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POLICY

The West Valley Demonstration Project (WVDP) Quality Assurance Program shall be implemented to the requirements of DOE Order 5700.6B, "Quality Assurance," and OGR/B-14, "Quality Assurance Requirements for High-Level Waste Form Production." It shall provide adequate assurance that an acceptable high-level radioactive waste form is produced at the WVDP for the federal repository operator in compliance with the Waste Acceptance Preliminary Specifications, (WAPS) OGR/B-9.

Each major participant shall implement the Quality Assurance requirements for which it is responsible, and each participant shall verify compliance by overview of the programs of participants below it in the chain-of-command. Overview shall be performed as an organized program of review and revision, as necessary, to assure continued compliance with this policy.

DRAFT

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Director of Waste Treatment Projects, NE-24

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This document describes the Quality Assurance Program of the West Valley Demonstration Project (WVDP) high-level waste form producer. The waste form producer is an organizational set of four separate, but interacting organizations:

1. DOE/NE, U.S. Department of Energy, Office of Nuclear Energy
2. DOE/ID, U.S. Department of Energy, Idaho Operations Office
3. WVPO, U.S. Department of Energy, West Valley Project Office
4. WVNS, West Valley Nuclear Services

They exist together as the WVDP's Vitrification Project organization in a vertical, descending line of authority. The authority, responsibility, and relationship of each organization to the others is described herein.

This QAPD is divided into five sections. The first four sections are the Quality Assurance Program Descriptions (QAPD) of each of the producer organizations, also referred to as the "major participants." Figure 1 shows how each major participant contributed to this QAPD document. Sections 1 through 4 describe the programs for DOE Assistant Secretary for Nuclear Energy (DOE/NE), DOE Idaho Operation Office (DOE/ID), DOE West Valley Project Office (DOE-WVPO) and West Valley Nuclear Services (WVNS) the Operating contractor, respectively. Section 5, Appendices, is applicable to all four participant's QAPD's contributions.

Each of the first four sections describes the Quality Assurance Program implemented by the contributing participant and how it interacts with the other participant's programs. Together they describe the entire Quality Assurance Program for the high-level radioactive waste acceptance process and production activities at the WVDP, and meet the requirements of DOE Order 5700.6B and OGR/B-14.

The paragraph numbering of sections 1 through 4, subsection 2.0, is such that it can be prefixed by the number 17 and comply with licensing application requirements imposed on the federal repository operator (see OGR/B-14, appendix A). It is intended that this document represent the portion of the repository operators' licensing application that is applicable to the WVDP's high-level Waste Acceptance Process activities.

The overall Quality Assurance Program is directed and administered by DOE/NE according to a causative process which impels greater accountability closer to the performing level of Vitrification Project activities. It facilitates efficient conduct of the Project activities, eliminating redundant implementation of elements that are not within the scope of activities of a major participant, and allowing higher levels of Project management to focus on administration, guidance and correction, as required. The causative process, which relies on delegation and overview, is shown in figure 2 and described within this QAPD.

WVDP - QAPD CONTRIBUTORS

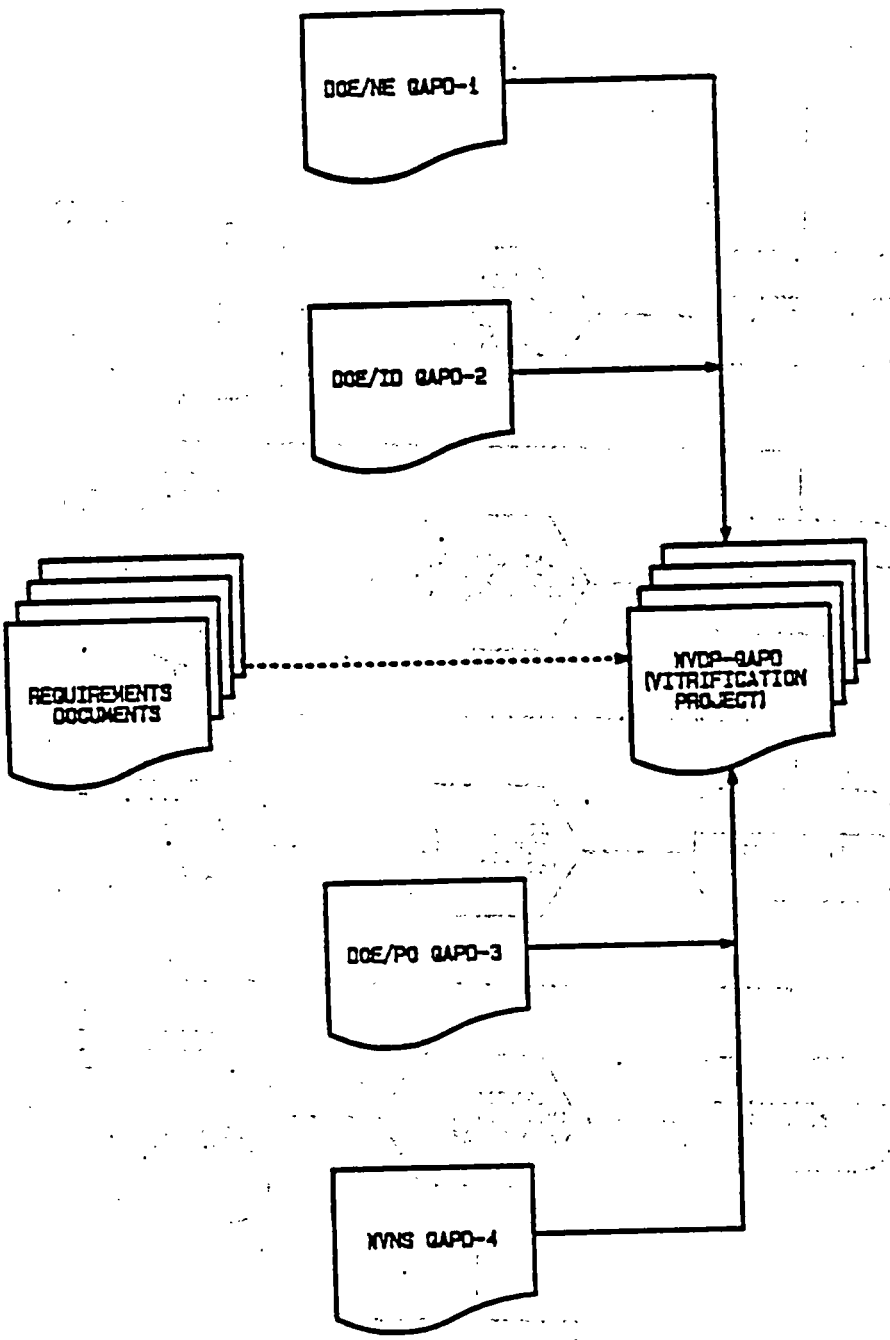

FIGURE 1

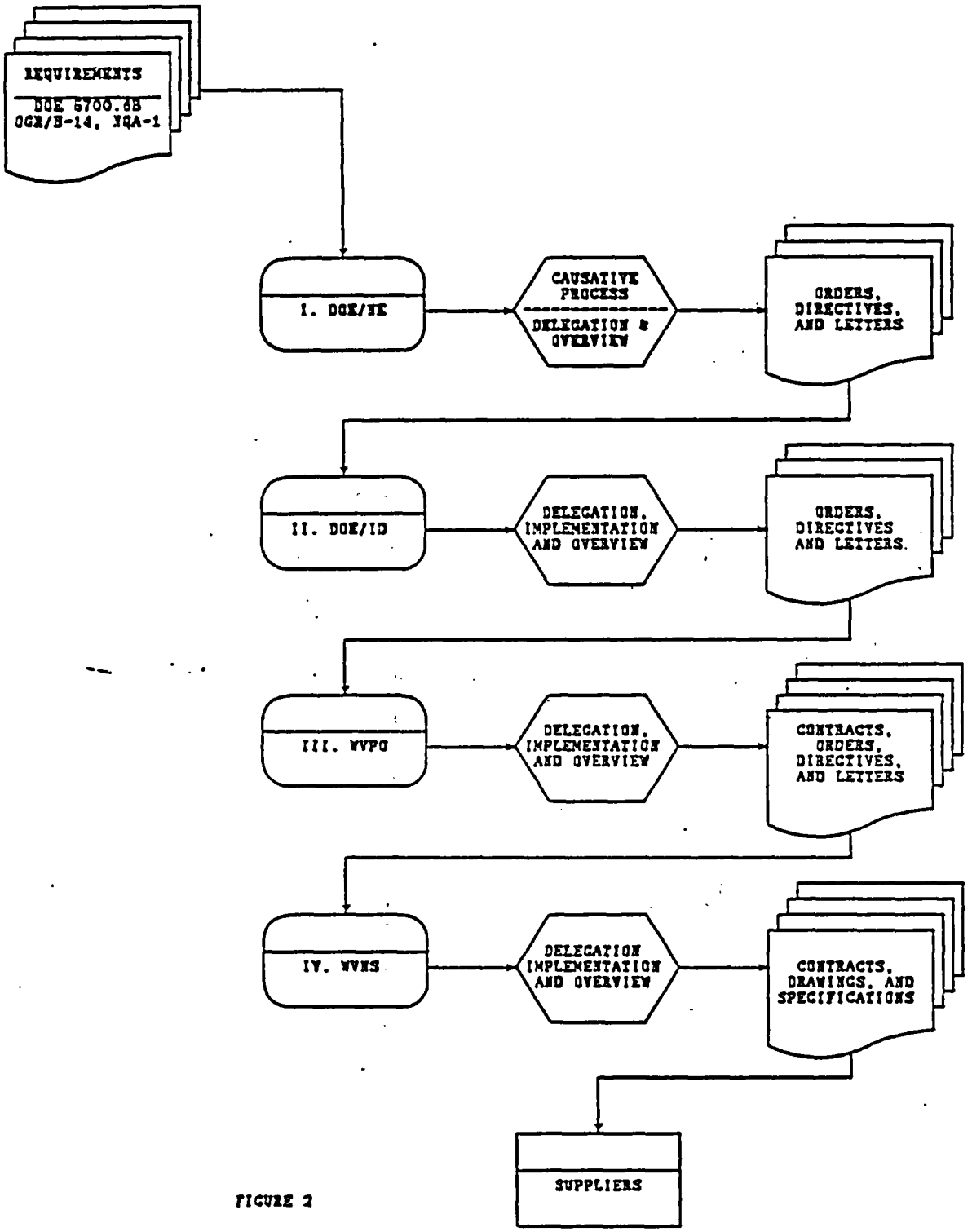
REQUIREMENTS
DOE 5700.6B
OGR/B-14, NQA-1
I. DOE/NE
CAUSATIVE PROCESS
DELEGATION & OVERVIEW
ORDERS, DIRECTIVES, AND LETTERS
II. DOE/ID
DELEGATION, IMPLEMENTATION AND OVERVIEW
ORDERS, DIRECTIVES AND LETTERS.
III. WVPO
DELEGATION, IMPLEMENTATION AND OVERVIEW
CONTRACTS, ORDERS, DIRECTIVES, AND LETTERS
IV. WVNS
DELEGATION IMPLEMENTATION AND OVERVIEW
CONTRACTS, DRAWINGS, AND SPECIFICATIONS
SUPPLIERS

FIGURE 2

TABLE OF CONTENTS

UNCONTROLLED

QAPD-1	SUBJECT	PAGE
0.0	INTRODUCTION	1
0.1	Scope	1
0.2	Basis	2
0.3	Application	2
1.0	ORGANIZATION	2
1.1	Function	3
1.2	Responsibility and Authority	4
1.3	Organizational Arrangement	5
1.4	Qualification Requirements	5
1.5	Communication	7
2.0	QUALITY ASSURANCE PROGRAM	8
2.1	Policy and Objectives	8
2.2	Responsibility	8
2.3	Requirements	10
2.4	Program Elements Implemented by DOE/NE	11
2.5	Program Elements Delegated to Others	11
2.6	Transfer of Requirements to Others	13
2.7	Indoctrination and Training	13
3.0	DESIGN CONTROL	14
3.1	DOE/NE Implementation	14
3.2	Requirements of Other Participants	14
4.0	PROCUREMENT DOCUMENT CONTROL	14
4.1	DOE/NE Implementation	14
4.2	Requirements of Other Participants	15
5.0	INSTRUCTIONS, PROCEDURES, AND DRAWINGS	15
5.1	DOE/NE Implementation	15
5.2	Requirements of Other Participants	15
6.0	DOCUMENT CONTROL	16
6.1	DOE/NE Implementation	16
6.2	Implementation of Other Participants	16
7.0	CONTROL OF PURCHASED ITEMS AND SERVICES	16
7.1	DOE/NE Implementation	16
7.2	Requirements of Other Participants	17

TABLE OF CONTENTS (CONTINUED)

QAPD-1	SUBJECT	PAGE
8.0	IDENTIFICATION AND CONTROL OF ITEMS	17
	8.1 DOE/NE Implementation	17
	8.2 Requirements for Other Participants	18
9.0	CONTROL OF PROCESSES	18
	9.1 DOE/NE Implementation	18
	9.2 Requirements of Other Participants	18
10.0	INSPECTION	19
	10.1 DOE/NE Implementation	19
	10.2 Requirements of Other Participants	19
11.0	TEST CONTROL	20
	11.1 DOE/NE Implementation	20
	11.2 Requirements of Other Participants	20
12.0	CONTROL OF MEASURING AND TEST EQUIPMENT	21
	12.1 DOE/NE Implementation	21
	12.2 Requirements of Other Participants	21
13.0	HANDLING, STORAGE, AND SHIPPING	22
	13.1 DOE/NE Implementation	22
	13.2 Requirements of Other Participants	22
14.0	INSPECTION, TEST, AND OPERATING STATUS	22
	14.1 DOE/NE Implementation	22
	14.2 Requirements of Other Participants	23
15.0	CONTROL OF NONCONFORMING ITEMS	23
	15.1 DOE/NE Implementation	23
	15.2 Requirements of Other Participants	24
16.0	CORRECTIVE ACTION	24
	16.1 DOE/NE Implementation	24
	16.2 Requirements of Other Participants	25
17.0	QUALITY ASSURANCE RECORDS	25
	17.1 DOE/NE Implementation	25
	17.2 Requirements of Other Participants	25

TABLE OF CONTENTS (CONTINUED)

QAPD-1	SUBJECT	PAGE
18.0	AUDITS	26
	18.1 DOE/NE Implementation	26
	18.2 Requirements of Other Participants	26
19.0	OTHER BASIC REQUIREMENTS	27
	19.1 DOE/NE Implementation	27
	19.2 Requirements of Other Participants	27
20.0	OGR/B-14 SUPPLEMENTAL REQUIREMENTS	28
	20.1 DOE/NE Implementation	28
	20.2 Requirements of Other Participants	28
21.0	GLOSSARY	28

FIGURES

Figure 1.3 - WVDP Organization Chart 6
Figure 2.3 - DOE/NE QA Program Description 12

THE DOE/NE QUALITY ASSURANCE PROGRAM DESCRIPTION FOR THE WEST VALLEY HIGH-LEVEL CANISTERED WASTE FORM PRODUCTION

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0.1 INTRODUCTION

0.1 Scope

This document describes that portion of the West Valley Demonstration Project (WVDP) Quality Assurance Program to be implemented by the DOE/NE headquarters organization for assuring acceptable production of a high-level canistered waste form from the West Valley site high-level radioactive wastes. This program applies to all activities essential for waste from acceptance as defined in the Waste Acceptance Preliminary Specifications (WAPS) for the canistered high-level waste form at the DOE West Valley site. Activities affecting quality of this waste form are to be performed in accordance with the requirements of the DOE Repository program as defined in the Quality Assurance Program Requirements for High-Level Waste Form Production (OGR/B-14). The program described herein describes the actions and activities of the DOE/NE in assuring that the requirements of the repository program are effectively implemented at the West Valley Demonstration Project Site by the site contractor, West Valley Nuclear Services Co. (WVNS), the DOE West Valley Project Office (WVPO), and the DOE Idaho Operations Office (DOE-ID). The activities covered include the development and qualification of an acceptable high-level waste form product, a canistered high-level waste form product, and the development of a production process (and equipment) to perform the process at the West Valley site. Associated design, procurement, fabrication, testing, and operational activities important to the quality of waste form development, qualification, and production are to be included in the overall Project Quality Assurance Program.

0.2 Basis

The overall responsibility for assuring that the Quality Assurance Program is effectively implemented at the West Valley Demonstration Project (WVDP) rests with the DOE/NE Office. Responsibility for establishing and implementing portions of the program are delegated by DOE/NE to the other participants at DOE/ID, WVPO and WVNS as necessary to assure effective program implementation.

0.3 Application

The program described in this document is applicable to essential high-level canistered waste form development, qualification, and production activities. This will include activities associated with: research and development essential to qualification of the waste form; control of materials, equipment, facilities, and processes that are essential to certification of the canistered waste form; and processing activities that are essential to the certification of canistered waste forms. The program implements those provisions necessary to assure that the canistered waste form will be acceptable to the licensed federal repository. The specific activities and systems that are covered by this program are listed in Appendix I.

1.0 ORGANIZATION

Responsibility for acceptance of high-level radioactive waste resulting from the WVDP Waste Acceptance Process Activities rests with the DOE Office of Civilian Radioactive Waste Management (DOE/OCRWM), also referred to as DOE-RW.

This document describes the DOE/NE responsibilities and the DOE/NE delegated responsibilities to assure that quality is achieved in the development, qualification, and production of an acceptable canistered high-level waste form product from the West Valley Demonstration Project

(WVDP). This responsibility is to assure that an acceptable high-level waste form, canister for the waste form, and ultimately the canistered waste form product is developed and qualified in a way that will conform to all the requirements of the DOE/OCRWM Waste Acceptance Preliminary Specification, WAPS, OGR/B-9. Also included is the design and development of the high-level waste form production process (and equipment) to perform that process essential to the certification of the waste form at the WVDP. It further includes the testing necessary to demonstrate that the canistered waste form product from the WVDP will satisfy all requirements of the WAPS.

