall be performed whenever a new procedure is issued or a major revision is made to an existing procedure.

2.3.5 Status

2.3.5.1 The status and adequacy of the Quality Assurance Program shall be reviewed every two years. Each organization is responsible for reviewing that part of the program which they are implementing.

2.3.5.2 The results of these reviews shall be documented in written reports. These reports shall be reviewed and consolidated by Quality Assurance and submitted to the Director of the Office of Waste Isolation.

QUALITY ASSURANCE MANUAL OFFICE OF WASTE ISOLATION OPERATED BY UNION CARBIDE CORPORATION NUCLEAR DIVISION OAK RIDGE, TENNESSEE	SECTION NO. 3.0		PAGE 1 OF 4
	REVISION NO. 0		EFFECTIVE DATE
	DATE	APPROVED	ORGANIZATION
			Q.A.
			T.P.
			F.P.
TITLE DESIGN CONTROL			R.A.
		N/A	PROC
			DIRECTOR

3.1.0 Purpose

This section of the Quality Assurance Manual establishes measures to assure that the configuration of structures, systems, and components covered by the Quality Assurance Program, as described in applicable engineering drawings and specifications, is controlled. This section contains the requirements for control of modifications and additions to these structures, systems, and components from initiation of a Design Change Request through design and to work authorization.

3.2.0 Responsibilities

3.2.1 The Quality Assurance Manager is responsible for developing a procedure to establish a system for design control at OWI.

3.2.2 Quality Assurance disciplines are responsible for:

- o developing procedures within their disciplinary responsibilities that implement the requirements of this section of the manual with regard to the review of design criteria, specifications, drawings, standards, etc.,
- o reviewing design criteria, specifications, drawings, standards, etc. for the purpose of determining their conformance to this section of the manual and the establishment of suitable quality criteria,
- o reviewing and approving deviations from standard quality criteria, and
- o surveilling the entire design control activity for conformance to this section of the manual.

3.2.3 Technical Projects is responsible for:

- o developing procedures for the control of geologic site evaluation and selection activities,
- o establishing geologic criteria for repository site evaluation and selection,

QUALITY ASSURANCE MANUAL	TITLE:	SECTION NO. 3.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION	DESIGN CONTROL	PAGE 2	OF 4

- o preparing, reviewing and approving criteria documents and changes thereto for geologic site evaluation and selection, and
- o maintaining records of criteria and criteria control documents for geologic site evaluation and selection.

3.2.4 Facility Projects is responsible for:

- o review and approval of criteria and documents for repository site evaluation and selection,
- o developing procedures for the control of design and design criteria with regard to safety related structures, systems and components,
- o establishing design criteria for safety related structures, systems and components,
- o preparing, reviewing and approving design documents and changes thereto for repository site evaluation and selection,
- o reviewing, approving and controlling deviations from codes and standards,
- o performing design verifications and safety analyses, and
- o maintaining records of design and design control documents for safety related structures, systems and components.
- o reviewing, approving and incorporating design change requests.

3.2.5 Regulatory Affairs is responsible for:

- o developing procedures for the control of environmental site evaluation and selection activities,
- o establishing environmental criteria for repository site evaluation and selection,
- o preparing, reviewing and approving criteria documents and changes thereto for environmental site evaluation and selection,
- o maintaining records of criteria and criteria documents for environmental site evaluation and selection,
- o ensuring that design verifications and safety analyses are performed in accordance with the applicable regulatory requirements, and
- o reviewing and approving deviations from regulatory standards.

QUALITY ASSURANCE MANUAL	TITLE:	SECTION NO. 3.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION	DESIGN CONTROL	PAGE 3 OF 4	

3.2.6 The Director of OWI shall review and approve any deviation from codes and standards that is determined to be safety related.

3.3.0 Requirements

3.3.1 Criteria and requirements for repository site evaluation and selection and for design of safety related structures, systems and components covered by this Quality Assurance Program shall be described by up-to-date engineering specifications and drawings as necessary to reflect applicable and approved regulatory requirements and the plant design basis as defined in the SAR. The specifications and drawings shall contain the technical, quality and documentation requirements necessary for the particular structure, system, or component. Existing engineering drawings shall be revised to include changes resulting from repository modifications.

3.3.2 All design control procedures shall provide for review of the design, including changes and modifications thereto, by an individual or individuals other than the ones who were responsible for the design, and who are technically competent in the area being reviewed.

3.3.3 Design Control Procedures shall be established to describe the design process from inception through final approval, release and distribution. The procedures shall provide for review of stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance, and repair; and acceptance criteria for inspections and tests.

3.3.4 Regulatory requirements, and applicable codes and standards shall be delineated for all proposed repository designs and modifications. These requirements shall be translated into specifications, drawings, and procedures by the appropriate design engineer and reviewed and approved as required by procedures. Appropriate quality standards shall be specified to assure that the modification will meet the design requirements.

3.3.5 Work authorization procedures will state that required documents and approvals are complete prior to the start of work on the repository. These procedures shall provide for verification by Quality Assurance that work is authorized to start.

3.3.6 Modifications shall be initiated by a design change request. Design change requests may be initiated by Technical Projects, Facility Projects, or Regulatory Affairs based on system or equipment deficiencies, new vendor requirements, design deficiencies or additional regulatory requirements.

QUALITY ASSURANCE MANUAL	TITLE: DESIGN CONTROL	SECTION NO. 3.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION		PAGE 4	OF 4
<div data-bbox="218 327 300 366">3.3.7</div> <div data-bbox="399 327 1427 600">Design and criteria changes, including field changes, shall be reviewed and approved in accordance with the same procedures as the original design or criteria. In general, changes shall be reviewed and approved by the organizations or individuals that performed the original review and approval. Where this is not practical, other responsible organizations or individuals may be designated, provided they have access to pertinent background information and are competent in the specific technical area.</div>			

QUALITY ASSURANCE MANUAL OFFICE OF WASTE ISOLATION OPERATED BY UNION CARBIDE CORPORATION NUCLEAR DIVISION OAK RIDGE, TENNESSEE	SECTION NO. 4.0		PAGE 1 OF 3	
	REVISION NO. 0		EFFECTIVE DATE	
	DATE	APPROVED	ORGANIZATION	
			Q.A.	
TITLE PROCUREMENT DOCUMENT CONTROL			T.P.	
			F.P.	
			R.A.	
			PROC	
			DIRECTOR	

4.1.0 Purpose

This section of the Quality Assurance Manual establishes the measures to assure that applicable regulatory requirements, design bases and other requirements which are necessary to assure adequate quality, are suitably included or referenced in the documents for procurement of material, equipment and services. Provisions of this section apply to both OWI and ERDA procurement documents that relate to either site evaluation and selection or safety related structures, systems and components for the repository.

4.2.0 Responsibilities

4.2.1 The Quality Assurance Manager shall be responsible for developing a procedure to establish a system for procurement document control at OWI.

4.2.2 Procurement Quality Assurance is responsible for establishing a procedure to control the preparation, review, and approval of purchase requisitions for material, equipment, and services covered by the Quality Assurance Program.