1.1 Function

The functions DOE/NE will perform in order to achieve the stated objective of assuring effective implementation of the repository quality assurance at the West Valley site are as follows:

a) provide for audit of project activities in accordance with the requirements of OGR/B-14,

b) coordinate and participate in DOE-RW and NRC audits of the Project,

c) assure implementation of the Project Quality Assurance Program through delegation of Project quality assurance responsibility to the WVPO through the DOE-ID field office,

d) assure implementation of DOE-ID monitoring programs through periodic evaluation of the ID Quality Assurance Program overview of West Valley and participation in audits of the Project conducted by DOE-ID,

e) perform or direct effectiveness evaluations of the Project Quality Assurance Program as appropriate to assure that implementation of the quality program is adequate and effective, and

f) provide for the interface between the field office, the project office, and the repository programs including the regulators (DOE/RW and NRC).

1.2 Responsibility and Authority

1.2.1 The Director of Waste Treatment Projects (NE-24) reports directly to the Director of the Office of Remedial Action and Waste Technology (NE-20). The Director (NE-20) reports to the Principal Deputy Assistant Secretary for Nuclear Energy (NE-2). The Director NE-24, is assigned the responsibility of assuring that the Quality Assurance Program requirements as defined in the "Quality Assurance Program Requirements for Waste Form Production" (OGR/B-14) are correctly implemented and carried out by the implementing organizations at DOE-ID and the WVPO. The NE-24 responsibilities are:

a) assure effectiveness of the overall WVDP QA program by initiating, recommending, or providing solutions to quality problems identified in audits or other program reviews through designated channels,

b) through audits or other reviews of the project, assess the adequacy of facilities and equipment,

c) authorize issuance of special instructions, if necessary, to perform his or her responsibilities for quality assurance, and

d) notify responsible higher management of unsatisfactory work or unapproved practices. Take steps (such as stop work) to bring unsatisfactory work into conformance.

1.2.2 The Director, NE-24, is directly responsible for assuring that the requirements of OGR/B-14 are correctly carried out. He shall accomplish this task through various means including the following:

a) auditing or causing to be audited the Quality Assurance Programs at DOE-ID, DOE-ID-WVPO, and the West Valley site contractor,

b) performing or causing effectiveness evaluations of the Quality Assurance Programs at DOE-ID and West Valley to be conducted as required by section 5.2.14 of OGR/B-14.

c) identifying and supporting the resolution of quality related problems.

1.3 Organizational Arrangement

1.3.1 The WVDP organizational structure for assuring the repository Quality Assurance Program requirements are met is identified in figure 1.3. The Director, NE-24 is responsible for assuring the effective implementation of quality programs at all levels of the organization within DOE and the DOE contractors.

1.4 Qualification Requirements

1.4.1 The Director NE-24 shall assure that personnel or organizations performing the Quality Assurance Program monitoring activities assigned to the headquarters NE organization are qualified by virtue of experience and training. A monitoring team, led by a qualified lead auditor and including other trained auditors, shall be of appropriate size and balanced among technical disciplines.

West Valley Demonstration Project Organizational Chart

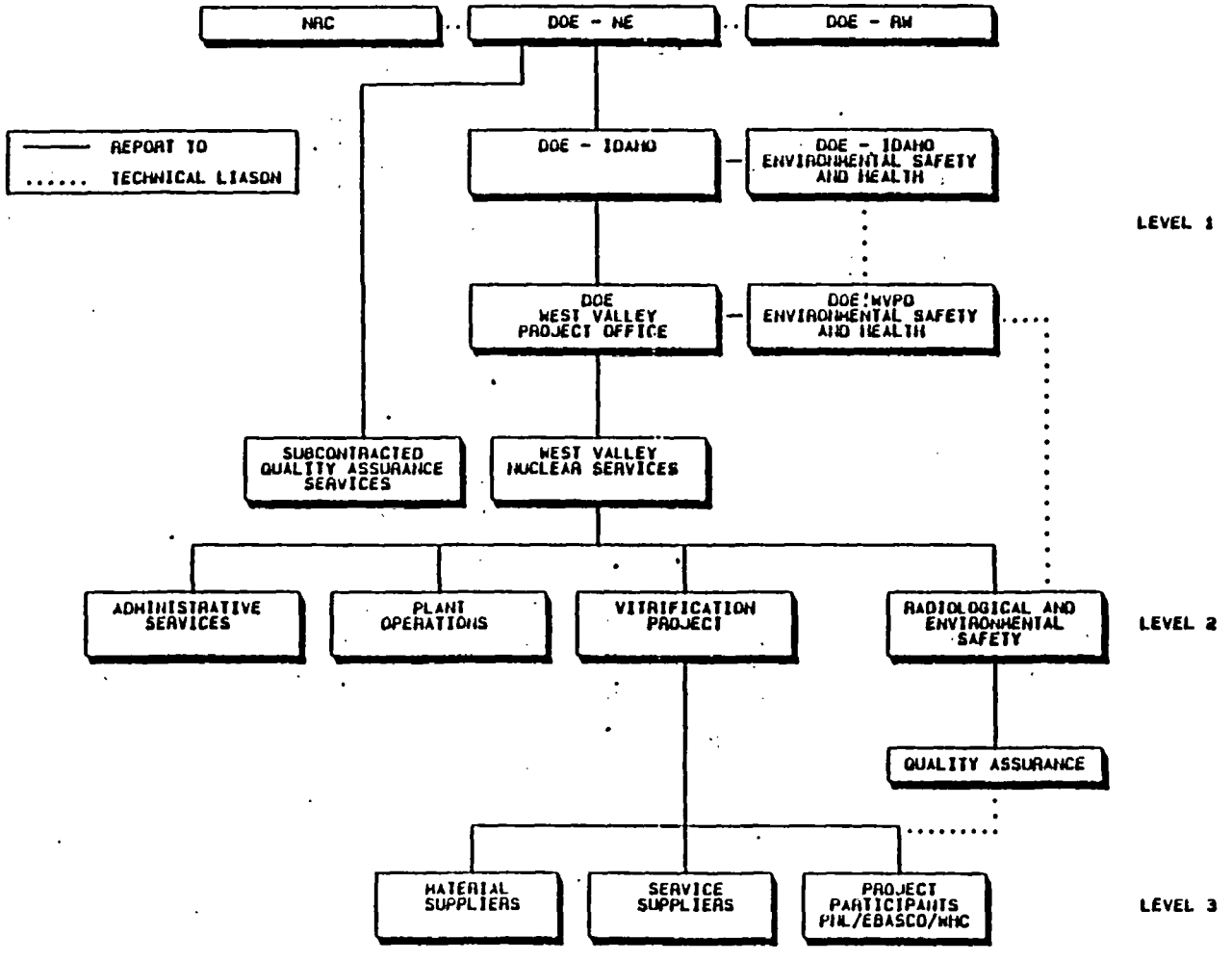

Figure 1.3

Education

The lead auditor shall be a graduate of a four-year accredited engineering or science college or university. A majority of the team members shall have an engineering or scientific background.

Experience

The lead auditor shall be qualified as a "lead auditor" in accordance with the requirements of OGR/B-14, have a minimum of 5 years experience in nuclear quality assurance, and have a minimum of 10 years experience in activities associated with nuclear facilities. He or she shall possess a broad knowledge of the quality assurance program requirements for the nuclear industry, government codes and standards, and the regulatory requirements associated with repository program high-level waste form work.

Team members from complementary disciplines shall have a minimum of 5 years experience in nuclear activities or quality assurance activities associated with industrial, government, or regulatory requirements.

1.5 Communication

1.5.1 To promote the flow of communications and to assure positive attention to quality programs with the Project participants, lines of communications between DOE/NE and the organizations of the other major Project participants are established as follows:

a) communications will be addressed to the responsible senior management official with copies to the major Project participants cognizant of the subject,

b) communications may be formal or informal, the choice of which shall depend on the significance of the subject and the judgement of the individuals involved, and

c) communication of quality assurance-related activities between the DOE/NE organization and the organizations of the major Project participants is promoted through periodic progress and status reporting by major Project participants.

2.0 QUALITY ASSURANCE PROGRAM

2.1 Policy and Objectives

The policy and objectives of the NE-24 Quality Assurance Program are:

a) to assure that quality is achieved in the development, qualification, and production of an acceptable canistered high-level waste form product from the WVDP, and

b) to assure that appropriate quality assurance activities are implemented by or for DOE.

2.2 Responsibility

2.2.1 DOE/NE

a) As stated in section 1.0, the Director of NE-24 has the responsibility to assure that the Quality Assurance Program at West Valley is implemented and maintained effectively throughout the duration of Project

activities. He has assigned the day-to-day responsibility for program implementation to the West Valley Demonstration Project Office Project Manager (WV-PM) through the Manager ID Operations and the Assistant Manager for Nuclear Programs DOE/ID. The WV-PM responsibilities are defined in detail in the WVPO Quality Assurance Program Plan (QAPD-3).

b) The Director NE-24 retains the right to monitor, overview, audit, perform effectiveness evaluations, and participate in readiness reviews as appropriate to assure that the quality programs for WVDP waste form development, qualification, and production are being implemented effectively. The Director shall assure that, as a minimum, annual audits of Project activities are performed.

c) The Director NE-24 also will act as the interface between the Project and the DOE/RW and the USNRC for waste form quality. In this capacity, the manager shall support the planning and scheduling and participate as necessary with these organizations in the audits and reviews performed of the Project at West Valley and Idaho.

d) To determine Quality Assurance Program status and to evaluate program adequacy, the Director conducts an overall program review to assess the scope, implementation, and effectiveness of the Quality Assurance Program. This review is performed by or at the direction of the Director at least annually using resources and information at his disposal, including the results from any previous Project surveillance, inspection, and audit activities.

e) The Director NE-24 monitors the status of Quality Assurance Program activities reported in the form of existing regular progress and status reports and other special reports as appropriate. These reports outline the progress and status of quality assurance activities, problems and nonconformances, quality trends, and results of audits. The Director reviews these reports and initiates whatever management action is required to improve conditions and further implement the program.

2.2.2 Participants

a) Although DOE retains responsibility for adequacy of the overall Project Quality Assurance Program, other major participants are assigned, by contract, the responsibility for establishing and implementing particular program practices. These delegated program elements are described in section 2.5.

b) Project participation responsibilities are described as a three-level structure. The DOE portion of the program is the first level. Other major program participants including major DOE subcontractors comprise the second level. The third level is made up of the multitude of systems, components, materials, and service suppliers directed by the second level. This three-level structure is depicted in figure 1.3.

2.3 Requirements

2.3.1 Overall

The requirements for the overall Quality Assurance Program are contained in DOE Order 5700.6B, Quality Assurance; DOE Order 5000.3, Unusual Occurrence Reporting System; Guidelines

for Application of Readiness Reviews to Department of Energy Activities; and ANSI/ASME NQA-1, Quality Assurance Program Requirements for Nuclear Facilities. In addition, requirements for the Project Quality Assurance Program applicable to waste acceptance process activities of high-level waste form production are contained in the Office of Civilian Radioactive Waste Management (OCRWM) Specification OGR B-14. These requirements are illustrated by the discussion of the program elements provided in later sections of this program description.

2.4 Program Elements Implemented by DOE/NE

The elements of the overall Project Quality Assurance Program which will be implemented by DOE-NE are those identified as Organization, Quality Assurance Program, and Audits. This is the DOE/NE portion of the program, and it will be conducted in accordance with the management practices of DOE/NE (figure 2.3).

2.5 Program Elements Delegated to Others

The responsibility for implementing development, design, testing, and production functions is delegated by DOE/NE to DOE/ID. DOE/ID may pass along those functions to subcontractors so that each function can be performed by those most qualified. The ultimate responsibility for adequate implementation and performance by each participant is retained by DOE/NE. DOE/ID through the WV-PM requires that WVNS documents its program in appropriate descriptions, plans, and procedures. WVNS' program is initially evaluated and approved by WVPO, DOE-ID, and DOE/NE. Subsequently, revised, updated, or new Quality Assurance Program plans and procedures are reviewed on an on-going basis and are accepted by the DOE WVPO for Project use. The program is monitored on a continuing basis through review and audit to assess its adequacy and to verify compliance with Project requirements.

DOE/NE QUALITY ASSURANCE PROGRAM ACTIVITIES

Overall Program
• Objectives
• Responsibilities
• Requirements
• Control and Verification

AND

PROGRAM MANAGEMENT
• Organization
Structuring
Documenting
• Quality Assurance Program
Planning
Developing
Documenting
• Audits and Reviews
Program Audits
Management Reviews
Corrective Actions
Unusual Occurence Reports

Figure 2.3 – Major Elements of the DOE/NE Quality Assurance Program

2.6 Transfer of Requirements to Others

2.6.1 The delegation of implementation responsibility for Quality Assurance Program elements is accomplished through contracts and program plans. These documents will specify applicable requirements for contractor Quality Assurance Programs.

2.6.2 The DOE's contracting practice is executed under controlled procedures through which only prospective contractors who are judged to be capable of performing to requisite quality standards are chosen to participate. During the course of their evaluation and selection, the quality achievement and assurance capabilities of prospective contractors are determined and verified through review and inspection and only those with demonstrated capability are awarded contracts. Existing contracts that have been placed will be changed only under controlled procedures.

2.7 Indoctrination and Training

Personnel who are assigned responsibility for performing Quality Assurance Program monitoring activities for DOE/NE are selected and assigned to their area of responsibility based upon experience, education, and management's assessment of their performance capabilities. They are observed for performance evaluation on a continuing basis by appropriate management. On-going training and indoctrination programs are conducted to familiarize personnel with the technical objectives of the activity being monitored, the requirements that the activity must meet, the practices and procedures to be executed in verifying conformance to requirements and the documentation of results.

3.0 DESIGN CONTROL

3.1 DOE/NE Implementation

DOE/NE delegates to DOE/ID the Project responsibility for design control activities. The design activities are required to be in compliance with the DOE orders and documents referenced in section 2.3 of this document.

DOE/NE monitors through program reviews and other means the major Project participant design control practices related to waste form development, qualification, and production activities and periodically audits the participants practices to assure proper implementation and adequacy.

3.2 Requirements of Other Participants

Each Project participant who is assigned Design Control responsibility in support of waste form development, qualification, and production activities is required by contract to implement and maintain a design control practice that meets the requirements of the documents referenced in section 2.3.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 DOE/NE Implementation

DOE/NE will not procure items to support waste form development, qualification, or production activities, but delegates this requirement to other Project participants. DOE authority and responsibility for procurement document control is delegated to DOE-ID. DOE/NE will monitor other Project participants through audit, program review, and other appropriate means.

4.2 Requirements of Other Participants

Each major Project participant who is assigned procurement responsibility in support of development, qualification, and operations activities is required by contract to implement and maintain a procurement document control practice that meets the requirements of the documents referenced in section 2.3.

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 DOE/NE Implementation

DOE/NE has delegated to DOE/ID the Project responsibility for control of Instructions Procedures and Drawings for activities affecting quality of waste form development, qualification, and production activities. DOE/NE shall assure that, as part of the reviews and audits performed by contractors on the behalf of DOE/NE, the procedures in effect at the Project locations at ID and West Valley are adequate, complete, and appropriate to the task being performed at those locations.

5.2 Requirements of Other Participants

Project participants, who are assigned responsibility for performing work activities affecting quality in support of development, qualification, and production activities, are required by contract to establish and implement a practice of prescribing those activities in accordance with documented instructions, procedures, and drawings in compliance with the quality assurance requirements identified in section 2.3 of this document. The Director DOE/NE shall require that organizations performing quality audit and overview functions have appropriate instructions and procedures.

6.0 DOCUMENT CONTROL

6.1 DOE/NE Implementation

DOE/NE has delegated to DOE/ID the Project responsibility for control of documents for waste form development, qualification, and production activities including implementing procedures that comply with Project requirements.

The Director NE-24 shall assure through the audits, overviews, and readiness reviews performed by or on behalf of the Director that the program participants have in place document control systems that meet the requirements of the repository program in accordance with the DOE Orders and other documents referenced in section 2.3.

6.2 Implementation of Other Participants

Each major Project participant shall be required to have a system and procedures in place for the control of quality affecting documents in accordance with the requirements identified in section 2.3.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 DOE/NE Implementation

DOE/NE delegates to DOE/ID the Project responsibility for control of purchased items for development, qualification, and production activities.

DOE/NE monitors through program reviews, readiness reviews, and other means the major participant procurement practices related to development, qualification, and production activities and periodically audits the participant practices to assure proper implementation and adequacy.

7.2 Requirements of Other Participants

Project participants, who are assigned responsibility for procurement of items and services in support of development, qualification, and operations activities, are required, by contract, to establish and implement a system for control of those procurements in accordance with the DOE Orders and other documents referenced in section 2.3.

8.0 IDENTIFICATION AND CONTROL OF ITEMS

8.1 DOE/NE Implementation

DOE/NE delegates to DOE/ID the Project responsibility for identification and control of items which support waste form development, qualification, and production activities.

DOE/NE monitors through program reviews, readiness reviews, and other means the major participant identification and control of item practices related to waste form development, qualification, and production activities and periodically audits the participant practices to assure proper implementation and adequacy.

8.2 Requirements of Other Participants

Each Project participant, who has an assigned responsibility for items which support waste form development, qualification, and production activities is required, by contract, to establish and implement identification and control practices required by DOE Orders and other documents referenced in section 2.3.

9.0 CONTROL OF PROCESSES

9.1 DOE/NE Implementation

DOE/NE delegates to DOE/ID the Project responsibility for control of special processes in support of development, qualification, and production activities.

DOE/NE monitors through program reviews, readiness reviews, and other means the major participant special processes control practices related to waste form development, qualification, and production activities and periodically audits the participant practices to assure proper implementation and adequacy.

9.2 Requirements of Other Participants

Project participants who are assigned responsibility for activities where special processes in support of development, qualification, and production activities are involved, are required, by contract, to establish and implement special process control practices. Special process control may be applicable to many of the melting, cleaning, or sampling processes used in waste form process development, demonstration, qualification, and production. These controls shall meet the requirements of the documents referenced in section 2.3.

10.0 INSPECTION

10.1 DOE/NE Implementation

DOE/NE delegates to DOE/ID the Project responsibility for inspection of items and work practices in support of waste form development, qualification, and production activities. DOE or an agent may perform or witness inspection on a selective basis. Should DOE elect to perform or have an agent perform inspections, the practice followed conforms to the same requirements imposed upon other participants. Authority for determining and establishing DOE participation or witnessing is delegated to the WV-PM through the ID-PM.

DOE/NE monitors through program reviews, readiness reviews, and other means the major Project participant inspection practices associated with waste form development, qualification, and production activities and periodically audits the participants practice to assure proper implementation and adequacy.

10.2 Requirements of Other Participants

Each participant who is assigned responsibility for performing procurement; manufacturing, fabrication, and assembly; or operation (operation of test activities) in support of development, qualification and operations activities is required, by contract, to establish and implement an inspection practice of sufficient scope to be fully effective. The documented inspection practices shall meet the requirements of the documents referenced in section 2.3.

11.0 TEST CONTROL

11.1 DOE/NE Implementation

DOE/NE delegates to DOE/ID the Project responsibility for testing and test control practices in support of waste form development, qualification, and production activities. DOE witnesses tests by the major Project participants on a selective basis and may, on limited occasions, conduct independent tests of its own. Should DOE elect to perform or have an agent perform tests, the test control practices will conform to the same requirements imposed upon other participants. Authority for determining and establishing DOE testing participation is delegated to the WV-PM through the ID-PM.

DOE/NE monitors through program reviews, readiness reviews, and other means the major Project participant test control practices related to development, qualification, and production activities and periodically audits the participant practices to assure proper implementation and adequacy.

11.2 Requirements of Other Participants

Each participant who is assigned responsibilities for performing manufacturing, fabrication, and assembly; or operation (operation of test activities) activities in support of waste form development, qualification, and production activities is required by contract to establish required tests, including proof tests prior to installation, preoperational tests, and product certification tests. The testing activities shall meet the requirements of the documents referenced in section 2.3.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 DOE/NE Implementation

DOE/NE delegates to DOE/ID the Project responsibility for control of measuring and test equipment which supports development, qualification, and production activities. Should DOE elect to perform or have an agent perform inspections, examinations, or tests, the measuring and test equipment is controlled in accordance with those requirements imposed upon the participants. DOE authority for determining and establishing such activity is delegated to the WV-PM through the ID-PM.

DOE/NE monitors through program reviews, readiness reviews, and other means the major Project participant measuring and test equipment control practices related to waste form development, qualification, and production activities and periodically audits participant practices to assure proper implementation and adequacy.

12.2 Requirements of Other Participants

Project participants who are assigned responsibility for performing inspections, examinations, or tests which support waste form development, qualification, and production activities are required by contract to establish and implement a system for calibration and control of measuring and test equipment that meets the requirements of the DOE Orders and other documents referenced in section 2.3.

13.0 HANDLING, STORAGE AND SHIPPING

13.1 DOE/NE Implementation

DOE/NE delegates to DOE/ID the Project responsibility for handling, storage, and shipping practices which support waste form development, qualification, and production activities.

DOE/NE monitors through program reviews, readiness reviews, and other means the major Project participant handling, storage, and shipping practices related to waste form development, qualification, and production activities and periodically audits participant practices to assure implementation and adequacy.

13.2 Requirements of Other Participants

Each participant who is assigned responsibility for manufacturing, fabrication, or assembly which support waste form development, qualification, and production activities is required by contract to establish and implement practices for handling, storage, and shipping of items. These practices shall meet the requirements of DOE Orders and other documents referenced in section 2.3.

14.0 INSPECTION, TEST, AND OPERATING STATUS

14.1 DOE/NE Implementation

DOE/NE delegates to DOE/ID the Project responsibility for inspection, test, and operating status measures which support development and qualification activities to the other major Project participants through contracts.

DOE/NE monitors through program reviews, readiness reviews, and other means the major participant practices related to waste form development, qualification, and production activities for indicating inspection, test, and operating status and periodically audits participant practices to assure implementation and adequacy.

14.2 Requirements of Other Participants

Participants who are assigned responsibility for manufacturing, fabrication, and assembly; or operation (operation of test activities) activities which support development, qualification, and production activities are required to establish and implement practices to indicate the status of inspection and test activities. These practices shall meet the requirements of the DOE orders and other documents referenced in section 2.3.

15.0 CONTROL OF NONCONFORMING ITEMS

15.1 DOE/NE Implementation

DOE/NE delegates the DOE/ID the Project responsibility for control, review, and disposition of nonconforming items or activities which support development, qualification, and production activities. Delegation requires that disposition of significant nonconformances have DOE approval. Contracts shall require that DOE review and approval authorities be specified in the contractor's nonconformance control procedures. DOE also retains authority to identify and require that DOE-identified nonconformances be entered into the participant contractor's nonconformance control system. Authority for determining and establishing DOE participation in nonconformance disposition is delegated to the WV-PM through the ID-PM.

DOE/NE monitors through program reviews, audits, overviews, and other means performed on its behalf that Project participants have adequate and effective systems and procedures for the control of nonconforming items.

15.2 Requirements of Other Participants

Program participants, who are assigned responsibility for Nonconformance Control in support of development, qualification, and production activities are required by contract, to establish and implement a system for control of nonconforming items and services in accordance with the DOE orders and other documents referenced in section 2.3.

16.0 CORRECTIVE ACTION

16.1 DOE/NE Implementation

DOE/NE delegates to DOE/ID the Project responsibility for corrective action. Corrective action is required for significant conditions adverse to quality such as failures, nonconformances, malfunctions, deficiencies, deviations, and defective material and equipment that are required to support development, qualification, and production of an acceptable canistered waste form product. DOE authority for determining and specifying required DOE approval of corrective action is delegated to the WV-PM through the ID-PM.

DOE/NE monitors major participant corrective action systems related to waste form development, qualification, and production activities and periodically audits the participant systems to assure implementation and adequacy.

16.2 Requirements of Other Participants

Program participants, who are assigned responsibility for corrective actions in support of development, qualification, and production activities are required by contract, to establish and implement a system for control of corrective actions in accordance with the DOE orders and other documents referenced in section 2.3.

17.0 QUALITY ASSURANCE RECORDS

17.1 DOE/NE Implementation

DOE/NE delegates to DOE/ID the Project responsibility for control of DOE-generated quality assurance records. Responsibility for records preparation, collection, storage, and maintenance related to waste form development, qualification, and production is delegated through DOE/ID to other major Project participants by contracts.

The Director NE-24 shall assure through audits, effectiveness evaluations, reviews, and other means that Program participants have adequate and effective systems for the collection, storage, and maintenance of records important to waste form development, qualification, and production. Audit records and effectiveness reports generated by DOE/NE will be transmitted to the WVPO for records control and retention.

17.2 Requirements of Other Participants

Project participants, who are assigned responsibility for quality assurance records in support of waste form development, qualification, and production activities, are required by

contract, to establish and implement a system for control of quality assurance records in accordance with the DOE orders and other documents referenced in section 2.3.

18.0 AUDITS

18.1 DOE/NE Implementation

The Director NE-24 is responsible for the performance of audits, overviews, effectiveness evaluations, and other techniques to assess the status and effectiveness of the quality programs of the Project participants at Idaho and West Valley. The planning, scheduling, performance, and reporting of DOE Headquarters audits of the WVDP will be established in collaboration with DOE-RW.

DOE/NE may participate in DOE-RW-directed audits of the West Valley Project. The Director NE-24 retains the authority to schedule and direct DOE/NE audits independent of the DOE-RW audit program. The Director NE-24 will also assure that all DOE-HQ audits are coordinated with NRC-conducted audits.

The scheduling and status of audits is reported to senior DOE/NE management. The audit program will also assure that follow-up of corrective actions is accomplished as scheduled.

DOE authority and responsibility for delegating audit responsibility to other Project participants is delegated to DOE/ID.

18.2 Requirements of Other Participants

Project participants, who are assigned responsibility for auditing, overviews or effectiveness evaluations in support of waste form development, qualification, and production activities,

are required by contract to establish and implement a system for control of these functions in accordance with the DOE orders and other documents referenced in section 2.3.

19.0 OTHER BASIC REQUIREMENTS

In addition to the specified NQA-1 Requirement, section 5.1.2 of OGR/B-14, identifies required compliance to: (1) DOE Order 5000.3, "Unusual Occurrence Reporting System," (2) DOE Order 5700.6B "Quality Assurance," and (3) the DOE-specified "Guidelines for Application of Readiness Reviews to Department of Energy Activities, January 1987."

19.1 DOE/NE Implementation

DOE delegates UOR, quality assurance, and readiness review implementation responsibilities to each major Project participant by contract. Authority for this delegation has been delegated by the Director NE-24 to the ID-PM. DOE review and approval roles are as specified by the DOE-level requirements, and are required to be incorporated into contractor procedures.

DOE/NE monitors major participant practices through program reviews and other means to assure that waste form development, qualification, and production activities are correctly performed and adequate.

19.2 Requirements of Other Participants

Each major Project participant who is assigned UOR, quality assurance, and readiness review responsibilities in support of waste form development, qualification, and production activities is required by contract to implement and maintain procedurally controlled practices that meet the requirements of OGR/B-14, section 5.1.2.

20.0 OGR/B-14 SUPPLEMENTAL REQUIREMENTS

20.1 DOE/NE Implementation

Section 5.2 of OGR/B-14 identifies fourteen (14) additional or amplified requirements for Waste Acceptance Process activities. As applicable, requirements for compliance are specified by contract with each major Project participant. Authority and responsibility for establishing appropriate contractor compliance is delegated by the Director NE-24 to the ID-PM. In the overall Quality Assurance Program, DOE has direct implementation responsibility for four (4), participatory involvement in three (3), and overview/monitoring responsibility for the remaining seven (7). Implementation responsibility for these DOE activities is delegated to the WV-PM by the ID-PM. Refer to QAPD-2 (appendix A), QAPD-3 (appendix A), and QAPD-4 (appendix B) for the corresponding lists of implementing procedures.

DOE/NE monitors through program reviews and other means, the adequacy and effectiveness of major Project participant compliance to assigned requirements as applied to waste form development, qualification, and production activities.

20.2 Requirements of Other Participants

Each participant is required by contract to establish and implement required controls and procedures for compliance to any or all of the fourteen (14) identified OGR/B-14, section 5.2, Supplemental Requirements. Identified controls and procedures are to be appropriately applied to waste form development, qualification, and production activities within their contractual jurisdiction.

21.0 GLOSSARY

Refer to Appendix II, for a glossary of the terms used in this document.

TABLE OF CONTENTS

UNCONTROLLED

QAPD-2	SUBJECT	PAGE
0.0	INTRODUCTION	1
	0.1 Scope	1
	0.2 Basis	2
	0.3 Application	2
1.0	ORGANIZATION	2
	1.1 Function	3
	1.2 Responsibility and Authority	4
	1.3 Organizational Arrangement	6
	1.4 Qualification Requirements	6
	1.5 Communications	8
2.0	QUALITY ASSURANCE PROGRAM	9
	2.1 Policy and Objectives	9
	2.2 Responsibility	9
	2.3 Requirements	11
	2.4 Staffing and Training	14
3.0	DESIGN CONTROL	14
	3.1 DOE Implementation	14
	3.2 Requirements of Other Participants	
4.0	PROCUREMENT DOCUMENT CONTROL	15
	4.1 DOE Implementation	15
	4.2 Requirements of Other Participants	15
5.0	INSTRUCTIONS, PROCEDURES, AND DRAWINGS	15
	5.1 DOE Implementation	15
	5.2 Requirements of Other Participants	16
6.0	DOCUMENT CONTROL	16
	6.1 DOE Implementation	16
	6.2 Requirements of Other Participants	17
7.0	CONTROL OF PURCHASED ITEMS AND SERVICES	17
	7.1 DOE Implementation	17
	7.2 Requirements of Other Participants	17

TABLE OF CONTENTS (CONTINUED)

QAPD-1	SUBJECT	PAGE
8.0	IDENTIFICATION AND CONTROL OF ITEMS	18
	8.1 DOE Implementation	18
	8.2 Requirements of Other Participants	18
9.0	CONTROL OF PROCESSES	18
	9.1 DOE Implementation	18
	9.2 Requirements of Other Participants	19
10.0	INSPECTION	19
	10.1 DOE Implementation	19
	10.2 Requirements of Other Participants	20
11.0	TEST CONTROL	20
	11.1 DOE Implementation	20
	11.2 Requirements of Other Participants	21
12.0	CONTROL OF MEASURING AND TEST EQUIPMENT	21
	12.1 DOE Implementation	21
	12.2 Requirements of Other Participants	22
13.0	HANDLING, STORAGE, AND SHIPPING	22
	13.1 DOE Implementation	22
	13.2 Requirements of Other Participants	23
14.0	INSPECTION, TEST, AND OPERATING STATUS	23
	14.1 DOE Implementation	23
	14.2 Requirements of Other Participants	23
15.0	CONTROL OF NONCONFORMING ITEMS	24
	15.1 DOE Implementation	24
	15.2 Requirements of Other Participants	24
16.0	CORRECTIVE ACTIONS	25
	16.1 DOE Implementation	25
	16.2 Requirements of Other Participants	25

TABLE OF CONTENTS (CONTINUED)

QAPD-1	SUBJECT	PAGE
17.0	QUALITY ASSURANCE RECORDS	26
	17.1 DOE Implementation	26
	17.2 Requirements of Other Participants	26
18.0	AUDITS	27
	18.2 DOE Implementation	27
	18.3 Requirements of Other Participants	27
19.0	OTHER BASIC REQUIREMENTS	28
	19.1 DOE Implementation	28
	19.2 Requirements of Other Participants	28
20.0	OGR/B-14 SUPPLEMENTAL REQUIREMENTS	29
	20.1 DOE Implementation	29
	20.2 Requirements of Other Participants	29
21.0	GLOSSARY	30

FIGURES

Figure 1.3 - WVDP Organization Chart 7
Figure 2.3 - DOE-ID Quality Assurance Program Activities 13

THE DOE-ID QUALITY ASSURANCE PROGRAM DESCRIPTION FOR THE WEST VALLEY HIGH-LEVEL CANISTERED WASTE FORM PRODUCTION

UNCONTROLLED

0.0 INTRODUCTION

0.1 Scope

This document contains a description of the Quality Assurance Program to be implemented by the U.S. Department of Energy/Idaho Operations Office (DOE-ID) to verify that the development, qualification, and production activities essential for waste acceptance as defined in the Waste Acceptance Preliminary Specifications (WAPS), OGR/B-9, for the canistered high-level waste form at the DOE West Valley site is acceptable for shipping to and retention at a DOE repository. This program meets the requirements defined in the Office of Geological Repositories Quality Assurance Requirements for High-Level Waste Form Production (OGR/B-14) and forms a part of the integrated WVDP Quality Assurance Program. The program described herein shall outline the actions and activities to be taken by the DOE-ID to assure that the requirements of the repository program are effectively implemented by the West Valley Project Office (DOE-WVPO) and West Valley Nuclear Services (WVNS), the site contractor. The activities include verification, through audit and document review, of the various design, fabrication, construction, testing, and operational activities required to produce an acceptable high-level waste form product, including the glass form, the canister, and the production methods developed at the West Valley Demonstration Project.

0.2 Basis

This description document defines the activities performed or directed by DOE-ID as a part of the integrated Project Quality Assurance Program. Responsibility for assuring effective implementation of the overall West Valley Demonstration Project (WVDP) Quality Assurance Program rests with DOE-NE office. Responsibility for establishing and implementing portions of the program are delegated by DOE-NE to the other participants at DOE-ID and West Valley.

0.3 Application

The DOE-ID Quality Assurance Program described in this document is applicable to all high-level canistered waste form development, qualification, and production activities conducted at the West Valley Project. The activities covered include that portion of the program addressing waste form development and acceptance associated with the waste qualification and acceptance process. Essential elements of these processes involve materials control, equipment, facilities, and methods used in the qualification and certification of the canistered waste form. The program applied to the waste acceptance activities assures that the canistered waste form will be acceptable to the licensed federal repository. Specific activities and systems that are covered by the High-Level Waste Quality Assurance Program are listed in Appendix I.

1.0 ORGANIZATION

Responsibility for acceptance of high-level radioactive waste resulting from the WVDP Waste Acceptance Process Activities rests with the DOE Office of Civilian Radioactive Waste Management (referred to as DOE-RW). A portion of this responsibility has been delegated for

implementation to the Manager, Idaho Operations Office (DOE-ID) via DOE-NE. This responsibility is to assure the high-level canistered waste form product produced at the WVDP is developed and qualified in a way that will conform to all requirements of the Office of Geological Repository Waste Acceptance Preliminary Specification (OGR/B-9) (WAPS). To provide this assurance DOE-NE has directed the establishment and implementation of an integrated Quality Assurance Program which shall have the objectives, carry out the functions, and be executed as described in the rest of this document.

1.1 Function

1.1.1 The functions that DOE-ID will perform in order to achieve the stated objective of assuring effective implementation of the Quality Assurance Program and fulfill its responsibility for program adequacy are as follows:

a. development of the DOE-ID Quality Assurance Program Description (QAPD) for conduct of the DOE-ID portion of the Project Quality Assurance Program (this document),

b. assignment and delegation of program implementation responsibilities to appropriate Project participants.

c. overview of the implementation of program responsibilities delegated to appropriate Project participants. These include the WVPO and WVNS and any service contractors who perform quality assurance activities for DOE-ID,

d. development of plans and procedures for conduct of Quality Assurance Program activities,

e. organizing and staffing appropriately or contracting work as appropriate to implement program functions,

f. provide for audit of project activities in accordance with the requirements of OGR/B-14,

g. interfacing DOE-WVPO programs with DOE-RW programs, and

h. evaluation and approval of the DOE-WVPO Quality Assurance Program.