4.2.3 Procurement is responsible for preparing procedures which detail how purchase orders are prepared, reviewed, approved, issued and controlled. Procurement is also responsible for preparing, reviewing, approving, issuing, and controlling purchase orders in accordance with the requirements of this manual.

4.2.4 Technical Projects is responsible for preparing specifications which detail the technical and quality requirements for procured material, equipment and services required for geologic site evaluation and selection of the repository. They are also responsible for preparing purchase requisitions for the same and are responsible for reviewing and approving the finalized procurement document prior to issuance.

4.2.5 Facility Projects is responsible for preparing engineering specifications which detail the technical and quality requirements for material, equipment, and services for safety related structures, systems and components. They are also responsible for preparing purchase requisitions for material, equipment, and services required for the same and are responsible for reviewing and approving the finalized procurement document prior to issuance.

QUALITY ASSURANCE MANUAL	TITLE: PROCUREMENT	SECTION NO. 4.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION	DOCUMENT CONTROL	PAGE 2	OF 3

4.2.6 Regulatory Affairs is responsible for preparing specifications which detail the technical and quality requirements for procured material, equipment and services required for environmental site evaluation and selection of the repository. They are also responsible for preparing purchase requisitions for the same and are responsible for reviewing and approving the finalized procurement document prior to issuance.

4.3.0 Requirements

4.3.1 Purchase requisitions for material, equipment, and services shall be initiated only by designated individuals in Technical Projects, Facility Projects and Regulatory Affairs. The purchase requisition shall contain the information such as quantity, item description, and technical and quality requirements necessary for procurement of the item. The purchase requisition shall invoke the requirements of applicable specifications and drawings when the technical and quality requirements for the item are contained in them.

4.3.2 Purchase requisitions shall include or invoke specifications which contain all the information necessary to assure that material, equipment and services are of adequate quality. This shall include material selection, design data, equipment description, examination and testing requirements, cleaning and packaging requirements, and required documentation.

4.3.3 Documentation required to provide evidence that materials, equipment, and services are of adequate quality shall be clearly delineated in purchasing documents. This shall include a listing of each item of documentation to be submitted, when the documentation is to be submitted, what documentation requires approval prior to manufacture, and who the documentation shall be submitted to.

4.3.4 To the extent necessary, procurement documents shall require suppliers of material, equipment, and services to have a quality assurance program complying with the pertinent provisions of 10CFR50, Appendix B. Suppliers shall be required to provide OWI access to their facilities and records for inspection and audit as required to determine compliance with provisions of the purchase order. These requirements shall extend to lower tier procurements as well.

4.3.5 Purchase requisitions and engineering specifications shall be reviewed by Quality Assurance to assure that all necessary technical and quality requirements are included or referenced.

4.3.6 Purchase orders shall be prepared based on the information contained in the purchase requisition. Purchase orders shall be reviewed prior to issuance by the originator of the purchase requisition and Quality Assurance to assure that all required information is correctly translated from the purchase requisition.

4.3.7 Changes in procurement documents shall be initiated and reviewed in

QUALITY ASSURANCE MANUAL	TITLE: PROCUREMENT	SECTION NO. 4.1	REVISION NO. 0
OFFICE OF WASTE ISOLATION	DOCUMENT CONTROL	PAGE 3 OF 3	

accordance with the same procedures utilized in preparation of the original document.

QUALITY ASSURANCE MANUAL OFFICE OF WASTE ISOLATION OPERATED BY UNION CARBIDE CORPORATION NUCLEAR DIVISION OAK RIDGE, TENNESSEE	SECTION NO. 5.0		PAGE 1 OF 2
	REVISION NO. 0		EFFECTIVE DATE
	DATE	APPROVED	ORGANIZATION
			Q.A.
			T.P.
TITLE INSTRUCTIONS, PROCEDURES AND DRAWINGS			F.P.
			R.A.
			PROC
			DIRECTOR

5.1.0 Purpose

This section of the Quality Assurance Manual establishes the requirements for prescribing and accomplishing safety related activities in accordance with documented and approved drawings, specifications, standards, instructions and procedures.

5.2.0 Responsibilities

5.2.1 The Quality Assurance Manager is responsible for preparing a procedure that establishes a system of accomplishing safety related activities in accordance with properly documented and approved documents.

5.2.2 Quality Assurance is responsible for developing and approving Quality Assurance documents to implement the requirements of this section of the manual. Quality Assurance is also responsible for the review of the documents developed by other departments and/or sections of OWI for the purpose of satisfying the requirements of this manual.

5.2.3 Technical Projects is responsible for developing and approving Technical Project documents required by this Quality Assurance Program.

5.2.4 Facility Projects is responsible for developing and approving Facility Project documents required by this Quality Assurance Program.

5.2.5 Regulatory Affairs is responsible for developing and approving Regulatory Affairs documents required by this Quality Assurance Program.

5.2.6 Procurement is responsible for developing and approving Procurement documents required by this Quality Assurance Program.

5.3.0 Requirements

5.3.1 Instructions, procedures, or drawings shall delineate the method and sequence by which an activity is to be performed. These documents shall include appropriate quantitative or qualitative acceptance criteria for determining that the activity has been satisfactorily performed.

QUALITY ASSURANCE MANUAL		TITLE:	SECTION NO.	REVISION NO.
OFFICE OF WASTE ISOLATION		INSTRUCTIONS, PROCEDURES AND DRAWINGS	5.0	0
			PAGE 2	OF 2
5.3.2	The department responsible for an activity shall be required to provide the necessary review and approval for instructions, procedures or drawings. The documents shall be reviewed and approved prior to performing the activity.			
5.3.3	Changes to or deviations from established instructions, procedures, or drawings will require the same review and approval as the original released document. Temporary changes to operating procedures which do not change the intent of the original procedure may be made in accordance with applicable and approved procedures.			
5.3.4	Design Control, Procurement Document Control, Document Control and other applicable sections of the Quality Assurance Manual shall be followed in the review, processing of changes or deviations, filing and distribution of procedures, drawings and specifications.			
5.3.5	Detailed instructions for operation of the repository shall be contained in procedures and checklists covering the following activities:			
	<ul style="list-style-type: none">a. administrative controlb. general repository operationc. startup, operation, and maintenance of safety related systemsd. correction of abnormal, offnormal, or alarm conditionse. combat of emergencies and other significant eventsf. radiation and contamination controlg. control of measuring and test equipmenth. chemical and radiochemical process controli. waste handling and storagej. others as required			
5.3.6	Instructions for maintenance and repair shall be contained in procedures. These procedures shall contain detailed instructions for preparation, performance, and checkout and return to service. The procedures shall reference manufacturer's instruction manuals, drawings, and other sources, as applicable.			
5.3.7	Detailed instructions for making plant modifications shall be contained in engineering specifications and drawings and work procedures.			
5.3.8	Design control, review, and approval shall be conducted in accordance with Technical Project and Facility Project procedures.			
5.3.9	Purchase order control, review, and approval shall be conducted in accordance with Procurement Department procedures.			