1.2 Responsibility and Authority

1.2.1 The DOE-ID Assistant Manager for Nuclear Programs (ID-PM) Manager reports to the Idaho Manager of the Operations Office. The ID-PM is assigned the responsibility of assuring that the Quality Assurance Program requirements as defined in the Quality Assurance Program Requirements for Waste Form Production (OGR/B-14) are correctly implemented and carried out by the implementing organizations at WVPO and WVNS. The ID-PM is authorized by the Manager, NE-24 through the Director, Idaho Operations to:

a. initiate, recommend, or provide solutions to quality related problems identified in audits or other program reviews through designated channels,

b. verify implementation of solutions,

c. through audits or other reviews of the project, determine the adequacy of facilities and equipment provided to carry out approved procedures and instructions,

d. authorize issuance of special instructions necessary to implement assigned quality assurance responsibilities, and

e. notify responsible higher management of unsatisfactory work or unapproved practices. Take steps (such as stop work) to bring unsatisfactory work into conformance.

1.2.2 The ID-PM has the delegated responsibility to assure that the requirements of OGR/B-14 are correctly carried out. He shall accomplish this task through various means including the following:

a. auditing or causing to be audited the Quality Assurance Programs of WVPO and the West Valley site contractor,

b. performing or causing to be performed effectiveness evaluations of the Quality Assurance Programs at West Valley as required by section 5.2.14 of OGR/B-14. These evaluations include the following:

- o a clear identification of the quality characteristics to be achieved in meeting the requirements of the WAPS.
- o the identification of an appropriate set of performance indicators that reflect actual quality characteristics being achieved.
- o a performance measuring process using review, surveillance, inspection, tests, audit or other techniques to monitor performance indicators.

- o an analysis process in which performance data are trended and problem areas identified.

- o a reporting practice in which program effectiveness information is prepared and fed back to top management.

c. participating in readiness review activities at West Valley at key milestones for the project, and

d. identifying and supporting the resolution of quality related problems.

The ID-PM has delegated to the West Valley Project Manager (WV-PM) the responsibility for assuring correct implementation of the requirements of OGR-B14 at the Project site.

1.3 Organizational Arrangement

1.3.1 The DOE-ID organizational structure for performing quality-related tasks that assure effective implementation of the repository Quality Assurance Program requirements is one part of the DOE overall organizational structure shown on figure 1.3. The DOE-ID-PM is responsible for assuring the effective implementation of quality programs at all levels within the project scope.

1.4 Qualification Requirements

1.4.1 The ID-PM shall assure that the personnel or organizations performing the Quality Assurance Program auditing and monitoring activities assigned to the DOE-ID organization are

West Valley Demonstration Project Organizational Chart

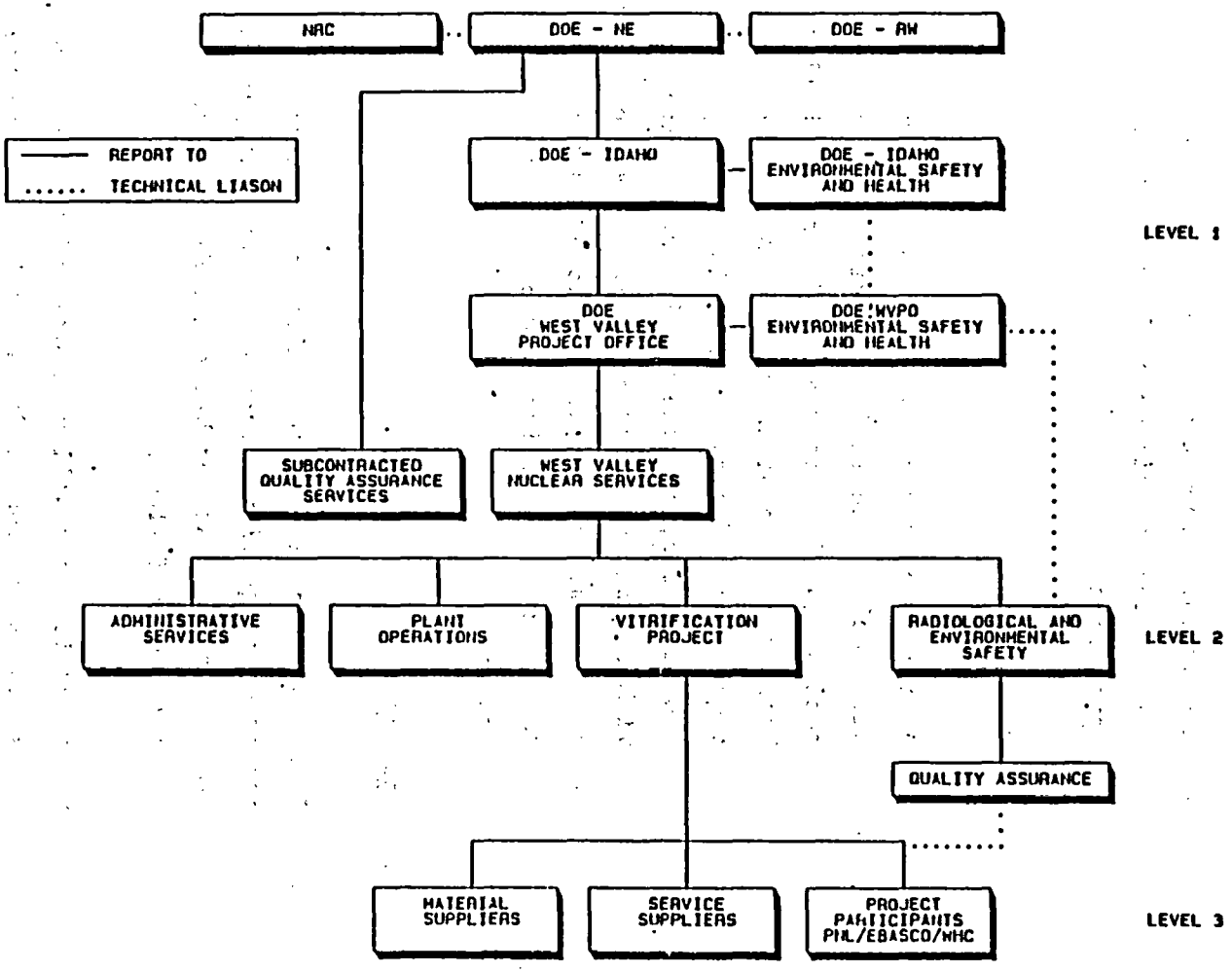

Figure 1.3

qualified by virtue of experience and training. The individuals or organizations performing the auditing and monitoring activities shall have the following qualifications as a minimum:

a. Education: Graduation from a four-year accredited engineering or science college or university, or equivalent.

b. Experience:

A minimum of seven (7) years in activities associated with nuclear facilities. A minimum of four (4) years in nuclear quality assurance. He or she shall possess a broad knowledge of the Quality Assurance Program requirements for the nuclear industry, government codes and standards, and the regulatory requirements associated with repository program high-level waste form work. He or she shall be a qualified lead auditor experienced in the planning, defining, and performing quality assurance practices.

1.5 Communications

1.5.1 To promote the flow of communications and to assure positive attention to quality programs with Project participants, lines of communications between DOE-ID and the WVPO are established as follows:

a. communications will be addressed to the responsible senior management official with copies to the major Project participants cognizant of the subject,

b. communications may be formal or informal, the choice of which shall depend on the significance of the subject and the judgement of the individuals involved, and

c. communication of quality assurance-related activities between DOE-ID and WVPO or the site contractor (WVNS) is promoted through periodic Project progress and status reporting by major Project participants.

2.0 QUALITY ASSURANCE PROGRAM

2.1 Policy and Objectives

The policy and objectives of the DOE-ID WVDP Quality Assurance Program are:

a. to assure quality is achieved in the development, qualification, and production of an acceptable canistered high-level waste form product from the WVDP,

b. to assure that appropriate quality assurance activities are implemented by or for DOE-ID.

2.2 Responsibility

DOE-ID

a. As stated in section 1.0, the DOE-ID-PM has the delegated responsibility, from DOE-NE via Director DOE-ID, to assure that the Quality Assurance Program at the West Valley Demonstration Project Office is established and implemented effectively throughout the duration of Project activities.

b. The ID-PM is authorized to monitor, overview, audit, perform effectiveness evaluations, and participate in readiness reviews as appropriate to assure that the Project quality programs for waste form production at West Valley are being implemented effectively. The ID-PM shall direct annual audits of Project activities, as a minimum.

c. The ID-PM will assist the Director (NE-24) in interfacing between the Project and the regulating organizations of DOE-RW and the NRC. The ID-PM shall support the DOE-ID Quality Assurance Branch in planning, scheduling, and will participate as necessary with these organizations in the audits and reviews performed by the Project at West Valley and Idaho.

d. The ID-PM shall review and, as appropriate, recommend DOE-NE approval of the WVDP Quality Assurance Program Description prepared by WVPO.

e. To determine program status and to evaluate program adequacy, the ID-PM will implement a program review practice to assess the scope, implementation, and effectiveness of the Project Quality Assurance Program. An annual effectiveness evaluation will be performed or directed by the ID-PM using available resources and information, including the results from Project surveillance, inspection, and audit activities.

f. The ID-PM monitors the status of program activities reported in the form of existing regular progress and status reports and other special reports as appropriate. These reports outline the progress and status of quality assurance activities, problems and nonconformances, quality trends, and results of audits. Management action, as required to improve conditions and further implement the program, will be initiated by the ID-PM.

Participants

a. Although DOE retains the responsibility for adequacy of the overall Project Quality Assurance program, other major participants are assigned by contract the responsibility for establishing and implementing particular program practices. These delegated program elements are described in section 2.3.

b. Program participation responsibilities are described as a three-level structure. The DOE portion of the program is the first level. Other major program participants including major DOE subcontractors form the second level. The third level is composed of the multitude of systems, components, materials, and service suppliers that are directed by the second level. This three-level organization is graphically depicted in figure 1.3.

2.3 Requirements

Overall

The requirements for the overall Quality Assurance Program are contained in DOE order 5700.6B, Quality Assurance; ID Order 5700.6C, Quality Assurance; DOE Order 5000.3, Unusual Occurrence Reporting System; Guidelines for Application of Readiness Reviews to Department of Energy Activities; and ANSI/ASME NQA-1, Quality Assurance Program Requirements for Nuclear Facilities. Additional and supplemental requirements applicable to waste form production are contained in OGR/B-14. These requirements are illustrated by the identification of the program elements described in later sections of this program description.

Program Elements Implemented by DOE-ID

Elements of the overall Project Quality Assurance Program which will be implemented by DOE-ID are those identified as Organization; Quality Assurance Program; Instructions, Procedures and Drawings; Document Control; Quality Assurance Records; and Audits. DOE-ID will conduct these program elements in accordance with documented procedures and management practices. Figure 2.3 illustrates the principal elements of the DOE-ID program. DOE-ID quality assurance implementing procedures are identified in Appendix A.

Program Elements Delegated to Others

a. The responsibility for implementation of development, design, testing, and operational program functions is delegated by DOE-ID to DOE-WVPO. WVPO may pass along those functions to the site contractor to assure that each function will be performed by the organization most qualified. The ultimate responsibility for adequate implementation and performance by the site contractor or its subcontractors is retained by DOE. Refer to QAPD-4 for details of the site contractor's Waste Acceptance Process Quality Assurance Program, and QAPD-3 for details of the WVPO's Quality Assurance Program.

b. Program elements delegated to DOE-ID may be executed through contracts. These contracts will specify applicable requirements for contractor Quality Assurance Programs.

c. The responsibility for establishing and implementing control systems for nonconformances and corrective action is delegated to major Project participants. DOE-ID delegates to WVPO the necessary responsibility and authority for participation and/or approvals to assure proper disposition of significant nonconformances and effectiveness of corrective action.

DOE/ID QUALITY ASSURANCE PROGRAM ACTIVITIES

Overall Program

- Objectives
- Responsibilities
- Requirements
- Control and Verification

AND

PROGRAM MANAGEMENT

- Organization
  - Structuring
  - Documenting
- Quality Assurance Program
  - Planning
  - Developing
  - Documenting
  - Reporting
  - Effectiveness Evaluation
- Instructions, Procedures, and Drawings
  - Preparation, Review, and Drawings
  - Issues and Distribution
  - Change Control
- Document Control
  - Implementing Procedures
- Records
  - Records Preparation
  - Records Management
- Audits
  - Project Audits
  - Audit Records

Figure 2.3 – Major Elements of the DOE/ID Quality Assurance Program

2.4 Staffing and Training

DOE-ID personnel who are assigned responsibility for verifying that quality assurance performance is in accordance with requirements are selected and assigned to their area of responsibility based upon experience, education, and management's assessment of their performance capabilities. Their performance is evaluated on a continuing basis by appropriate DOE-ID management. On-going training and indoctrination programs are conducted to familiarize personnel with the technical objectives of the activity being monitored, the requirements that the activity must meet, the practices and procedures to be executed in verifying conformance to requirements, and the documentation of results.

3.0 DESIGN CONTROL

3.1 DOE Implementation

DOE-ID delegates implementation responsibility for design control activities to major Project participants through contracts. DOE-ID has delegated to WVPO the authority and responsibility for determining and establishing appropriate contractual delegation. The design activities are required to be in compliance with the DOE orders and documents referenced in section 2.3 of this document.

DOE-ID monitors these activities for adequacy through reviews, audits, and other appropriate means.

3.2 Requirements of Other Participants

Project participants who are assigned design control responsibility in support of waste form development, qualification, and production activities are required by contract to implement and maintain a design control practice that meets the requirements of the documents referenced in section 2.3.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 DOE Implementation

DOE-ID will not procure items to support WVDP development, waste form, qualification, and production directly, but delegates this requirement to other Project participants through the WVPO.

DOE-ID monitors these activities for adequacy through reviews, audits, and other appropriate means.

4.2 Requirements of Other Participants

Each major Project participant who is assigned procurement responsibility in support of waste form development, qualification, and production activities is required by contract to implement and maintain a procurement document control practice that meets the requirements of the documents referenced in section 2.3.

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 DOE Implementation

DOE-ID shall establish and implement appropriate procedures and instructions for DOE-ID conducted or directed quality assurance activities.

DOE-ID has delegated to WVPO authority and responsibility for requiring that participant organizations performing activities affecting quality of waste form development, qualifications, and production use instructions and procedures appropriate to the task being performed.

DOE-ID shall assure through reviews, audits, and other appropriate means that procedures in effect at the West Valley Project are adequate and complete and appropriate to the task being performed.

5.2 Requirements of the Participants

Each Project participant is required to have an adequate and effective system of instructions, procedures, and drawings for activities affecting quality of waste form development, qualification, and production. This system is to be in accordance with the requirements of the DOE Orders and other documents referenced in section 2.3.

6.0 DOCUMENT CONTROL

6.1 DOE Implementation

DOE-ID has established practices for document control that are consistent with the scope of its involvement with the West Valley Project. The responsibility and authority for determining and assigning document control requirements to major Project participants is delegated to WVPO. Document control requirements applicable to waste form development, qualification, and production activities are identified in section 2.3.

DOE-ID shall assure through the audits, overviews, and readiness reviews performed by or on behalf of the ID-PM that the program participants have in place adequate and effective document control systems.

6.2 Requirements of Other Participants

Each major Project participant shall be required by contract to have a system and procedures in place for the control of quality affecting documents that is in accordance with the requirements of the documents identified in section 2.3.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 DOE Implementation

DOE-ID has delegated to WVPO the responsibility and authority for assigning to Project participants the implementation responsibility for control of purchased items for waste form development, qualification, and production activities that comply with applicable requirements from the documents identified in section 2.3.

DOE-ID monitors through program reviews, readiness reviews, and other means the major participant procurement practices related to development and qualification activities and periodically audits the participant practices to assure proper implementation and adequacy.

7.2 Requirements of Other Participants

Project participants, who are assigned responsibility for procurement of items and services in support of waste form development, qualification, and production activities, are required, by contract, to establish and implement a system for control of those procurements in accordance with the DOE Orders and other documents referenced in section 2.3.

8.0 IDENTIFICATION AND CONTROL OF ITEMS

8.1 DOE Implementation

DOE-ID has delegated to WVPO the responsibility and authority for assigning implementation responsibility for identification and control of items which support waste form development, qualification, and production activities to the other major Project participants through contracts.

DOE-ID monitors through program reviews, readiness reviews, and other means the major participant identification and control of item practices related to waste form development, qualification, and production activities and periodically audits the participant practices to assure proper implementation and adequacy.

8.2 Requirements of Other Participants

Each Project participant, who has an assigned responsibility for items which support waste form development, qualification, and production activities is required, by contract, to establish and implement identification and control practices required by DOE Orders and other documents referenced in section 2.3.

9.0 CONTROL OF PROCESSES

9.1 DOE Implementation

DOE-ID has delegated to WVPO the authority and responsibility for assignment of implementation responsibility for control of special processes in support of waste form development, qualification, and production activities to major Project participants through contracts.

DOE-ID monitors through program reviews, readiness reviews, and other means the major participant special processes control practices related to waste form development, qualification, and production activities and periodically audits the participant practices to assure proper implementation and adequacy.

9.2 Requirements of Other Participants

Project participants who are assigned responsibility for activities where special processes in support of waste form development, qualification, and production activities are involved, are required, by contract, to establish and implement practices to assure adequate performance and control of special processes. Controls shall meet the requirements of the documents referenced in section 2.3.

10.0 INSPECTION

10.1 DOE Implementation

DOE-ID has delegated to WVPO the authority and responsibility for assignment of implementation responsibility for direct inspection of items and work practices in support of waste form development, qualification, and production activities to major Project participants in their contractually assigned scope of work. DOE or an agent may perform or witness inspection on a selective basis. Should WVPO elect to perform or have an agent perform inspections, the practice followed conforms to the same requirements imposed upon other participants.

DOE-ID monitors through program reviews, readiness reviews, and other means the major Project participant inspection practices associated with waste form development, qualification, and production activities and periodically audits the participants' practice to assure proper implementation and adequacy.