QUALITY ASSURANCE MANUAL OFFICE OF WASTE ISOLATION OPERATED BY UNION CARBIDE CORPORATION NUCLEAR DIVISION OAK RIDGE, TENNESSEE	SECTION NO. 6.0		PAGE 1 OF 2	
	REVISION NO. 0		EFFECTIVE DATE	
	DATE	APPROVED	ORGANIZATION	
			Q.A.	
			T.P.	
TITLE DOCUMENT CONTROL			F.P.	
			R.A.	
			PROC	
			DIRECTOR	

6.1.0 Purpose

This section of the Quality Assurance Manual establishes the requirements for controlling the issuance of procedures, standards, instructions, drawings, and specifications, including revisions thereto.

6.2.0 Responsibilities

6.2.1 The Quality Assurance Manager shall be responsible for developing a standard procedure that establishes a systematic method for the issuance of procedures, standards, drawings, instructions and specifications required by the Quality Assurance Program.

6.2.2 Quality Assurance is responsible for developing procedures that implement the requirements of this section of the manual with regard to the issuance and control of quality assurance documents. Quality Assurance is also responsible for the proper issuance and control of these documents and for the surveillance of document control activities for conformance to the requirements of this section of the manual.

6.2.3 Technical Projects is responsible for developing procedures that implement the requirements of this section of the manual with regard to the issuance and control of Technical Project documents. Technical Projects is also responsible for the issuance of these documents.

6.2.4 Facility Projects is responsible for developing procedures that implement the requirements of this section of the manual with regard to the issuance and control of Facility Project documents. Facility Projects is also responsible for the issuance of these documents.

6.2.5 Regulatory Affairs is responsible for developing procedures that implement the requirements of this section of the manual with regard to the issuance and control of Regulatory Affairs documents. Regulatory Affairs is also responsible for the issuance of these documents.

6.2.6 Procurement is responsible for developing procedures that implement the requirements of this section of the manual with regard to the issuance and control of Procurement documents. Procurement is also responsible for the issuance of these documents.

QUALITY ASSURANCE MANUAL	TITLE: DOCUMENT CONTROL	SECTION NO. 6.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION		PAGE 2	OF 2

6.3.0 Requirements

6.3.1 Procedures shall be established to control the issuance of instructions, procedures, standards, drawings and specifications covered by the Quality Assurance Program. A standard document control procedure shall be prepared to provide a uniform system of document identification and control. Separate procedures shall be prepared for the control of documents within Quality Assurance, Technical Projects, Facility Projects, Planning and Analysis, Regulatory Affairs, and Procurement in accordance with the standard system.

6.3.2 All documents shall be assigned a control number, title, date, and revision number. Documents shall be filed and controlled by use of this identification. Each type of document shall be filed in a central location identified in the standard document control procedure.

6.3.3 Drawings, standards, specifications, instructions and procedures, including revisions, shall be reviewed for adequacy and approved for release by authorized personnel. The required reviews and approvals shall be clearly delineated in document control procedures for each type of document.

6.3.4 Quality Assurance, Technical Projects, Facility Projects, Regulatory Affairs and Procurement shall assure that current documents are distributed to and used at the location where the prescribed activity is performed. Documents and revisions shall be distributed in accordance with predetermined distribution lists. Superseded documents shall be controlled to prevent their inadvertent use. Preliminary documents shall be clearly identified and closely controlled to preclude their inadvertent use.

6.3.5 Document control procedures shall provide for filing of documents in the records system following their use.

6.3.6 An index of each type of document shall be established and distributed to provide the current status of documents. The index shall contain at least the following information:

- a. Title
- b. Control Number
- c. Latest Revision
- d. Revision Date
- e. Originator of Document

6.3.7 Revisions to documents shall be reviewed and approved by the same procedures as the original document.

QUALITY ASSURANCE MANUAL OFFICE OF WASTE ISOLATION OPERATED BY UNION CARBIDE CORPORATION NUCLEAR DIVISION OAK RIDGE, TENNESSEE	SECTION NO. 7.0		PAGE 1 OF 3	
	REVISION NO. 0		EFFECTIVE DATE	
	DATE	APPROVED	ORGANIZATION	
			Q.A.	
TITLE CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES			T.P.	
			F.P.	
			R.A.	
			PROC	
			DIRECTOR	

7.1.0 Purpose

This section of the Quality Assurance Manual establishes the requirements to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. The provisions of this section also apply to material, equipment or services purchased directly by ERDA for the repository.

7.2.0 Responsibilities

7.2.1 The Quality Assurance Manager is responsible for developing a procedure to establish a system for control of purchased material, equipment and services.

Procurement Quality Assurance is responsible for:

- o developing and implementing procedures for source evaluation, source selection, supplier audits, source inspection and receiving inspection activities,
- o coordinating supplier evaluation and selection activities,
- o evaluating supplier quality assurance programs,
- o performing supplier audits.

7.2.3 Technical Projects is responsible for evaluating the technical capabilities of suppliers providing material, equipment or services for the geologic site evaluation and selection of the repository.

7.2.4 Facility Projects is responsible for evaluating the technical capabilities of suppliers providing material, equipment or services for safety related structures, systems or components for the repository.

7.2.5 Regulatory affairs is responsible for evaluating the technical capabilities of suppliers providing material, equipment or services for the environmental site evaluation and selection of the repository.

7.2.6 Procurement is responsible for:

- o evaluating the commercial and industrial capabilities of suppliers,

QUALITY ASSURANCE MANUAL	TITLE: CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES	SECTION NO. 7.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION		PAGE 2	OF 3

- o developing and implementing procedures for the overall scope of supplier evaluation and selection,

- o maintaining a Qualified Supplier List.

7.3.0 Requirements

7.3.1 Supplier Qualification

Qualification of suppliers shall depend upon OWI's experience with the supplier, the supplier's reputation and experience in the field, and in the nuclear industry, and his quality assurance program and other factors, as appropriate. Qualification of suppliers not on the OWI Qualified Suppliers List maintained by Procurement shall be accomplished by a detailed evaluation which shall include an audit of or assessment of suppliers management capability, financial resources, plant facilities, and his compliance with applicable commercial, technical and quality assurance requirements. Visits to contractor's or supplier's facilities shall be made when necessary to assist in the evaluation process.

7.3.2 Source Surveillance

7.3.2.1 Suppliers shall be required to furnish OWI with sufficient information concerning their manufacturing and inspection plan to permit OWI to plan and implement a source surveillance plan if required.

7.3.2.2 Surveillance plans shall include witness and hold points for inspection of items, witnessing of processes or tests, and audit of required quality documentation.

7.3.3 Receiving Inspection

7.3.3.1 Items shall be examined upon receipt at the repository or sample storage facility for shipping damage, correctness of identification, and specified quality documentation.

7.3.3.2 Documentary evidence that safety related items conform to purchase order requirements shall be available at the repository or sample storage facility prior to installation or use of the item.