10.2 Requirements of Other Participants

Each participant who is assigned responsibility for performing procurement; manufacturing, fabrication, and assembly; or operational activities (operation of test activities) in support of waste form development, qualification, and production activities is required, by contract, to establish and implement an inspection practice of sufficient scope to be fully effective. The inspection practice will identify and verify conformance of items and services with the document specifications, instructions, procedures, and drawings for accomplishing the required activities. The documented inspection practices shall meet the requirements of the documents referenced in section 2.3.

11.0 TEST CONTROL

11.1 DOE Implementation

DOE-ID has delegated to WVPO authority and responsibility for assignment of implementation responsibility for testing and test control practices in support of waste form development, qualification, and production activities to major Project participants by contracts. DOE may witness tests by major Project participants on a selective basis and may, on limited occasions, conduct independent tests of its own. Should WVPO elect to perform or have an agent perform tests, the test control practices will conform to the same requirements imposed upon other participants.

DOE-ID monitors through program reviews, readiness reviews, and other means the major Project participant test control practices related to waste form development, qualification, and production activities and periodically audits the participant practices to assure proper implementation and adequacy.

11.2 Requirements of Other Participants

Each participant who is assigned responsibilities for performing manufacturing, fabrication, and assembly; or operational (operation of test activities) activities in support of waste form development, qualification, and production activities is required by contract when applicable to establish tests, such as proof tests prior to installation, preoperational tests, and product certification tests. The testing activities shall meet the requirements of the documents referenced in section 2.3.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 DOE Implementation

DOE-ID has delegated to WVPO the authority and responsibility for assigning implementation for responsibility for control of measuring and test equipment which supports waste form development, qualification, and production activities to the other major Project participants through contracts. Should DOE elect to perform or have an agent perform inspections, examinations, or tests, the measuring and test equipment is controlled in accordance with those requirements imposed upon the other participants.

DOE-ID monitors through program reviews, readiness reviews, and other means the major Project participant measuring and test equipment control practices related to waste form development, qualification, and production activities and periodically audits participant practices to assure proper implementation and adequacy.

12.2 Requirements of Other Participants

Project participants who are assigned responsibility for performing inspections, examinations, or tests which support waste form development, qualification, and production activities are required by contract to establish and implement a system for calibration and control of measuring and test equipment that meets the requirements of the DOE orders and other documents referenced in section 2.3.

13.0 HANDLING, STORAGE, AND SHIPPING

13.1 DOE Implementation

DOE-ID has delegated to WVPO the authority and responsibility for assigning implementation responsibility for handling, storage, and shipping practices which support waste form development, qualification, and production activities to the other major Project participants through contracts.

DOE-ID monitors through program reviews, readiness reviews, and other means the major Project participant handling, storage, and shipping practices related to waste form development, qualification, and production activities and periodically audits participant practices to assure implementation and adequacy.

13.2 Requirements of Other Participants

Each participant who is assigned responsibility for manufacturing, fabrication, or assembly which support waste form development, qualification, and production activities is required by contract to establish and implement practices for handling, storage, and shipping of items. These practices shall meet the requirements of DOE orders and other documents referenced in section 2.3.

14.0 INSPECTION, TEST, AND OPERATING STATUS

14.1 DOE Implementation

DOE-ID has delegated to WVPO authority and responsibility for assigning implementation responsibility for inspection, test, and operating status measures which support waste form development, qualification, and production activities to the other major Project participants through contracts.

DOE-ID monitors through program reviews, readiness reviews, and other means the major participant practices related to waste form development, qualification, and production activities for indicating inspection, test, and operating status and periodically audits participant practices to assure implementation and adequacy.

14.2 Requirements of Other Participants

Participants who are assigned responsibility for manufacturing, fabrication, and assembly; or operational (operation of test activities) activities which support waste form development, qualification, and production activities are required to establish

and implement practices to indicate the status of inspection and tests performed upon individual items throughout waste form development, qualification, and production activities by using such markings as stamps, tags, labels, routing cards, or other suitable means. These practices shall meet the requirements of DOE Orders and other documents referenced in section 2.3.

15.0 CONTROL OF NONCONFORMING ITEMS AND SERVICES

15.1 DOE Implementation

DOE-ID has delegated to WVPO the authority and responsibility for assuring control, review, and disposition of nonconforming items or activities which support waste form development, qualification, and production activities. Direct responsibility for nonconformance control is assigned to major Project participants by contract. DOE shall have the authority to identify nonconforming items or activities and require that DOE-identified nonconformances be entered into the participant contractor's nonconformance control system.

DOE-ID shall assure through audits, overviews, and other means that the Project participants at the West Valley Project have adequate and effective systems and procedures in place and functioning for the control of nonconforming items.

15.2 Requirements of Other Participants

Participants who are assigned responsibility for manufacturing, fabrication, and assembly; or test activities which support waste form development, qualification, and production activities are

required to establish and implement practices that control nonconforming items and services. These practices shall meet the requirements of DOE orders and other documents referenced in section 2.3.

16.0 CORRECTIVE ACTIONS

16.1 DOE Implementation

DOE-ID has delegated to WVPO the authority and responsibility for assuring implementation of an adequate and effective correction system for waste form development, qualification, and production activities. Direct implementation responsibility for corrective action is assigned to major Project participants by contract. DOE review and approval authority shall be appropriately specified by WVPO-approved contractor procedures.

DOE-ID shall assure through audits, overviews, and other means performed on its behalf that the major Project participants have in place systems and procedures that define and implement a corrective action system that meets the requirements of DOE orders and other documents referenced in section 2.3.

16.2 Requirements of Other Participants

Participants who are assigned responsibility for manufacturing, fabrication, and assembly; or operational test activities which support waste form development, qualification, and production activities are required to establish and implement practices that determine the causes of and require corrective action to be taken to correct conditions adverse to quality. These practices shall meet the requirements of DOE orders and documents referenced in section 2.3.

17.0 QUALITY ASSURANCE RECORDS

17.1 DOE Implementation

DOE-ID has an established record system for collection and retention of DOE-ID-generated records required to support the overall Project Quality Assurance Program. DOE-ID has delegated to WVPO the authority and responsibility for assigning records implementation responsibility for records preparation, collection, storage, and maintenance to major Project participants by contract. DOE-ID has also delegated to WVPO the authority and responsibility for establishing an acceptable Project records repository for DOE-generated records supporting DOE verification of acceptable waste form development, qualification, and production activities.

DOE-ID shall assure through audits and other means performed on its behalf that the Project participants have in place systems for the collection, storage, and maintenance of records important to the development, qualification, and production activities. These systems shall meet the requirements for record control identified by the DOE orders and documents referenced in section 2.3.

17.2 Requirements of Other Participants

Program participants, who are assigned responsibility for Quality Assurance records in support of development, qualification, and production activities, are required by contract to establish and implement a system for control of those Quality Assurance records in accordance with the DOE orders and other documents referenced in section 2.3.

18.0 AUDITS

18.1 DOE Implementation

DOE-ID is responsible for implementing through contract or other means a system for the performance of audits, overviews, effectiveness evaluations, and other techniques to assess the status and effectiveness of the quality programs of Project participants at the West Valley Project. The system shall provide for the planning, scheduling, performing, and reporting on the status of the quality programs to senior DOE-ID management. The system shall also assure that follow up of identified conditions adverse to quality is performed until satisfactory resolution is obtained.

DOE-ID has delegated to WVPO the responsibility and authority for assuring implementation of effective audit programs by other major Project participants. Assignment of Project audit responsibility, as required by the DOE Orders and documents referenced in section 2.3, is established by contract.

18.2 Requirements of Other Participants

Program participants, who are assigned responsibility for quality assurance audits in support of waste form development, qualification, and production activities, are required by contract to establish and implement a system for control of those quality assurance audits in accordance with the DOE orders and other documents referenced in section 2.3.

19.0 OTHER BASIC REQUIREMENTS

In addition to the specified NQA-1 Requirement, section 5.1.2 of OGR/B-14, identifies required compliance to: (1) DOE Order 5000.3, "Unusual Occurrence Reporting System," (2) DOE Order 5700.6B "Quality Assurance," and (3) the DOE-specified "Guidelines for Application of Readiness Reviews to Department of Energy Activities, January 1987."

19.1 DOE Implementation

DOE delegates UOR, quality assurance, and readiness review implementation responsibilities to each major Project participant by contract. Authority for this delegation has been delegated to the WV-PM by the ID-PM. DOE review and approval roles are as specified by the DOE level requirements, and are required to be incorporated into contractor procedures.

DOE-ID monitors major participant practices through program reviews and other means to assure that waste form development, qualification, and production activities are correctly performed and adequate.

19.2 Requirements of Other Participants

Each major Project participant who is assigned UOR, quality assurance, and readiness review responsibilities in support of waste form development, qualification, and production activities is required by contract to implement and maintain procedurally controlled practices that meet the requirements of OGR/B-14, section 5.1.2.

20.0 OGR/B-14 SUPPLEMENTAL REQUIREMENTS

20.1 DOE Implementation

Section 5.2 of OGR/B-14 identifies fourteen (14) additional or amplified requirements for Waste Acceptance Process activities. As applicable, requirements for compliance are specified by contract with each major Project participant. Authority and responsibility for determining applicability and establishing appropriate contractor compliance are delegated to the WV-PM by the ID-PM. In the overall Quality Assurance Program, DOE has direct implementation responsibility for four (4), participatory involvement in three (3), and overview/monitoring responsibility for the remaining seven (7). Implementation responsibility for these DOE activities is delegated to the WV-PM by the ID-PM. The procedures to be implemented by DOE-ID are listed in Appendix A.

DOE-ID monitors through program reviews and other means, the adequacy and effectiveness of major Project participant compliance to assigned requirements as applied to waste form development, qualification, and production activities.

20.2 Requirements of Other Participants

Each participant is required by contract to establish and implement required controls and procedures for compliance to any or all of the fourteen (14) identified OGR/B-14, section 5.2, Supplemental Requirements. Identified controls and procedures are to be appropriately applied to waste form development, qualification, and production activities within the participants' contractual jurisdiction. Refer to QAPD-3, Appendix A and QAPD-4, Appendix B for details of the DOE's and the SC's implementing procedures for the fourteen supplemental requirements.

21.0 GLOSSARY

Refer to Appendix II, for a glossary of the terms used in this document.

APPENDIX A

Schedule for DOE-ID Implementing Procedures

Requirement	Implementing Procedures
NQA-1	
1. Organization	TBAL*
2. QA Program	TBAL
5. Instructions and Procedures	TBAL
6. Document Control	TBAL
17. QA Records	TBAL
18. Audits	TBAL

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* TBAL - to be added later

TABLE OF CONTENTS

UNCONTROLLED

QAPD-3	SUBJECT	PAGE
0.0	INTRODUCTION	1
0.1	Scope	1
0.2	Basis	2
0.3	Application	2
1.0	ORGANIZATION	2
1.1	Function	3
1.2	Responsibility and Authority	4
1.3	Organizational Arrangements	6
1.4	Qualification Requirements for Quality Assurance Management Position	8
1.5	Communication	9
2.0	QUALITY ASSURANCE PROGRAM	10
2.1	Policy and Objectives	10
2.2	Responsibility	10
2.3	Requirements	13
2.4	Staffing and Training	17
3.0	DESIGN CONTROL	17
3.1	DOE Implementation	17
3.2	Requirements of Other Participants	18
4.0	PROCUREMENT DOCUMENT CONTROL	18
4.1	DOE Implementation	18
4.2	Requirements of Other Participants	19
5.0	INSTRUCTIONS, PROCEDURES, AND DRAWINGS	19
5.1	DOE Implementation	19
5.2	Requirements of Other Participants	20
6.0	DOCUMENT CONTROL	20
6.1	DOE Implementation	20
6.2	Requirements of Other Participants	22
7.0	CONTROL OF PURCHASED ITEMS AND SERVICES	22
7.1	DOE Implementation	22
7.2	Requirements of Other Participants	23

TABLE OF CONTENTS (CONTINUED)

QAPD-3	SUBJECT	PAGE
8.0	IDENTIFICATION AND CONTROL OF ITEMS	23
	8.1 DOE Implementation	23
	8.2 Requirements of Other Participants	24
9.0	CONTROL OF PROCESSES	24
	9.1 DOE Implementation	24
	9.2 Requirements of Other Participants	24
10.0	INSPECTION	25
	10.1 DOE Implementation	25
	10.2 Requirements of Other Participants	25
11.0	TEST CONTROL	26
	11.1 DOE Implementation	26
	11.2 Requirements of Other Participants	26
12.0	CONTROL OF MEASURING AND TEST EQUIPMENT	27
	12.1 DOE Implementation	27
	12.2 Requirements of Other Participants	27
13.0	HANDLING, STORAGE, AND SHIPPING	28
	13.1 DOE Implementation	28
	13.2 Requirements of Other Participants	28
14.0	INSPECTION, TEST, AND OPERATING STATUS	28
	14.1 DOE Implementation	28
	14.2 Requirements of Other Participants	29
15.0	CONTROL OF NONCONFORMING ITEMS	29
	15.1 DOE Implementation	29
	15.2 Requirements of Other Participants	30
16.0	CORRECTIVE ACTION	30
	16.1 DOE Implementation	30
	16.2 Requirements of Other Participants	31
17.0	QUALITY ASSURANCE RECORDS	31
	17.1 DOE Implementation	31
	17.2 Requirements of Other Participants	33

TABLE OF CONTENTS (CONTINUED)

QAPD-3	SUBJECT	PAGE
18.0	AUDITS AND SURVEILLANCES	33
	18.1 DOE Implementation	33
	18.1.1 Audits	33
	18.1.2 Surveillance	35
	18.2 Requirements of Other Participants	36
19.0	OTHER BASIC REQUIREMENTS	36
	19.1 DOE Implementation	36
	19.2 Requirements of Other Participants	37
20.0	OGR/B-14 SUPPLEMENTAL REQUIREMENTS	37
	20.1 DOE Implementation	39
	20.2 Requirements of Other Participants	42
21.0	GLOSSARY	42

FIGURES

Figure 1.3 - WVDP Organization Chart 7
Figure 2.3 - DOE-WVPO QA Program Activities 14

QAPD-3
Rev. 0
05/17/89

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DOE/WVDP-WVPO

QUALITY ASSURANCE PROGRAM DESCRIPTION FOR THE WEST VALLEY HIGH-LEVEL CANISTERED WASTE FORM PRODUCTION

0.0 INTRODUCTION

0.1 Scope

This document contains a description of the plans and actions by the US Department of Energy (DOE), West Valley Operations Office (WVPO), through the Idaho Operations Office (DOE-ID) to assure that quality is achieved in the development, qualification, and production as defined in the Waste Acceptance Preliminary Specifications (WAPS) for the canistered high-level waste form product from the West Valley Demonstration Project (WVDP). Development and qualification activities include the research and development work to arrive at an acceptable high-level waste form, canister for the waste form, and ultimately the canistered waste form product. Also included is the design and development of the high-level waste form production process (and equipment) to perform that process at the DOE West Valley Demonstration Project. It further includes the testing necessary to demonstrate that the canistered waste form product from the WVDP will satisfy all requirements of the Waste Acceptance Preliminary Specifications (WAPS). The program consisting of the specific Quality Assurance plans and actions referenced above is hereafter referred to as the "Project Quality Assurance Program."

0.2 Basis

This program description document defines the Project-level activities and responsibility for assuring the adequacy and effectiveness of the overall Project Quality Assurance Program. Responsibility for establishing and implementing portions of the overall Project Quality Assurance Program has been delegated by WVPO to others participating in the Project, with responsibility for the adequacy of their performance retained by the WVPO.

0.3 Application

The WVPO Quality Assurance Program described herein is an inclusive program applicable to all high-level canistered waste form development, qualification, and production activities essential to product acceptance. These activities are associated with research and development that are essential to qualification of the waste form; control of materials, equipment, facilities, and processes that are essential to the certification of the canistered waste forms; and processing operations that are essential to the certification of canistered waste forms. The program applied to waste acceptance activities implements additional provisions to assure the canistered waste form will be acceptable to a licensed federal repository. Specific activities and systems covered by this program are listed in Appendix I.

1.0 ORGANIZATION

Responsibility for acceptance of high-level radioactive waste resulting from the WVDP Waste Acceptance Process Activities rests with the DOE Office of Civilian Radioactive Waste Management (DOE-RW).

Responsibility for implementation has been delegated to the DOE West Valley Project Office (WVPO) through DOE-NE, the Idaho Operations Office (DOE-ID) Manager, and the DOE-ID Assistant Manager for Nuclear Programs (ID-PM). This delegated responsibility includes assurance that the high-level canistered waste form product produced in the WVDP is developed and qualified in a way that will conform to all requirements of the Waste Acceptance Preliminary Specification (WAPS). To provide this assurance, the ID-PM has directed the establishment and conduct of an overall integrated Project Quality Assurance Program which shall have the objectives, carry out the functions, and be implemented as described in the rest of this document.

1.1 Function

1.1.1 Functions the WVPO will perform in order to achieve the stated objectives of the Project Quality Assurance Program and fulfill its responsibility for program adequacy are as follows:

a) Development of an overall plan for conduct of the Project Quality Assurance Program (this document).

b) Assignment and delegation of program implementation responsibility to appropriate Project participants. These include the contractors and subcontractors who participate in the Project, as well as service contractors who only perform independent quality assurance verification activities.

c) Development of instructions, plans, and procedures for conduct of QA program activities.

d) Organizing and staffing appropriately or contracting work as appropriate to implement QA program functions.

e) Implementation of WVPO program activities.

f) Interfacing of major participant programs with DOE's program.

g) Evaluation and approval of major participant Quality Assurance Programs.

h) Development and implementation of programs where DOE elects to retain execution responsibility in lieu of assigning it to another organization.