7.3.3.3 Documentary evidence shall be sufficient to identify the specific requirements such as codes, standards, and specifications met by the purchased item. This requirement shall be satisfied by having available at the repository or sample storage facility copies of the purchase order and all documents referenced therein.

QUALITY ASSURANCE MANUAL	TITLE: CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES	SECTION NO. 7.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION		PAGE 3	OF 3

- 7.3.3.4 All materials, parts, and components will be tagged with hold tags upon receipt and will be placed in a receiving inspection hold area separate from stocking areas. After acceptance, the material will be retagged with an accept tag and placed in specified stocking areas.
- 7.3.3.5 During receiving inspection, if a nonconformance or discrepancy exists, the material shall be tagged with a hold tag and will remain in a hold status. A material deficiency report shall be initiated in accordance with Section 15 of this manual.
- 7.3.3.6 Items dispositioned as unacceptable for use shall be retagged with a reject tag, and removed from the controlled receiving inspection area.

QUALITY ASSURANCE MANUAL OFFICE OF WASTE ISOLATION OPERATED BY UNION CARBIDE CORPORATION NUCLEAR DIVISION OAK RIDGE, TENNESSEE	SECTION NO. 8.0		PAGE 1 OF 2
	REVISION NO. 0		EFFECTIVE DATE
	DATE	APPROVED	ORGANIZATION
			Q.A.
			T.P.
TITLE IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS			F.P.
		N/A	R.A.
			PROC
			DIRECTOR

8.1.0 Purpose

This section of the Quality Assurance Manual establishes the requirements for identification and control of material, parts, components and test samples from receipt through installation, storage or use.

8.2.0 Responsibilities

8.2.1 The Quality Assurance Manager is responsible for establishing the procedure for the identification and control of material, parts, components and test samples from receipt through installation, storage or use.

8.2.2 Siting, Construction and Operations Quality Assurance are responsible for developing procedures that implement the requirements of this section of the manual for each of their disciplinary responsibilities. They are also responsible for surveilling this activity in each of their areas for conformance to this section of the manual.

8.2.3 Technical Projects is responsible for developing and implementing a procedure that establishes a method by which specifications, drawings and test procedures are annotated to denote the identification and serialization required for test samples having to do with the geologic site evaluation and selection.

8.2.4 Facility Projects is responsible for developing and implementing a procedure that establishes a method by which specifications, drawings, standards and test procedures are annotated to denote the identification and serialization required for safety related systems, components and parts.

8.2.5 Procurement is responsible for developing and implementing a procedure that establishes a method for passing on the identification, serialization and control requirements to contractors and suppliers via formal procurement documentation. This procedure shall also provide a method of tying the purchasing documentation number into the overall identification, serialization and control requirements of this section.

QUALITY ASSURANCE MANUAL	TITLE: IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS	SECTION NO. 8.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION		PAGE 2 OF 2	

8.3.0 Requirements

8.3.1 Approved instructions and procedures shall be implemented for the identification and control of materials, parts, components and test samples from receipt through installation, storage or use. An identification system shall be established for identification of material, parts, components and test samples.

8.3.2 Engineering specifications shall require that materials, parts, and components be identified in accordance with formal procedures and shall require that documentation have identification providing traceability to the item.

8.3.3 Physical identification shall be used to the maximum extent possible for relating an item at any time to applicable documentation. Identification shall be either on the item or records traceable to the item. Where physical identification is impractical, physical separation, procedural control, or other appropriate means shall be employed.

QUALITY ASSURANCE MANUAL OFFICE OF WASTE ISOLATION OPERATED BY UNION CARBIDE CORPORATION NUCLEAR DIVISION OAK RIDGE, TENNESSEE	SECTION NO. 9.0		PAGE 1 OF 3	
	REVISION NO. 0		EFFECTIVE DATE	
	DATE	APPROVED	ORGANIZATION	
			Q.A.	
			T.P.	
			F.P.	
TITLE CONTROL OF SPECIAL PROCESSES		N/A	R.A.	
		N/A	PROC	
			DIRECTOR	

9.1.0 Purpose

This section of the Quality Assurance Manual establishes the measures necessary to assure that special processes are controlled in a manner necessary to provide the quality required. A special process is normally defined as a process that affects an item in such a way that visual inspection after the process has been accomplished cannot verify whether the process has been accomplished satisfactorily or not. In this light, processes such as welding, heat treating, plating, bonding, cleaning and nondestructive evaluation and other like processes are identified as special. For the purpose of the repository, core drilling, geophysical testing, down hole hydrological testing, and bore hole plugging are also identified as special processes.

Because of the peculiarity of these processes, additional steps must be taken to assure item quality and the process must be accomplished by qualified personnel using qualified procedures that are in accordance with established codes, standards, specification, and other special criteria and requirements.

9.2.0 Responsibilities

9.2.1 Quality Assurance is responsible for:

- o Establishing procedures which describe how personnel and procedures are qualified for accomplishing special processes.
- o Monitoring the accomplishment of special processes to ensure they are performed correctly.
- o Preparation and implementation of nondestructive evaluation procedures.
- o Qualification of personnel in the nondestructive evaluation process.
- o Maintenance of records of qualified personnel and procedures.

QUALITY ASSURANCE MANUAL	TITLE: CONTROL OF SPECIAL PROCESSES	SECTION NO. 9.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION		PAGE 2	OF 3

9.2.2 Technical Projects is responsible for:

- o Preparation of standards that denote the requirements for the control of both personnel and procedures that relate to the special processes of core drilling, geophysical testing, down hole hydrological testing and bore hole plugging.
- o Preparation and implementation of procedures for the processes listed above.
- o Qualification of personnel and procedures for the processes listed above.

9.2.3 Facility Projects is responsible for:

- o Preparation and implementation of procedures for special processes other than those listed in paragraphs 9.2.1 and 9.2.2.
- o Qualification of personnel and procedures for special processes other than those listed in paragraphs 9.2.1 and 9.2.2.

9.3.0 Requirements

9.3.1 Special processes shall be accomplished under controlled conditions in accordance with applicable codes, standards, specifications and other special criteria and requirements, using qualified personnel and procedures. Qualification of personnel and procedures shall comply with the requirements of established codes and standards. In the case of special processes that are unique to assuring the safe construction of the repository (e.g. core drilling) and where established codes and standards are not yet available, qualification of personnel and procedures shall comply with the requirements set forth in the standards prepared by the Technical Projects section.

9.3.2 Welders and welding procedures shall be qualified in accordance with the applicable industry codes. Records of the test results obtained in welding procedure and welder performance qualifications and a listing of qualified personnel and procedures shall be maintained.

9.3.3 Nondestructive evaluation personnel shall be qualified in accordance with the American Society for Nondestructive Testing Standard SNT-TC-1A. Records of training, test results, and a listing of qualified personnel shall be maintained.

9.3.4 Personnel and/or laboratories performing core drilling, geophysical testing, down hole hydrological testing and bore hole plugging shall be qualified in accordance with standards that are prepared by the Technical Projects section.