1.2 Responsibility and Authority

1.2.1 The West Valley Project Director (WV-PM), who reports directly to the DOE Idaho Assistant Manager for Nuclear Programs, is assigned responsibility for development, implementation, and effective application of the overall Project Quality Assurance Program. In carrying out these responsibilities, the WV-PM is authorized by the DOE-ID through the Idaho Operations Office Manager to:

a) Initiate, recommend, or provide solutions to quality problems identified in audits, surveillances, or other program reviews through designated channels.

b) Verify implementation of solutions.

c) Determine the adequacy of facilities and equipment provided to carry out approved procedures and instructions.

d) Authorize issuance of special instructions necessary to execute his or her responsibilities.

e) Notify responsible contractor management of unsatisfactory work or unapproved practices, and if necessary, stop unsatisfactory work or control further processing, delivery, or installation of nonconforming materials.

1.2.2 The WV-PM is responsible for the following specific tasks:

a) Organizing the overall Project Quality Assurance Program and for making further assignments of implementation responsibility as appropriate.

b) Assuring that each major participant's program enables the person or organization responsible for assuring an appropriate Quality Assurance Program to have sufficient authority to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions.

c) Recommending to the DOE-ID Manager the organization and staffing plan for the WVPO in the conduct of quality assurance activities necessary to fulfill DOE responsibilities for establishment and adequacy of the overall Project Quality Assurance Program.

d) Technical and administrative control of individuals within the WVPO performing quality assurance-related activities.

e) Performing or causing to be performed effectiveness evaluations of the Quality Assurance Programs at West Valley as required by section 5.2.14 of OGR/B-14. These evaluations include the following:

- o a clear identification of the quality characteristics to be achieved in meeting the requirements of the WAPS.
- o the identification of an appropriate set of performance indicators that reflect actual quality characteristics being achieved.
- o a performance measuring process using review, surveillance, inspection, tests, audit or other techniques to monitor performance indicators.
- o an analysis process in which performance data are trended and problem areas identified.
- o a reporting practice in which program effectiveness information is prepared and fed back to top management.

1.3 Organizational Arrangements

1.3.1 DOE's overall organizational structure for performing quality-related activities is reflected in Figure 1.3.

West Valley Demonstration Project Organizational Chart

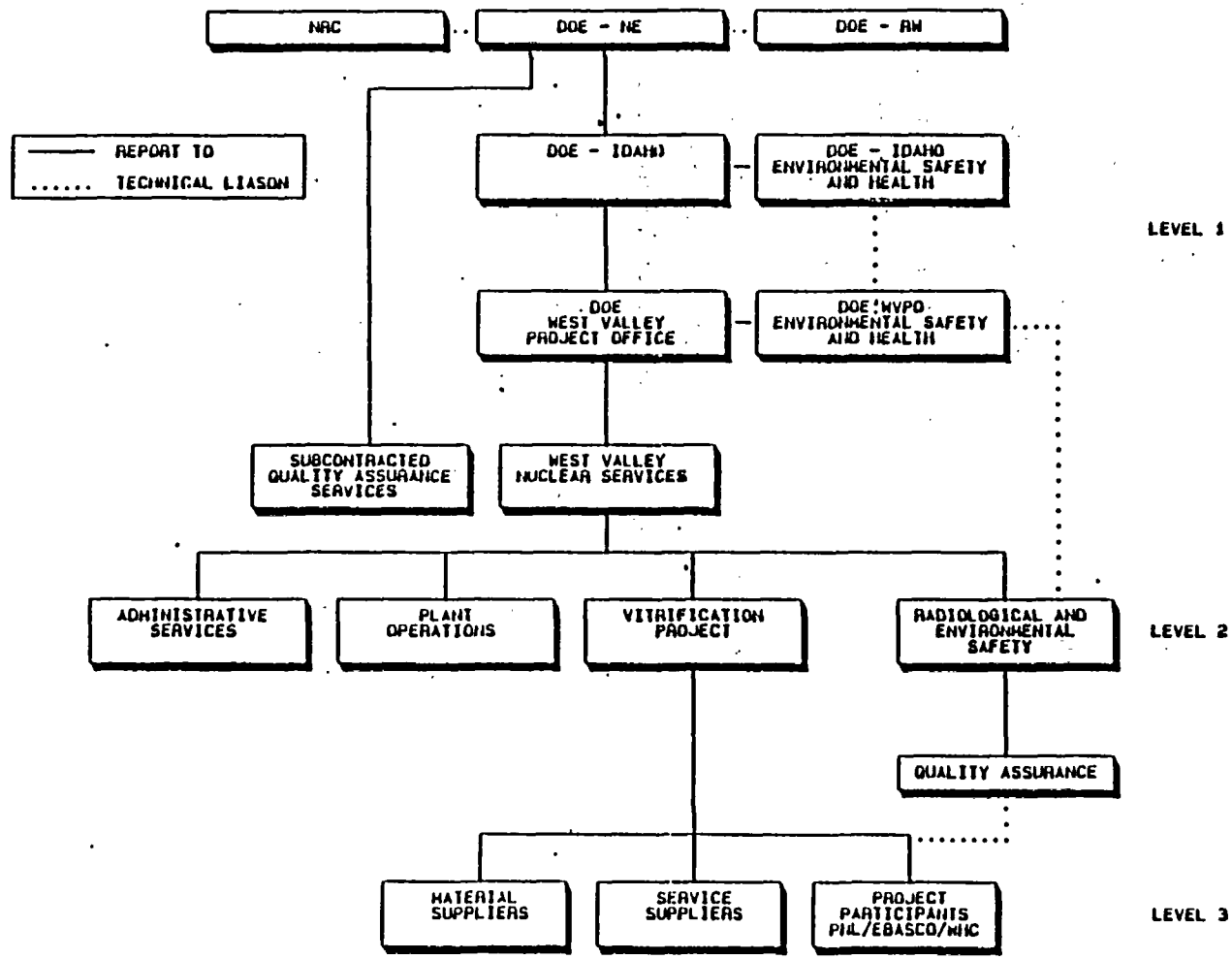

Figure 1.3

The Lead Engineer for Quality Assurance in the WVPO is responsible for the following quality assuring functions:

a) Quality Verification
b) Quality Engineering

1.4 Qualification Requirements for Quality Assurance Management Position

1.4.1 Lead Engineer for Quality Assurance

The individual assigned to establish an adequate and effective overall Project Quality Assurance Program is the WVPO Lead Engineer for Quality Assurance, who is the functional manager for directing and managing the WVPO Quality Assurance Program. He or she will have the following qualifications:

Education

He or she shall be a graduate of a four-year accredited engineering or science college or university, or equivalent.

Experience

General - He or she shall have a minimum of five (5) years experience in activities associated with nuclear facilities or equivalent industry. A minimum of three (3) years experience shall be in quality assurance.

Speciality - He or she shall possess a broad knowledge and understanding of applicable industry and government codes, standards and regulations defining quality assurance requirements and practices.

He or she shall have a broad knowledge and understanding of quality assurance methods and their application.

He or she shall have experience in planning, defining and performing quality assurance practices and the application of procedures.

1.5 Communications

1.5.1 To promote the flow of communications and to assure positive attention to quality programs with Project participants, lines of communications between DOE and the organization of other major Project participants are established as follows:

a) Communications will be addressed to the responsible senior management official with copies to the major Project participants cognizant of the subject.

b) Communications may be formal or informal, the choice of which shall depend on the significance of the subject and the judgement of the individuals involved.

c) Communication of quality assurance-related activities between the DOE organization and the organizations of major Project participants is promoted through periodic progress and status reporting by major participants.

2.0 QUALITY ASSURANCE PROGRAM

2.1 Policy and Objectives

The policy and objectives of the WVPO Quality Assurance Program are:

a) To assure that quality is achieved in the development qualification and production of an acceptable canistered high-level waste form product from the WVDP.

b) To assure that appropriate quality assurance activities are implemented by or for DOE.

c) To assure production of an acceptable canistered waste form.

2.2 Responsibility

2.2.1 DOE-WVPO

a) As described in section 1.0 of this document, DOE's principal operations officer for the Project is the WV-PM. The WV-PM has day-to-day management overview involvement in the overall Project Quality Assurance Program and execution of DOE's portion of the program.

b) Responsibility for the execution of the WVPO DOE program rests with the WV-PM and the assigned WVPO Lead Engineer for Quality Assurance. Quality Assurance Program management and administrative activities are performed primarily by the Lead Engineer for Quality Assurance, while other organizations within the WVPO are responsible for performing selected technically related functions that are required for proper implementation of program activities. WVPO quality assurance implementation procedures and the requirement matrix for their application are identified in Appendix A.

c) Technically related functions that are performed by other organizations within the WVPO include:

- o Participation in multi-discipline audits and reviews.
- o Review and acceptance of program plans and procedures.
- o Review and concurrence with proposed corrective actions resulting from findings of deficiency.
- o Execution of essential design control and document control activities.
- o Execution of essential contracting control activities.

d) To determine program status and to evaluate program adequacy, WVPO executes an overall program review to assess the scope, implementation, and effectiveness of the Project Quality Assurance Program. This review is performed and reported annually using resources and information at its disposal, including the results from surveillance, inspection, and audit activities.

e) The WV-PM receives on-line program status in the form of existing progress and status reports and other special reports as appropriate. These reports outline the progress and status of quality assurance activities, problems and nonconformances, quality trends, and results of audits. The WV-PM reviews these reports and initiates whatever management action is required to improve conditions and further implement the program.

2.2.2 Participants

a) Although DOE retains the responsibility for adequacy of the overall Project Quality Assurance Program, other major participants are assigned by contract the responsibility for establishing and implementing particular program practices. Delegated program elements are discussed in section 2.3.

b) Program participation responsibilities are organized in a three-level structure. The DOE portion of the program is the first level. The other major program participants including major

subcontractors are shown at the second level. At the third level are the multitude of systems, components, materials, and service suppliers. This three-level structure is depicted by figure 1.3.

2.3 Requirements

Overall

The requirements for the overall Project Quality Assurance Program are contained in DOE Order 5700.6B, Quality Assurance; ID Order 5700.6B, Quality Assurance; DOE Order 5000.3, Unusual Occurrence Reporting System; Guidelines for Application of Readiness Reviews to Department of Energy Activities; and ANSI/ASME NQA-1, Quality Assurance Program Requirements for Nuclear Facilities. In addition, amplified and supplementing requirements for waste form production are contained in the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements for High-Level Waste Form Production, OGR/B-14. These requirements are illustrated by the identification of the program elements described in later sections of this program description.

Program Elements Executed by WVPO

Elements of the overall WVDP Quality Assurance Program which will be executed by WVPO are those identified as Organization; Quality Assurance Program; Instructions, Procedures and Drawings; Document Control; Control of Nonconforming Items, Corrective Action, Quality Assurance Records; and Audits. This is the WVPO portion of the program, and it will be executed in accordance with documented procedures, and management practices. Figure 2.3 illustrates the principal elements of the WVPO Quality Assurance Program, see also Appendix A.

DOE–WVPO QUALITY ASSURANCE PROGRAM ACTIVITIES

Overall Program

- Objectives
- Responsibilities
- Requirements
- Control and Verification

AND

PROGRAM MANAGEMENT

- Organization
  - Structuring
  - Documenting
  - Staffing and Training
- Quality Assurance Program
  - Planning
  - Developing
  - Documenting
  - Reporting
  - Effectiveness Evaluation
- Instructions, Procedures, and Drawings
  - Preparation, Review, and Drawings
  - Issues and Distribution
  - Change Control
- Document Control
  - Implementing Procedures
- Nonconformance Control
  - Review and Dispostion
- Corrective Action
  - Review
  - Selective Approval
- Records
  - Records Preparation
  - Records Management
- Audits and Reviews
  - Program Audits
  - Management Reviews

Figure 2.3 – Major Elements of the WVPO Quality Assurance Program

Instructions to WVPO personnel for implementation of WVPO quality assurance activities are described by six (6) quality assurance procedures. These are:

- Organizational Functions and Responsibilities
- Preparation, Review, Approval, Issue, Change, and Distribution of Controlled Quality Assurance Documents
- Quality Assurance Indoctrination and Training of DOE WVPO Personnel
- Planning and Performance of QA Audits, Surveillances, Reviews, and Effectiveness Evaluations
- Identification and Control of WVPO Quality Assurance Records
- Review and Approval of Participant Unusual Occurrences, Nonconformance Dispositions, and Corrective Actions

Implementation of these procedures covers the performing and verification responsibilities of WVPO personnel involved in review, approval, and monitoring of participant high-level waste activities affecting quality. Specific products will include but not be limited to documented records of:

- WVPO reviews and approvals of participant documents
- Surveillances and audits
- Program assessments and evaluations
- WVPO personnel training and qualification

Program Elements Delegated to Others

a) The responsibility for implementation of development, design, construction, testing and operations program functions is delegated by DOE to West Valley Nuclear Services Company (WVNS), a subsidiary of the Westinghouse Electric Corporation. WVNS may pass along functional

activities to subcontractors so that each function can be performed by those most qualified. The ultimate responsibility for adequate implementation and performance by each participant is retained by DOE. The WVPO requires WVNS to document its program in appropriate descriptions, plans, and procedures. The WVNS program is initially evaluated and approved by DOE. Revised, updated, or new program plans and procedures are reviewed and approved by WVPO on an on-going basis. The WVNS program is monitored on a continuing basis through review and audit to assess its adequacy and to verify compliance with Project requirements.

b) Delegation of implementation responsibility for program elements including the Supplemental Requirements of OGR/B-14 is accomplished through contracts. These contracts will specify applicable requirements for contractor Quality Assurance Programs. Where delegated responsibilities require direct inspection, testing, or other verification activities by DOE, this involvement will be contractually documented.

c) The responsibility for establishing and implementing control systems for nonconformances and corrective action is delegated to major Project participants. DOE WVPO, as necessary, retains responsibility and authority for participation and/or approvals to assure proper disposition of significant nonconformances and effectiveness of corrective action.

2.4 Staffing and Training

WVPO personnel who are assigned responsibility for verifying that contractor performance is in accordance with requirements are selected and assigned to their area of responsibility based upon experience, education, and management's assessment of their performance capabilities. They are observed for performance evaluation on a continuing basis by appropriate WVPO management. On-going training and indoctrination programs are conducted to familiarize personnel with the technical objectives of the activity being monitored, the requirements that the activity must meet, the practices and procedures to be executed in verifying conformance to requirements, and the documentation of results.

3.0 DESIGN CONTROL

3.1 DOE Implementation

WVPO delegates implementation responsibility for design control activities to major Project participants through contracts. The design activities are required to be in compliance with the DOE orders and documents referenced in section 2.3 of this document. Through contracts, WVPO retains the responsibility and authority for design control participation and selective approval of design documents.

WVPO monitors major participant design control activities related to waste form development and qualification activities, and periodically audits the participants' practices to assure proper implementation and adequacy and to verify that activities have been satisfactorily accomplished.

3.2 Requirements of Other Participants

Each Project participant who is assigned Design Control responsibility in support of waste form development, qualification, and production activities is required by contract to implement and maintain a design control practice that meets the requirements of the documents referenced in section 2.3.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 DOE Implementation

DOE does not normally procure items to support development and qualification but delegates to other Project participants. However, when DOE does choose to procure items or services which support development, qualification, and production activities, it accomplishes this action in accordance with the same requirements as imposed on other Project participants. DOE will establish and implement a practice for control of procurement documents to assure that procurement functions are accomplished in accordance with the applicable contracts, codes, standards, drawings, and specifications. This practice will be carried out under written procedures which provide for coordination and implementation of procurement planning, procurement activities among Project participants, and review of procurement documents such as preprocurement plans and purchase orders and changes and/or modifications thereto by designated personnel to assure these documents are complete and correct.

WVPO monitors the procurement document control practices of major participant procurement activities related to waste form development, qualification, and production activities, and periodically audits the participants practices to assure proper implementation and adequacy and to verify that activities have been satisfactorily accomplished.

4.2 Requirements of Other Participants

Each major Project participant who is assigned procurement responsibility in support of development, qualification and production activities is required by contract to implement and maintain a procurement document control practice that meets the requirements of the documents referenced in section 2.3.

5.0 INSTRUCTIONS, PROCEDURES AND DRAWINGS

5.1 DOE Implementation

WVPO has a procedural control system for WVPO Quality Assurance procedures which provides instructions and procedures for WVPO activities affecting quality. These procedures assign responsibility for preparation, review, approval, release, issuance, distribution, and control of changes to these documents. Associated record requirements are also specified.

The WVPO Lead Engineer for Quality Assurance both participates in and monitors the execution of these practices related to development, qualification, and production activities. Periodically the Lead Engineer for Quality Assurance audits or arranges for independent audit of these practices to assure implementation and adequacy.

WVPO monitors major participant documentation practices related to waste form development, qualification, and production activities and periodically audits the participants' practices to assure proper implementation and adequacy and to verify that activities have been satisfactorily accomplished.

5.2 Requirements of Other Participants

WVDP Project participants, who are assigned responsibility for performing work activities affecting quality in support of development, qualification, and production activities, are required by contract to establish and implement a practice of prescribing those activities in accordance with documented instructions, procedures, and drawings in compliance with the Quality Assurance requirements identified in section 2.3 of this document.

6.0 DOCUMENT CONTROL

6.1 DOE Implementation

WVPO has established and implemented document control practices in support of development, qualification, and production activities that fulfill the Quality Assurance Program requirements and apply to those types of documents prepared by WVPO and identified in sections 5.0, 17.0, and 18.0 of this program description.

Documents originated by DOE are processed in a controlled manner to assure the following:

a) Uniformity of format of initial and subsequent issuances.

b) Proper identification as to the originator and date of origin of a document, and a mechanism for verification of the authenticity of information.

c) Positive review and approval by persons qualified to determine the correctness of the information presented and to judge its ultimate usefulness.

d) Prompt and controlled issuance and distribution, including a mechanism for receipt control, of both the original document and subsequent revisions to prevent inadvertent use of superseded material and to assure that correct documents are available in work areas in a timely manner.

e) Efficient revision of documents when necessary to clarify, correct, augment, or update the content of a document, while preserving the integrity of originally approved and released information.

f) Quality Assurance requirements are properly stated, are adequate, and are included prior to implementation.

Documents to be controlled are standardized by procedure as to identification, format, and numbering. These documents are reviewed for adequacy by the originator, the Lead Engineer for Quality Assurance, and/or the WV-PM, as appropriate. The originator of the controlled document and/or the Lead Engineer for Quality Assurance determines the extent of necessary reviews. The draft controlled document is routed to the appropriate reviewing personnel/organizations. Comments of reviewing personnel are resolved prior to final approval of the document. A record of the review sequence which has been accomplished is documented and retained. Changes or revisions are reviewed and approved by the same organizations that performed the original review and approval.

The WVPO Lead Engineer for Quality Assurance establishes and maintains a listing of WVPO controlled documents. As appropriate, controlled documents (or manuals) shall have assigned copy distribution and receipt control. This requires individually numbered copies, signed acknowledgment of transmittal receipt (including revisions), and periodic control verification. The Lead Engineer for Quality Assurance both participates in and monitors the execution of the document control system. Periodically the Lead Engineer for Quality Assurance audits or arranges for independent audit of the WVPO document control system to assure implementation and adequacy.

WVPO monitors major participant document control systems related to waste form development, qualification, and production activities and periodically audits the participant systems to assure proper implementation and adequacy.

6.2 Requirements of Other Participants

Each Project participant is required to implement and maintain a document control system in support of development, qualification, and production activities that fulfills the assigned requirements required by the documents identified in section 2.3.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 DOE Implementation

WVPO has delegated to current Project participants the responsibility for control of purchased items for development, qualification, and production activities including implementing procedures that comply with Project requirements.

WVPO monitors major participant procurement practices related to waste form development, qualification, and production activities and periodically audits the participant practices to assure proper implementation and adequacy.

7.2 Requirements of Other Participants

Project participants, who are assigned responsibility for procurement of items and services in support of development, qualification, and production activities, are required, by contract, to establish and implement a system for control of those procurements in accordance with the DOE orders and other documents referenced in section 2.3.

8.0 IDENTIFICATION AND CONTROL OF ITEMS

8.1 DOE Implementation

WVPO delegates implementation responsibility for identification and control of items which support development, qualification, and operations activities to the other major Project participants through contracts.

WVPO monitors major participant identification and control of item practices related to waste form development, qualification, and production activities and periodically audits the participant practices to assure proper implementation and adequacy.

8.2 Requirements of Other Participants

Each Project participant, who has an assigned responsibility for items which support development, qualification, and production activities is required, by contract, to establish and implement identification and control practices required by DOE orders and other documents referenced in section 2.3.

9.0 CONTROL OF PROCESSES

9.1 DOE Implementation

WVPO delegates implementation responsibility for control of special processes in support of development, qualification, and production activities to major project participants through contracts.

WVPO monitors major participant special processes control practices related to waste form development, qualification, and production activities and periodically audits the participant practices to assure proper implementation and adequacy.

9.2 Requirements of Other Participants

Project participants who are assigned responsibility for activities where special processes in support of development, qualification, and production activities are involved, are required, by contract, to establish and implement practices to assure adequate performance and control of special processes such as melting, cleaning, and sampling processes used in the design and development of experiments and their qualification. These controls shall meet the requirements of the documents referenced in section 2.3.

10.0 INSPECTION

10.1 WVPO delegates execution responsibility for direct inspection of items and work practices in support of development, qualification, and production activities to each major participant in its assigned scope of work by contract. DOE or an agent may perform or witness inspection on a selective basis. When DOE elects to perform or have an agent perform inspections, the practice followed conforms to the same requirements imposed upon other participants.

WVPO monitors major Project participant inspection practices associated with waste form development, qualification, and production activities and periodically audits the participants' practices to assure proper implementation and adequacy.

10.2 Requirements of Other Participants

Each participant who is assigned responsibility for performing procurement; manufacturing, fabrication, and assembly; construction or operation (operation of test activities) in support of development, qualification, and production activities is required, by contract, to establish and implement an inspection practice of sufficient scope to be fully effective. The inspection practice will identify and verify conformance of items and services with the document specifications, instructions, procedures, and drawings for accomplishing the required activities. The documented inspection practices shall meet the requirements of the documents referenced in section 2.3.

11.0 TEST CONTROL

11.1 DOE Implementation

WVPO delegates implementation responsibility for testing and test control practices in support of development, qualification, and production activities to major participants by contracts. DOE witnesses tests by the major Project participants on a selective basis and may, on limited occasions, conduct independent tests of its own. When DOE elects to perform or have an agent perform tests, the test control practices will conform to the same requirements imposed upon other participants.

WVPO monitors major Project participant test control practices related to waste form development, qualification, and production activities and periodically audits the participant practices to assure proper implementation and adequacy.

11.2 Requirements of Other Participants

Each participant who is assigned responsibilities for performing manufacturing, fabrication, and assembly; or operation (operation of test activities) activities in support of development, qualification and operations activities is required by contract to establish required tests, including proof tests prior to installation, preoperational tests, and product certification tests. The testing activities shall meet the requirements of the documents referenced in section 2.3.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 DOE Implementation

WVPO delegates implementation responsibility for control of measuring and test equipment which supports development, qualification, and production activities to the other major Project participants through contracts. In those instances where DOE elects to perform or have an agent perform inspections, examinations, or tests, the measuring and test equipment is controlled in accordance with those requirements imposed upon the participants.

WVPO monitors major Project participant measuring and test equipment control practices related to waste form development, qualification, and production activities and periodically audits participant practices to assure proper implementation and adequacy.

12.2 Requirements of Other Participants

Project participants who are assigned responsibility for performing inspections, examinations, or tests which support development, qualification, and production activities are required by contract to establish and implement a system for calibration and control of measuring and test equipment that meets the requirements of the documents referenced in section 2.3.

13.0 HANDLING, STORAGE AND SHIPPING

13.1 DOE Implementation

WVPO delegates implementation responsibility for handling, storage, and shipping practices which support development, qualification, and production activities to the other major Project participants through contracts.

WVPO monitors major Project participant handling, storage, and shipping practices related to waste form development, qualification, and production activities and periodically audits participant practices to assure implementation and adequacy.

13.2 Requirements of Other Participants

Each participant who is assigned responsibility for manufacturing, fabrication or assembly which support development, qualification, and production activities is required by contract to establish and implement practices for handling, storage, and shipping of items. These practices shall meet the requirements of the documents referenced in section 2.3.

14.0 INSPECTION, TEST, AND OPERATING STATUS

14.1 DOE Implementation

WVPO delegates implementation responsibility for inspection, test and operating status measures which support development, qualification, and production activities to the other major Project participants through contracts.

WVPO monitors major participant practices related to waste form development, qualification, and production activities for indicating inspection, test, and operating status and periodically audits participant practices to assure implementation and adequacy.

14.2 Requirements of Other Participants

Participants who are assigned responsibility for manufacturing, fabrication, and assembly; or operation (operation of test activities) activities which support development, qualification, and production activities are required to establish and implement practices to indicate the status of inspection and test performed upon individual items throughout development, qualification and operations activities. They also are required to establish and implement practices to indicate the status of inspections and tests performed upon individual items throughout development and qualification activities by using such markings as stamps, tags, labels, routing cards, or other suitable means. These practices shall meet the requirements of the documents referenced in section 2.3.

15.0 CONTROL OF NONCONFORMING ITEMS

15.1 DOE Implementation

WVPO delegates direct responsibility for control, review, and disposition of nonconforming items or activities which support development, qualification, and production activities to other major Project participants through contracts. Delegation requires that disposition of significant nonconformances have DOE approval. Contracts shall require that DOE review and approval authorities be specified in the contractor's nonconformance control procedures. DOE also retains authority

to identify and require that DOE-identified nonconformances be entered into the participant contractor's nonconformance control system.

WVPO monitors the major Project participant nonconformance control practices related to waste form development, qualification, and production activities and periodically audits the major Project participant nonconformance practices to assure implementation and adequacy.

15.2 Requirements of Other Participants

Each participant who is assigned responsibility for procurement; manufacturing, fabrication and assembly; or operation activities is required by contract to establish and implement a practice for the control of nonconforming items or activities in support of waste form development, qualification, and production activities. These practices shall be in compliance with the documents referenced in section 2.3.

16.0 CORRECTIVE ACTION

16.1 DOE Implementation

WVPO delegates direct implementation responsibility for corrective action to other major Project participants through contracts. Corrective action is required for conditions adverse to quality such as failures, nonconformances, malfunctions, deficiencies, deviations, and defective material and equipment that are required to support development and qualification of an acceptable canistered waste form product. Significant conditions adverse to quality identified by DOE overview and audits of the participant activities will require participant corrective action. Contracts shall require that DOE review and approval authorities be specified by contractor corrective action procedures.

WVPO monitors major participant corrective action systems related to waste form development, qualification, and production activities and periodically audits the participant systems to assure implementation and adequacy.

16.2 Requirements of Other Participants

Each participant is required by contract to establish and implement a corrective action system which supports development, qualification, and production activities that meet the requirements of the documents referenced in section 2.3.

17.0 QUALITY ASSURANCE RECORDS

17.1 DOE Implementation

WVPO has established a quality assurance records system that provides for the collection, storage, and maintenance of DOE-generated records in support of WVPO overview and audit of WVDP of waste form development, qualification, and production activities in accordance with approved records management procedures.

WVPO has delegated implementation responsibility for records preparation, collection, storage, and maintenance related to development, qualification, and production activities to the other major participants by contract.

The WVPO quality assurance records system contains the following additional provisions for waste acceptance process activities of high-level waste form production:

a) DOE documentation that supports demonstration of canistered waste form compliance with the WAPS and implementation of the Specification of Quality Assurance Requirements for High-Level Waste Form Production will be prepared and maintained as quality records. These records are collected and maintained as follows:

   - DOE-generated documentation providing evidence of satisfactory implementation of the Waste Form Compliance Plan is collected and maintained by WVPO as lifetime quality records. Copies of these records are made available to the federal repository Operator at the time the repository is ready to begin accepting canistered waste forms from the waste form producer. Such records will be maintained by the federal repository operator to satisfy any repository requirements. Other DOE record documentation generated during preparation and implementation of the Waste Form Compliance Plan is collected and maintained as nonpermanent quality records.

WVPO participates in and monitors the implementation of the major Project participants record systems as related to waste form development, qualification, and production activities. Periodically WVPO audits or arranges for independent audit of the records systems to assure implementation and adequacy.

17.2 Requirements of Other Participants

Each major Project participant is required by contract to maintain a Quality Assurance records system which supports development, qualification, and production activities in compliance with the documents referenced in section 2.3.

18.0 AUDITS AND SURVEILLANCE

18.1 DOE Implementation

18.1.1 Audits

WVPO has established a quality assurance audit practice which supports waste form development, qualification, and production activities. The audit program will provide a comprehensive independent verification and evaluation, both internally and externally, of the status and adequacy of the overall Project Quality Assurance Program methods, quality-related procedures and activities. This practice includes the WVPO program as well as the programs of the other major program participants and their suppliers. Audits are designed to assure that procedures and activities are meaningful and comply with the overall Project Quality Assurance Program requirements.

WVPO audits are planned and scheduled to support the development, qualification, and production of an acceptable canistered high-level waste form product and are initiated early enough to assure effective quality assurance practices during design, procurement, manufacturing, fabrication and assembly, and operational activities. Audits are planned on an annual basis, with a more detailed plan and schedule

prepared and issued quarterly. Audits are planned to include evaluation of internal practices of the WVPO program, but are directed toward the practices of each of the major Project participants. Audit planning for each major participant program is designed to include an objective evaluation of quality-related practices, procedures and instructions; the effectiveness of implementation; and the conformance with policy directives. These audits include the evaluation of work areas, activities (including personnel training and indoctrination), processes, and items. They also include review of documents and records to ensure that the Quality Assurance Programs are effective and properly implemented. In each major participant program, identified elements of interface control are evaluated with respect to each participant's internal activities as well as interfacing activities with customer and subcontractors. Scheduled audits will be supplemented by additional audits where the need becomes evident.

An audit plan is prepared for each audit and audits are conducted in accordance with written procedures and checklists. A pre-audit meeting with responsible management personnel will be held before the audit to review scope, purpose, and schedule of the audit and at the conclusion, to review audit findings with management having responsibility in the area audited. The need for any corrective actions is established and the audit results are documented in a formal report. Each audit is conducted by trained personnel who do not have direct responsibilities in the areas being audited.

Responsible management is required to take the necessary action to correct deficiencies revealed by the audit and to provide the auditing organization with a statement of proposed and completed corrective action. Deficient areas are monitored and, when necessary, reaudited until corrections have been accomplished.

DOE audits are performed in those areas of the overall Project Quality Assurance Program where the requirements of ANSI/ASME NQA-1 and OGR/B-14 are being implemented. Each major Project participant is required to prepare a matrix showing which procedures are used for implementation of each of the eighteen (18) Basic and Supplementary requirements of ANSI/ASME NQA-1 plus OGR/B-14 specified Supplemental Requirements. The activities and practices which carry out these procedures are audited on a prescheduled basis. See Appendix A for the matrix applying to the WVPO program.

18.1.2 Surveillance

As required by section 5.2.11 of OGR/B-14, WVPO performs planned surveillances of participant activities affecting waste form quality. The WVPO procedure for surveillance requires planning and documentation. Surveillances are performed by personnel who are not directly responsible for performing the work, and will use written checklists whenever practicable. Significant deficiencies, nonconformances, and potential quality problems are

documented and reported by a written surveillance report. Requested nonconformance disposition and/or corrective action will be required to be conducted in accordance with WVPO approved procedures. See sections 15.0 and 16.0 of this document.

18.2 Requirements of Other Participants

Each major Project participant is required by contract to establish and implement an audit practice which supports waste form development, qualification, and production activities and satisfies the documented quality assurance requirements referenced in section 2.3.

19.0 OTHER BASIC REQUIREMENTS

In addition to the specified NQA-1 Requirements, section 5.1.2 of OGR/B-14 identifies required compliance to: (1) DOE Order 5000.3 "Unusual Occurrence Reporting System," (2) DOE Order 5700.6B "Quality Assurance," and (3) the DOE specified "Guidelines for Application of Readiness Reviews to Department of Energy Activities, January 1987."

19.1 DOE Implementation

WVPO has delegated UOR, quality assurance, and readiness review implementation responsibilities to each major Project participant by contract. WVPO review and approval roles are as specified by the DOE level requirements, and are required to be incorporated into contractor procedures. Additional instructions applicable to WVPO personnel involvement will be provided by WVPO procedures and/or training programs.

WVPO monitors major participant practices for compliance to these procedures as applied to waste form development, qualification, and production activities, and periodically audits the participant systems to assure implementation and adequacy.

19.2 Requirements of Other Participants

Each major Project participant who is assigned UOR, quality assurance, and readiness review responsibilities in support of waste form development, qualification, and production activities is required by contract to implement and maintain procedurally controlled practices that meet the requirements of OGR/B-14, section 5.1.2.

20.0 OGR/B-14 SUPPLEMENTAL REQUIREMENTS

Section 5.2 of OGR/B-14 identifies fourteen (14) additional or amplified requirements for Waste Acceptance Process Activities. As applicable, requirements for compliance are specified by contract with each major Project participant. In the overall Quality Assurance Program, WVPO has direct implementation responsibility for four (4), participatory involvement in three (3), and overview/monitoring responsibility only for the remaining seven (7). Those requiring direct DOE implementation and DOE participation are identified below. Where the DOE role is participatory, controlling procedures are prepared by the involved contractor.

Direct WVPO Implementation:

- 5.2.10, Selection, Indoctrination, and Training of Personnel
- 5.2.11, Overview of Quality Assurance Activities
- 5.2.12, Quality Records
- 5.2.14, Effectiveness Evaluation

WVPO Participatory Role and Responsibility:

- 5.2.2, Peer Review
- 5.2.7, Product Certification
- 5.2.8, Readiness Review

WVPO Overview, Monitoring, and Audit Only:

- 5.2.1, Control of Essential Software
- 5.2.3, Control of Experiments and Developmental Activities
- 5.2.4, Qualification of Data
- 5.2.5, Archival of Samples
- 5.2.6, Control of Special Processes
- 5.2.9, Selective Application of Program Activities (Quality Level)
- 5.2.13, Modification Control

As determined for each contract, WVPO will assign and delegate implementation responsibility to major Project participants for any or all of the fourteen above-listed requirements. Where a responsibility is delegated to the contractor, WVPO retains responsibility for monitoring and audit, and where appropriate, will identify specific DOE approval requirements. For example, responsibility for compliance to all fourteen requirements is assigned to West Valley Nuclear Services. DOE approval requirements are to be identified and described by the contractor Quality Assurance Program description.

20.1 DOE Implementation

20.1.1 Selection, Indoctrination, and Training of WVPO Personnel

WVPO has established practices and procedures for assuring that WVPO personnel involved in the performance or acceptance of activities affecting the quality of waste form development, qualification, and production are appropriately trained and indoctrinated as defined in ANSI/ASME NQA-1, Supplement 2S-4. Qualification of WVPO personnel for inspection and testing, or nondestructive testing according to NQA-1 Supplements 2S-1 and 2S-2 is not required by the WVPO portion of the overall Project Quality Assurance Program. Where WVPO takes responsibility for the direct performance of inspection, test, or NDE, appropriately qualified and certified personnel will be obtained from service or consultant sources. A WVPO practice and procedure for auditor qualification in accordance with NQA-1 Supplement 2S-3 will be established; however, it is anticipated that additional auditors with appropriate NQA-1 qualification and certification will be required from service or consultant sources.

20.1.2 Overview of Quality Assurance Activities

Section 5.2.11 of OGR/B-14 requires that each major participant establish and conduct an appropriate overview program including: (1) review and approval of participant quality assurance descriptions (or plans),

(2) surveillance of participant activities affecting quality, and (3) performance of audits to verify adequacy and effectiveness of participant Quality Assurance Program activities. The WVPO Quality Assurance Program provides for implementation of these overview elements, including specific procedural instructions for planning and conduct of surveillance and audit. Section 18.0 of this document discusses and describes implementation of the WVPO audit and surveillance program.