QUALITY ASSURANCE MANUAL	TITLE: CONTROL OF SPECIAL PROCESSES	SECTION NO. 9.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION		PAGE 3	OF 3
<p>9.3.5 A detailed Quality Assurance implementing procedure shall be established to describe the requirements for qualification of personnel and procedures.</p> <p>9.3.6 Equipment used for accomplishing special processes shall be calibrated, maintained, stored, handled, and issued in accordance with recognized standards.</p>			

QUALITY ASSURANCE MANUAL OFFICE OF WASTE ISOLATION OPERATED BY UNION CARBIDE CORPORATION NUCLEAR DIVISION OAK RIDGE, TENNESSEE	SECTION NO. 10.0		PAGE 1 OF 2
	REVISION NO. 0		EFFECTIVE DATE
	DATE	APPROVED	ORGANIZATION
			Q.A.
TITLE INSPECTION		N/A	T.P.
		N/A	F.P.
		N/A	R.A.
			PROC
			DIRECTOR

10.1.0 Purpose

This section of the Quality Assurance Manual establishes a program and the requirement for the inspection of all safety related activities to verify that those activities conform to the approved procedures, drawings, instructions, and specifications.

10.2.0 Responsibilities

10.2.1 The Quality Assurance Manager is responsible for establishing the procedures to implement the requirements for an inspection program.

10.2.2 The Design Quality Assurance discipline is responsible for assuring that adequate inspection criteria is contained in engineering drawings, standards, specifications and procedures.

10.2.3 Siting, Construction and Operations Quality Assurance are responsible for establishing inspection procedures and ensuring that adequate inspection requirements are included in manufacturing, test, assembly and installation procedures for each of their respective disciplines. They are also responsible for performing required inspections with properly qualified personnel.

10.2.4 The Procurement Quality Assurance discipline is responsible for ensuring that adequate inspection criteria is contained in procurement documentation and that contractors and suppliers have established inspection programs consistent with the requirements of this section of the manual.

10.3.0 Requirements

10.3.1 Inspections shall only be performed by qualified personnel. In no case shall the inspection be performed by the individual who performed the activity.

QUALITY ASSURANCE MANUAL	TITLE: INSPECTION	SECTION NO. 10.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION		PAGE 2	OF 2

- 10.3.2 Surveillance of personnel, procedures, and equipment shall be provided where inspection of an activity is impossible or disadvantageous.
- 10.3.3 Mandatory inspection hold points, which require witnessing or inspecting of an activity before proceeding, shall be indicated in the appropriate procedures or specifications. The inspection shall be documented to indicate approval and release prior to continuation of the activity.
- 10.3.4 Inspection requirements shall apply to all activities whether performed by company personnel or contractor personnel.

QUALITY ASSURANCE MANUAL OFFICE OF WASTE ISOLATION OPERATED BY UNION CARBIDE CORPORATION NUCLEAR DIVISION OAK RIDGE, TENNESSEE	SECTION NO.		PAGE 1 OF 3	
	11.0			
	REVISION NO.		EFFECTIVE DATE	
	0			
TITLE TEST CONTROL	DATE	APPROVED	ORGANIZATION	
			Q.A.	
			T.P.	
			F.P.	
			R.A.	
		N/A	PROC	
		DIRECTOR		

11.1.0 Purpose

This section of the Quality Assurance Manual establishes the requirements for a test program to demonstrate that safety related structures, systems, and components will perform satisfactorily in service. In addition, this section establishes the requirements for a test program of a core drilling, geophysical testing, down hole hydrological testing and bore hole plugging that will provide the basis for the objective and accurate determination of repository siting. The test program shall include, but not be limited to, surveillance testing, special tests, sample testing, environmental testing, post maintenance testing, physical testing, and testing following modification or significant changes in operating procedures.

11.2.0 Responsibilities

11.2.1 The Quality Assurance Manager is responsible for establishing the requirements to control the test program.

11.2.1 Siting, Design, Construction and Operations Quality Assurance are responsible for the following:

- o developing procedures within their disciplinary responsibility necessary to implement the requirements of this section of the manual,
- o reviewing test specifications and procedures for proper establishment of criteria and sequence,
- o surveillance during testing to determine conformance to the requirements of this section, and
- o reviewing test results.

11.2.3 Technical Projects is responsible for the following:

- o establishing and implementing the test program for repository geologic site evaluation and selection,
- o establishing specifications, requirements and acceptance criteria for chemical and physical properties of the test program for repository site evaluation and selection.

QUALITY ASSURANCE MANUAL	TITLE: TEST CONTROL	SECTION NO. 11.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION		PAGE 2	OF 3

- o developing and implementing procedures for the proper conduct of tests for repository site evaluation and selection, and
- o reviewing and approving test results for the repository site evaluation and selection test program.

11.2.4 Facility Projects is responsible for the following:

- o reviewing and approving the test program for repository site evaluation and selection,
- o establishing and implementing the test program to demonstrate that safety related structures, systems and components will perform satisfactorily in service,
- o establishing specifications, requirements and criteria for testing for safety related structures, systems and components,
- o developing and implementing test procedures for the proper conduct of tests of safety related structures, systems and components, and
- o reviewing and approving test results for the repository site evaluation and selection and safety related structures, systems and components test program.

11.2.5 Regulatory Affairs is responsible for the following:

- o reviewing and approving the specifications, requirements and criteria for the environmental site evaluation and selection test program.
- o reviewing and approving test results for the environmental site evaluation and selection test program.

11.3.0 Requirements

11.3.1 A program shall be established to ensure that all testing required to demonstrate that safety related structures, systems and components will perform satisfactorily in service is identified and documented.

11.3.2 A program shall be established to ensure that all testing required to provide the basis for the objective and accurate determination of repository siting is identified and documented.

11.3.3 Testing shall be performed in accordance with approved test procedures which incorporate or reference the requirements and acceptance criteria contained in applicable design documents and specifications.

QUALITY ASSURANCE MANUAL	TITLE:	SECTION NO.	REVISION NO.
	TEST CONTROL	11.0	0
OFFICE OF WASTE ISOLATION		PAGE 3	OF 3

- 11.3.4 Test procedures shall incorporate requirements for such items as: test prerequisites, hold points, witness points, caution notes, and test results.
- 11.3.5 Test reports shall include identification of the inspector, individual conducting the test, the data recorder, the type of observation made, the equipment used, the test results, the acceptability of the test results, and approved disposition for any deviations.
- 11.3.6 Test results which fail to meet the requirements and acceptance criteria shall be reported and reviewed in accordance with Section 16 of this manual.

QUALITY ASSURANCE MANUAL OFFICE OF WASTE ISOLATION OPERATED BY UNION CARBIDE CORPORATION NUCLEAR DIVISION OAK RIDGE, TENNESSEE	SECTION NO. 12.0		PAGE 1 OF 2	
	REVISION NO. 0		EFFECTIVE DATE	
	DATE	APPROVED	ORGANIZATION	
			Q.A.	
TITLE CONTROL OF MEASURING AND TEST EQUIPMENT		N/A	T.P.	
		N/A	F.P.	
		N/A	R.A.	
		N/A	PROC	
			DIRECTOR	

12.1.0 Purpose

This section establishes the requirement for written procedures for the control, calibration and periodic adjustment of tools, gauges, instruments and other measuring and test equipment used to verify conformance to established requirements.

12.1.0 Responsibilities

12.2.1 The Quality Assurance Manager is responsible for establishing requirements for a program for the control, calibration, and periodic adjustment of tools, gages, instruments, and other measuring and test equipment used by personnel responsible for making measurements that must conform to established requirements.

12.1.1 Siting Quality Assurance is responsible for periodic surveillance of the control, calibration, and periodic adjustment of tools, gages and instruments and other measuring and test equipment used to assure compliance with the implementing procedures instituted for the control of special processes of core drilling, geophysical testing, down-hole hydrological testing and borehole plugging.

12.2.3 Construction Quality Assurance is responsible for periodic surveillance of the control, calibration, and periodic adjustment of tools, gages and instruments and other measuring and test equipment used to assure compliance with the implementing procedures instituted for the control of the construction activities of the repository.

12.2.4 Operations Quality Assurance is responsible for periodic surveillance of the control, calibration, and periodic adjustment of tools, gages and instrument and other measuring and test equipment used to assure compliance with the implementing procedures instituted for the control of the operational phase, including decommissioning of the repository.

12.3.0 Requirements

12.3.1 Inspection, test and work procedures shall include provisions to assure that tools, gages, instruments, and other inspection, measuring, and test equipment and devices used in activities affecting quality are of the proper range, type and accuracy to verify conformance to established requirements and test parameters.

QUALITY ASSURANCE MANUAL	TITLE: CONTROL OF MEASURING AND TEST EQUIPMENT	SECTION NO. 12.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION		PAGE 2	OF 2

12.3.2 To assure equipment accuracy, inspection, measuring, and test equipment shall be controlled, calibrated, adjusted, and maintained at prescribed intervals, or prior to use in accordance with detailed procedures. Calibration shall be performed against certified measurement standards that are traceable to recognized standards. Control measures and procedures shall prevent the use, by unauthorized personnel, of calibrated tools, gages, instruments and other measuring and test equipment. Special calibration and control measures are not required for devices when normal commercial practices provide adequate accuracy.

12.3.3 Measuring and test equipment shall be controlled by a permanently affixed serial number. The item serial number, calibration status, date of calibration, and the recall for calibration date shall be maintained via an established system.

QUALITY ASSURANCE MANUAL		SECTION NO. 13.0		PAGE 1 OF 2	
OFFICE OF WASTE ISOLATION OPERATED BY UNION CARBIDE CORPORATION NUCLEAR DIVISION OAK RIDGE, TENNESSEE		REVISION NO. 0		EFFECTIVE DATE	
		DATE	APPROVED	ORGANIZATION	
				Q.A.	
				T.P.	
				F.P.	
			N/A	R.A.	
TITLE	HANDLING, STORAGE AND SHIPPING		N/A	PROC	
				DIRECTOR	

13.1.0 Purpose

This section of the Quality Assurance Manual establishes the requirements for procedures to control the handling, storage, shipping, cleaning, packaging, and preservation of material and equipment to prevent damage, deterioration or loss from shipment through installation or use. This section of the manual also applies to the control of test samples having to do with site selection and site evaluation of the repository.

13.2.0 Responsibilities

13.2.1 The Quality Assurance Manager is responsible for establishing a procedure that implements the requirements for the handling, storage and shipping of materials, parts, components and test samples covered by the quality assurance program.

13.2.2 Siting, Construction and Operations Quality Assurance are responsible for developing procedures that establish controls for the handling, storage, shipping, cleaning, packaging and preservation of items within their disciplinary responsibility. They are also responsible for monitoring activities affecting the items within their responsibility to ensure compliance with the requirements of this section.

13.2.3 Technical Projects is responsible for developing and implementing procedures for the proper handling, storage, shipping, cleaning, packaging and preservation of test samples having to do with site selection and site evaluation.

13.2.4 Facility Projects is responsible for developing and implementing procedures for the proper handling, storage, shipping, cleaning, packaging and preservation of materials, parts and components covered by this quality assurance program.

QUALITY ASSURANCE MANUAL	TITLE: HANDLING, STORAGE AND SHIPPING	SECTION NO. 13.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION		PAGE 2	OF 2

13.3.0 Requirements

- 13.3.1 The requirements for handling, storage, shipping, cleaning and preservation of materials and equipment shall be documented in approved procedures.
- 13.3.2 Procurement documents shall include instructions for the handling, storage, shipping, cleaning, and preservation of the item being supplied.
- 13.3.3 Procurement documents shall specify marking and taping requirements, special covering, and protective environments, such as inert gas atmosphere, moisture content levels, and temperature levels.
- 13.3.4 Specifications and procedures shall establish the requirements for special handling tools and equipment to ensure safe and adequate handling of critical, sensitive, or radioactive items.
- 13.3.5 Special handling tools and equipment shall be inspected and tested in accordance with approved procedures, at specified intervals, to verify that tools and equipment are adequately maintained.
- 13.3.6 Materials and equipment shall normally be handled by stockroom personnel. Radioactive waste and other special shipments which require special equipment and handling shall be performed by others. The proper use of radioactive waste handling equipment shall be described in radioactive waste handling procedures, which are defined in the operations manual for the repository.
- 13.3.7 Storage of material and equipment covered by the quality assurance program shall be in areas free from fumes, vapors and dust to the extent necessary. Storage shall be in areas protected from the weather and in which chemical storage is excluded, except as may be specifically authorized in writing. Storage shall be in areas which satisfy the handling and storage requirements for the particular equipment, item or test sample specification.

QUALITY ASSURANCE MANUAL OFFICE OF WASTE ISOLATION OPERATED BY UNION CARBIDE CORPORATION NUCLEAR DIVISION OAK RIDGE, TENNESSEE	SECTION NO. 14.0		PAGE 1 OF 2	
	REVISION NO. 0		EFFECTIVE DATE	
	DATE	APPROVED	ORGANIZATION	
			Q.A.	
		N/A	T.P.	
TITLE INSPECTION, TEST AND OPERATING STATUS		N/A	F.P.	
		N/A	R.A.	
		N/A	PROC	
			DIRECTOR	

14.1.0 Purpose

This section of the manual establishes a system for indicating the inspection and test status of materials, parts, components and systems of the repository. The system will encompass test samples having to do with the siting of the repository. This section of the manual also establishes the system for indicating the operating status of an item during the construction and operational phase of the repository to prevent its inadvertent operation.

14.2.0 Responsibilities

14.2.1 The Quality Assurance Manager is responsible for establishing the procedures whereby the requirements of this section of the manual are implemented.

14.2.2 Siting, Design, Procurement, Construction and Operations Quality Assurance are responsible for developing procedures at the level necessary to ensure that the requirements of this section are implemented within their discipline. They are also responsible for monitoring the activities within their disciplinary responsibility to ensure compliance to the requirements of this section of the manual.

14.3.0 Requirements

14.3.1 Equipment, systems, or test samples not ready for normal service shall be clearly identified by use of tags, control logs, and other suitable means to indicate in a positive manner the status of a particular item. This also includes items involved with modifications.

14.3.2 Equipment, system or test sample inspection and test status shall be indicated by use of test tags, labels, or work inspection and test status sheets.

14.3.3 Systems, components, equipment and test samples which are found to be unacceptable during or after testing shall be clearly identified.

QUALITY ASSURANCE MANUAL	TITLE: INSPECTION, TEST AND OPERATING STATUS	SECTION NO.	REVISION NO.
		14.0	0
OFFICE OF WASTE ISOLATION		PAGE 2	OF 2

14.3.4 Operations involving the receipt and handling of contaminated waste or other radioactive sources will require a verification that the material is properly packaged and identified prior to storage.

14.3.5 Repository maintenance, repair, or modification of components, systems, or structures will utilize a work inspection or test status sheet to indicate its acceptance or rejection for a particular component, system or structure. Work inspection or test status sheets will be established and maintained at a designated control location to indicate the status of work on the completion of required inspections and tests.

QUALITY ASSURANCE MANUAL		SECTION NO. 15.0		PAGE 1 OF 2	
OFFICE OF WASTE ISOLATION OPERATED BY UNION CARBIDE CORPORATION NUCLEAR DIVISION OAK RIDGE, TENNESSEE		REVISION NO. 0		EFFECTIVE DATE	
		DATE	APPROVED	ORGANIZATION	
				Q.A.	
				T.P.	
				F.P.	
			N/A	R.A.	
TITLE	NONCONFORMING MATERIALS, PARTS OR COMPONENTS			PROC	
				DIRECTOR	

15.1.0 Purpose

This section of the manual establishes the way in which materials, parts or components which do not conform to established requirements are controlled in order to prevent their inadvertent use or installation. For the purpose of the repository, requirements of this section also apply to test samples having to do with site evaluation and selection.

15.2.0 Responsibilities

15.2.1 The Quality Assurance Manager is responsible for establishing a procedure for the control, evaluation and disposition of material, parts, components and test samples that do not conform to the specified requirements.

15.2.2 Siting, Design, Procurement, Construction and Operations Quality Assurance are responsible for:

- o implementing the procedure to control nonconforming material within the prescribed discipline,
- o issuing material deficiency reports,
- o recommending disposition of the material,
- o initiating rework or repair action as applicable,
- o obtaining or performing satisfactory verification of the material as required, and
- o initiating requests for corrective action where applicable.

15.2.3 Technical Projects is responsible for:

- o reviewing nonconforming test samples and recommending remedial action and/or disposition,
- o preparing procedures that might fix the nonconformance of the test sample and allow it to be tested and/or stored correctly, and

QUALITY ASSURANCE MANUAL	TITLE: NONCONFORMING MATERIALS, PARTS OR COMPONENTS	SECTION NO. 15.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION		PAGE 2	OF 2
	<ul style="list-style-type: none"> o preparing procedures for work around test methods that would allow the samples to be used in their nonconforming state. <p>15.2.4 Facility Projects is responsible for:</p> <ul style="list-style-type: none"> o reviewing nonconforming materials, parts and components and recommending remedial action and/or disposition, and o preparing procedures for rework and repair of nonconforming items. <p>15.2.5 Procurement is responsible for coordinating the disposition of procured items found to be nonconforming with suppliers.</p> <p>15.3.0 <u>Requirements</u></p> <p>15.3.1 Materials, parts, or components which do not conform to requirements shall be identified with a hold tag and reported on a material deficiency report. Nonconforming items shall remain in a designated Quality Assurance area until approved disposition has been received.</p> <p>15.3.2 When a procured item is found to be nonconforming on receipt the supplier shall be notified and requested to correct the deficiency.</p> <p>15.3.3 Nonconformances which cannot be corrected by substitution or replacement shall be reviewed by the applicable engineering section to recommend repair, rework, accept or reject. Items shall be repaired or reworked only in accordance with documented procedures. Quality Assurance shall assure that documented and approved procedures are available prior to repair or rework and shall ensure all repaired or reworked items are inspected.</p> <p>15.3.4 Items which are accepted for use with a known deficiency shall be fully documented with the specification requirement, justification for acceptance, and effect of use. The use of such items shall be approved by the proper technical and quality assurance personnel.</p>		

QUALITY ASSURANCE MANUAL OFFICE OF WASTE ISOLATION OPERATED BY UNION CARBIDE CORPORATION NUCLEAR DIVISION OAK RIDGE, TENNESSEE	SECTION NO. 16.0		PAGE 1 OF 2	
	REVISION NO. 0		EFFECTIVE DATE	
	DATE	APPROVED	ORGANIZATION	
			Q.A.	
			T.P.	
TITLE CORRECTIVE ACTION			F.P.	
			R.A.	
		N/A	PROC	
			DIRECTOR	

16.1.0 Purpose

This section of the Quality Assurance Manual establishes measures to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected.

16.2.0 Responsibilities

16.2.1 The Quality Assurance Manager is responsible for developing a procedure that establishes a system that ensures prompt and effective identification and correction of conditions that are adverse to quality.

16.2.2 Siting, Design, Procurement, Construction and Operations Quality Assurance are responsible for developing procedures for each of their disciplinary responsibilities to identify, review, and correct conditions adverse to quality as expeditiously as possible. They are also responsible for identifying and/or verifying, reviewing and correcting conditions adverse to quality.

16.2.3 Technical Projects is responsible for reviewing conditions adverse to quality with respect to geologic site evaluation and selection activities to determine the cause of the condition and for recommending corrective action to preclude repetition.

16.2.4 Facility Projects is responsible for reviewing conditions adverse to quality with respect to safety related structures, systems and components to determine the cause of the condition and for recommending corrective action.

16.2.5 Regulatory Affairs is responsible for reviewing conditions adverse to quality with respect to environmental site evaluation and selection activities to determine the cause of the condition and for recommending corrective action to preclude repetition.

16.2.6 The Director of OWI is responsible for reviewing conditions cited as adverse to quality and their corrective action on a monthly basis.

16.2.7 All OWI personnel are responsible to responding to notices of conditions of adverse quality by implementing the required corrective action promptly and correctly.

QUALITY ASSURANCE MANUAL	TITLE: CORRECTIVE ACTION	SECTION NO. 16.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION		PAGE 2	OF 2

16.3.0 Requirements

- 16.3.1 Conditions adverse to quality, such as failures, malfunctions deficiencies, deviations, defective material and equipment, and nonconformances shall be reported on a Quality Assurance Deficiency Report. Conditions adverse to quality shall include conditons affecting safety, conditions which could result in reduced repository operation, repetitive maintenance items, and procedural deficiencies. The Quality Assurance Deficiency Report shall identify the condition, the cause of the condition, and the corrective action taken.
- 16.3.2 Quality Assurance Deficiency Reports may be initiated by anyone but shall be submitted to Quality Assurance for proper discription and verification of the validity of the deficiency.
- 16.3.3 When a condition adverse to quality is identified, Quality Assurance shall evaluate the effect of continuing the activity. If continuing the activity would cover up the deficiency and preclude identification and correction, or continuing the activity would increase the extent of the deficiency, stop work action shall be taken.
- 16.3.4 Conditions adverse to quality which involve design deficiencies or recommended corrective action which involves a design change shall be reviewed by either Technical Projects, Facility Projects or Regulatory Affairs as applicable.
- 16.3.5 Quality Assurance shall review all Quality Assurance Deficiency Reports to assure that the cause of the condition has been determined and that corrective action has been taken to preclude repetition.
- 16.3.6 Quality Assurance Deficiency Reports shall be submitted to the Director of OWI on a monthly basis.

QUALITY ASSURANCE MANUAL OFFICE OF WASTE ISOLATION OPERATED BY UNION CARBIDE CORPORATION NUCLEAR DIVISION OAK RIDGE, TENNESSEE	SECTION NO.		PAGE 1 OF 2	
	17.0			
	REVISION NO.		EFFECTIVE DATE	
	0			
	DATE	APPROVED	ORGANIZATION	
		Q.A.		
		T.P.		
		F.P.		
		R.A.		
		PROC		
		DIRECTOR		
TITLE		QUALITY ASSURANCE RECORDS		

17.1.0 Purpose

17.1.1 This section established the requirements for a historical record of all activities that lead to the establishment and maintenance of the repository. By so doing, it establishes the requirements for a document storage and retrieval system. It also establishes a requirement that such records are safeguarded properly whether through duplication or through judicious use of their placement and safeguarding by whatever means are deemed necessary. This section requires that sufficient records be generated and maintained to furnish documentary evidence that all specified quality items have been accomplished and/or satisfied.

17.1.2 This section specifically covers the requirement for documents and records associated with the siting, design, procurement, fabrication, installation, testing and maintenance of the structures, systems and components covered by this quality assurance program.

17.2.0 Responsibilities

17.2.1 The Quality Assurance Manager is responsible for establishing the requirements of this section of the manual.

17.2.2 Siting, Design, Procurement, Construction and Operations Quality Assurance are responsible for developing the necessary procedures to implement the requirements of this section of the manual as they relate to the particular discipline.

17.2.3 Each Department Manager affected by the procedures developed in paragraph 17.2.2 is responsible for ensuring that they are implemented to the extent necessary to comply with the requirements of this section of the manual.

17.3.0 Requirements

17.3.1 Storage

17.3.1.1 The record storage facility shall be constructed in such a manner that it will safeguard its contents from extreme variations in temperature and moisture.

QUALITY ASSURANCE MANUAL	TITLE: QUALITY ASSURANCE RECORDS	SECTION NO. 17.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION		PAGE 2	OF 2

17.3.1.2 Records shall be stored in closed, fire-retardant cabinets designed to accommodate the size and shape of records on file.

17.3.1.3 Duplicate records will be stored in a vault at a location that is geographically separated from the primary storage location. Duplicate records will be reproducible so that they can replace working record copies in the event they may be lost.

17.3.1.4 Entry to the record storage room shall be controlled such that only authorized personnel are permitted access to the records.

17.3.2 System

17.3.2.1 A system shall be established for receiving records, classifying and indexing them, labeling, and preparing them for filing or microfilming. This system shall also include provisions for periodic record maintenance. All records shall be indexed and the indexing system documented and available for the benefit of those seeking information and desiring access to records.

17.3.2.2 A retention system shall be established to identify all documents that must be kept permanently (lifetime records) with a symbol that can be easily read both in hardcopy and microfilm form. All nonpermanent records shall be identified with a date indicating when the document should be redispositioned or destroyed.

17.3.2.3 The approved document listing will be reviewed on a regular basis to verify that the record file contains the latest revisions of all required documents.

17.3.2.4 A system will be established to control the issuance and return of all records.

QUALITY ASSURANCE MANUAL OFFICE OF WASTE ISOLATION OPERATED BY UNION CARBIDE CORPORATION NUCLEAR DIVISION OAK RIDGE, TENNESSEE	SECTION NO. 18.0		PAGE 1 OF 2	
	REVISION NO. 0		EFFECTIVE DATE	
	DATE	APPROVED	ORGANIZATION	
			Q.A.	
		N/A	T.P.	
TITLE AUDITS		N/A	F.P.	
		N/A	R.A.	
		N/A	PROC	
		DIRECTOR		

18.1.0 Purpose

This section of the manual establishes the requirements for a comprehensive system of planned and documented audits to verify compliance with all aspects of the Quality Assurance Program contained in this manual, and to assure the effectiveness of the program. The system provides for the reporting and review of audit results by appropriate levels of OWI supervision and management.

18.2.0 Responsibility

The Quality Assurance Manager is responsible for implementing this section of the manual. The Quality Assurance Manager is responsible for developing audit checklists, designating and training audit personnel and conducting audits.

18.2.2 Siting, Design, Procurement, Construction, and Operations Quality Assurance are responsible for surveillance of the activities correlated with their responsibilities that are covered by this quality assurance program.

18.3.0 Requirements

18.3.1 Audits shall be performed in accordance with written procedures or checklists by appropriately trained personnel having no direct responsibilities in the area audited.

18.3.2 Audits may be conducted by Quality Assurance engineers or other qualified personnel, such as technical specialists from other sections of OWI and/or outside consultants.

18.3.3 Audit and surveillance results shall be documented and reviewed with supervision responsible for the area audited who shall take necessary action to correct reported deficiencies.

18.3.4 Audit results shall be documented and reported to the manager having responsibility in the area audited and to the Director of OWI.

QUALITY ASSURANCE MANUAL	TITLE: AUDITS	SECTION NO. 18.0	REVISION NO. 0
OFFICE OF WASTE ISOLATION		PAGE 2	OF 2

18.3.5 Quality Assurance Auditors shall be trained to assess the following elements:

- o evaluation of quality assurance practices, procedures and instructions,
- o effectiveness of implementation,
- o conformance with policy directives.

18.3.6 Audits shall include but not be limited to the following:

- o evaluation of work area,
- o evaluation of activities,
- o evaluation of processes,
- o evaluation of items, and
- o review of documents and records.

18.3.7 Scheduled audits shall be conducted yearly. In addition audits shall be conducted on a random, unscheduled basis, when one or more of the following conditions exist:

- a. When significant changes are made in functional areas of the quality assurance program, including significant reorganizations and procedural revisions.
- b. When it is suspected that safety, performance, or reliability of an item is questionable due to deficiencies or nonconformances in the quality assurance program.
- c. When a systematic, independent assessment of program effectiveness or item quality, or both, is considered necessary.
- d. When it is considered necessary to verify the implementation of required corrective actions.