WVPO will review and approve the Quality Assurance Program descriptions of contractors and subcontractors under its jurisdiction. The types of additional documents to be submitted for WVPO review and approval will be identified by these contractor program descriptions. Appropriate WVPO review and approval action is established by the WV-PM, with the assistance of the WVPO QA representative. Approval authority is retained by the WV-PM.

20.1.3 Quality Records

As discussed in section 17.0 of this document, WVPO has delegated direct responsibility for generation and control of quality records providing direct evidence of the quality of items and activities involved in waste form development, qualification, and production to major participant contractors. DOE retains overall responsibility for records adequacy, and will assure implementation and adequacy through WVPO overview, monitoring, and audit of major participant activities.

20.1.4 Effectiveness Evaluation

As described in section 1.2.2 of this document, the WV-PM has responsibility for the conduct of effectiveness evaluations in accordance with OGR/B-14, section 5.2.14. The direct performance functions required for identifying quality characteristics, performance indicators, performance measuring, trending, and reporting will be primarily implemented through the procedures and actions of the participating contractor Quality Assurance Programs. WVPO will maintain an ongoing oversight and review of overall program effectiveness, and as described in section 2.2.1 d) of this document will annually provide a report of this activity.

20.1.5 Peer Review

Responsibility for planning, conduct, and overall management of Peer Reviews is delegated by WVPO to WVNS. Overall responsibility for the adequacy of the Peer Review process is retained by WVPO. To determine the adequacy of Peer Reviews, WVPO also retains the authority and right to participate in the conduct of Peer Reviews. Procedural controls as established by WVNS will identify the decision and selection process for this participation.

20.1.6 Product Certification

Performance responsibility for developing and retention of necessary product certification records has been delegated by WVPO to WVNS. Overall responsibility for

adequacy is retained by WVPO. To implement this responsibility, WVPO will require, through approval of WVNS implementation procedures, specific WVPO role and participation in the review and approval of product certification packages.

20.1.7 Readiness Review

Performance responsibility for the planning and conduct of readiness reviews has been delegated by WVPO to WVNS. Overall responsibility for adequacy is retained by WVPO. To implement this responsibility, WVPO will require, through approval of WVNS implementation procedures, specific WVPO role and participation in the readiness review process.

20.2 Requirements of Other Participants

Each participant is required by contract to establish and implement required controls and procedures for compliance to any or all of the fourteen (14) identified OGR/B-14 section 5.2, Supplemental Requirements. Identified controls and procedures are to be appropriately applied to waste form development, qualification, and production activities within their contractual jurisdiction.

21.0 GLOSSARY

Refer to Appendix II, for a glossary of the terms used in this document.

APPENDIX A

WVPO Implementation Procedures

QAP-0	Organizational Functions and Responsibilities
QAP-1	Preparation, Review, Approval, Issue, Change, and Distribution of Controlled Quality Assurance Documents
QAP-2	Quality Assurance Indoctrination and Training of DOE WVPO Personnel
QAP-3	Planning and Performance of Quality Assurance Audits, Surveillances, Reviews, and Effectiveness Evaluations
QAP-4	Identification and Control of WVPO Quality Assurance Records
QAP-5	Review and Approval of Participant Unusual Occurrence, Nonconformance Dispositions, and Corrective Actions

WVPO QA Program Requirements/Procedure Matrix

Requirement	Implementing Procedures
NQA-1	
1. Organization	QAP-0
2. QA Program	QAP-0 and QAP-2
5. Instructions and Procedures	QAP-1
6. Document Control	QAP-1
15. Nonconformance Control	QAP-5
16. Corrective Action	QAP-5
17. QA Records	QAP-4
18. Audits	QAP-3
OGR/B-14 Supplementary	
Unusual Occurrence (5.1.2)	QAP-5
Readiness Reviews (5.1.2)	QAP-0
Training (5.2.10)	QAP-2
Overview (5.2.11)	QAP-3
Quality Records (5.2.12)	QAP-4
Effectiveness Evaluation (5.2.14)	QAP-3

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POLICY

At West Valley Nuclear Services, Co., Inc. (WVNS), quality assurance is applied commensurate with the complexity of the product/service and consequence of failure. Controls are based on item classification which range from items important to worker and public safety to commercial-grade items. The controls are in accordance with the requirements of OGR/B-14 and are consistent with the provisions of 10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Processing Plants," and NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities." Classification and levels of control are applied as appropriate to assure that each task is done right the first time to meet requirements in a cost-effective manner.

A preventive Quality Assurance Program shall be reviewed and periodically maintained and verified to assure that WVNS' products and services for high-level waste form qualification and production meet requirements, are fit for use, and satisfy the customer's contract requirements.

The Quality Assurance Program, as documented in the WVNS Quality Management Manual, shall cover functional activities involved in production of WVNS' items, products, and services. The Program shall provide for prevention or errors, as well as for detection and correction of deficient conditions. The Program shall include operating elements and procedures that comply with legal, regulatory, contractual, and corporate requirements related to quality.

The Quality Management Manual shall be responsive to DOE Order 5700.6B, "Quality Assurance." The Quality Management Manual shall implement, through selective and judicious application, the requirements of ANSI/ASME NQA-1 and the requirements of OGR/B-14.

Responsibilities and authority for execution of this policy are detailed in this document and the referenced procedures. The overall responsibilities and procedures are for more specific elements of the WVNS Quality Assurance Program and delineated in WVNS' Quality Management Manual.

Compliance with the requirements of the Quality Management Program is mandatory for all WVNS personnel.

DRAFT

R. A. Thomas, President and General Manager
West Valley Nuclear Services Co., Inc.

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TABLE OF CONTENTS

QAPD-4	SUBJECT	PAGE
0.0	INTRODUCTION	1
	0.1 Overview	1
	0.2 Scope	2
	0.3 Mission	2
	0.4 Strategy	2
	0.5 Requirements	6
	0.6 Application	6
	0.7 Terms and Definitions	7
1.0	EXISTING WVNS QUALITY ASSURANCE PROGRAM	8
	1.1 Background	8
	1.2 Current WVNS Quality Assurance Program	9
2.0	WVNS QUALITY ASSURANCE PROGRAM DURING PRODUCTION	11
	2.1 Organization	15
	2.2 Quality Assurance Program	19
	2.3 Design Control	26
	2.4 Procurement Document Control	35
	2.5 Instructions, Procedures, and Drawings	36
	2.6 Document Control	37
	2.7 Control of Purchased Items and Services	37
	2.8 Identification and Control of Items	39
	2.9 Control of Processes	40
	2.10 Inspection	42
	2.11 Test Control	44
	2.12 Control of Measuring and Test Equipment	45
	2.13 Handling, Storage, and Shipping	46
	2.14 Inspection, Test, and Operating Status	48
	2.15 Control of Nonconforming Items	49
	2.16 Corrective Action	50
	2.17 Quality Assurance Records	51
	2.18 Audits	54

APPENDIX A - Supplemental Requirements Implementation Schedule
APPENDIX B - Matrix Table of Implementing Procedures

TABLE OF CONTENTS (CONTINUED)

ITEM	SUBJECT	PAGE
Figure 1	West Valley Demonstration Project.....	3
Figure 2	Waste Acceptance Process.....	4
Figure 3	WVNS Organization Chart.....	16
Figure 4	Participants Chart.....	17
Table 1	WVNS Quality Assurance Program Matrix (04-07-87).....	12
Table 2	Major Participant NQA-1 Activity Table.....	13
Table 3	Major Participant OGR/B-14 Activity Table.....	14

WEST VALLEY NUCLEAR SERVICES (WVNS)
QUALITY ASSURANCE PROGRAM DESCRIPTION
FOR THE PRODUCTION OF HIGH-LEVEL CANISTERED RADIOACTIVE WASTE
AT THE WEST VALLEY DEMONSTRATION PROJECT (WVDP)

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0.0 INTRODUCTION

0.1 Overview

Though the overall responsibility for the success of the West Valley Demonstration Project (WVDP)* is retained by DOE/NE, the responsibility for establishing and implementing the WVDP Quality Assurance Program is shared by all four organizations that comprise the WVDP. Each of the four organizations has been required to develop, document, and implement a separate but interacting Quality Assurance Program, and each has described its QA Program in a separate Quality Assurance Program Description (QAPD) document. The WVDP organizational structure is one of descending authority, as listed below with the document numbers of each QAPD:

a) DOE/NE, QAPD-1
b) DOE/ID, QAPD-2
c) DOE/WVPO, QAPD-3
d) WVNS (Site Contractor), QAPD-4

Because the Project is a composite of organizations, the Project's QAPD is a composite of the four organizations' QAPDs.

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* The West Valley Demonstration Project is referred throughout this document as "the Project."

0.2 Scope

This document describes the WVNS Quality Assurance Program that applies to Waste Acceptance Process Activities of high-level waste form production at the WVDP, including how the WVNS Quality Assurance Program relates to other Quality Assurance Programs within the WVDP waste form producer organization and how it interacts with the Quality Assurance Programs of the other participants. This document also describes the role of the WVNS Quality Assurance Program in fulfilling the Project mission, and how it meets the specifications contained in the requirements documents. The relationship of waste producer organizational elements to each other and to other accountable organizations (participants) is shown in figure 1.3.

0.3 Mission

The Project mission is to develop, qualify, and produce stabilized radioactive waste forms suitable for deposit in a licensed federal repository. The specifications for acceptable high-level waste forms are delineated in the Waste Acceptance Preliminary Specifications (WAPS), OGR/B-9.

0.4 Strategy

The strategy for realization of the Project mission divides the Project activities into three periods and four elements, known collectively as the Waste Acceptance Process. These are shown in figure 2 and summarized below:

West Valley Demonstration Project Organizational Chart

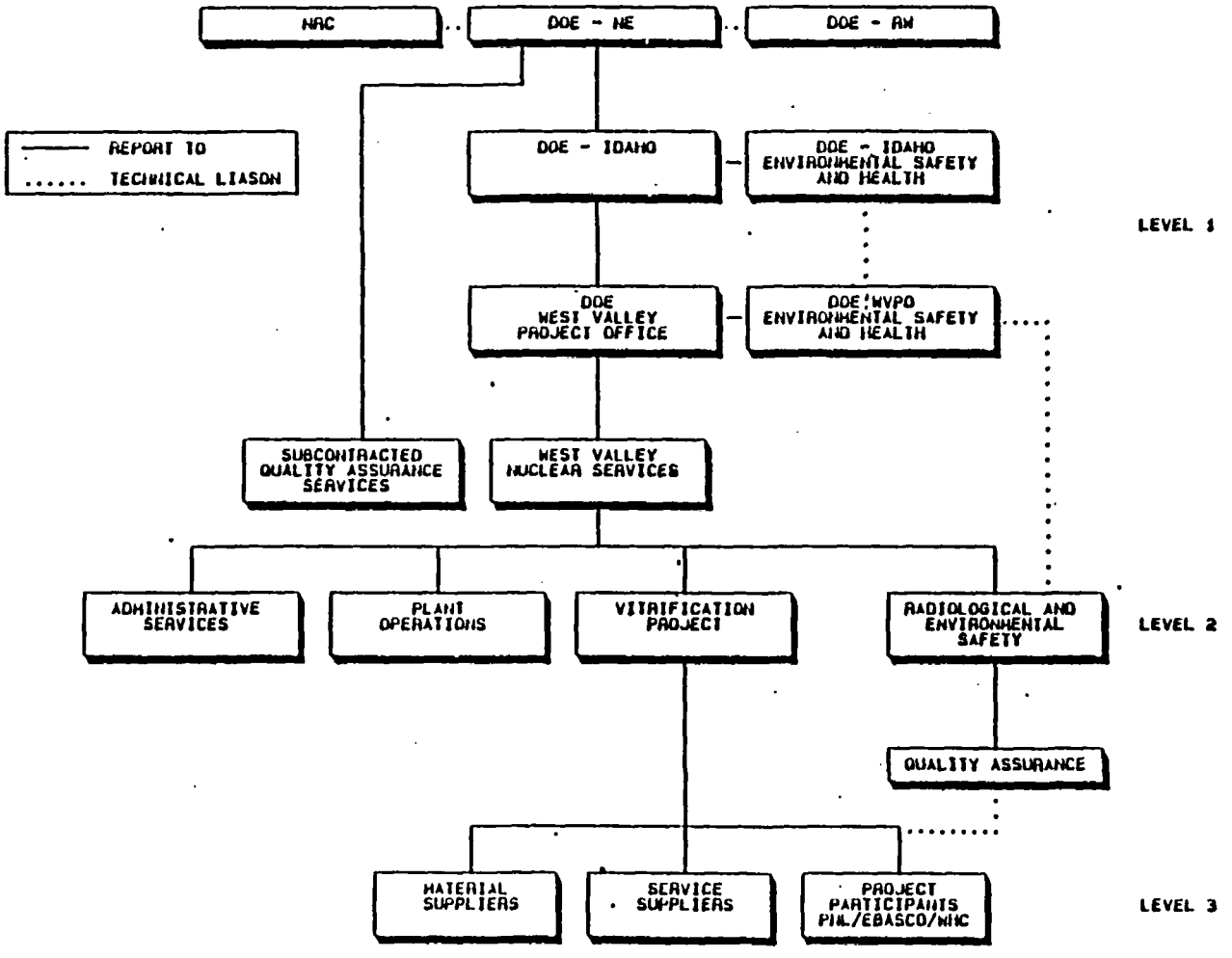

Figure 1.3

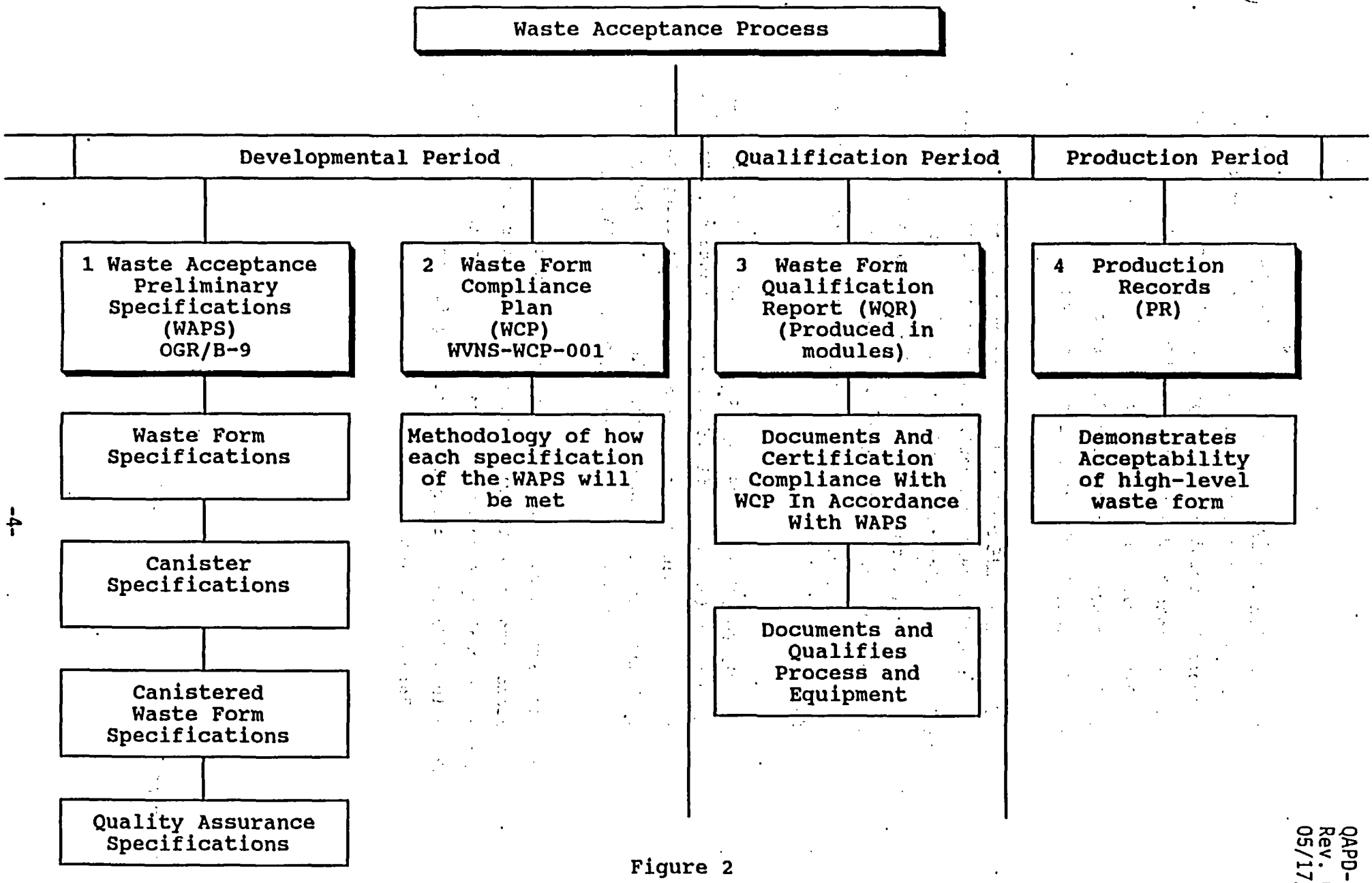
Waste Acceptance Process
Developmental Period
Qualification Period
Production Period
1 Waste Acceptance Preliminary Specifications (WAPS) OGR/B-9
Waste Form Specifications
Canister Specifications
Canistered Waste Form Specifications
Quality Assurance Specifications
2 Waste Form Compliance Plan (WCP) WVNS-WCP-001
Methodology of how each specification of the WAPS will be met
3 Waste Form Qualification Report (WQR) (Produced in modules)
Documents And Certification Compliance With WCP In Accordance With WAPS
Documents and Qualifies Process and Equipment
4 Production Records (PR)
Demonstrates Acceptability of high-level waste form

Figure 2

1. Developmental Period - The developmental period includes the essential research and development activities performed by accountable organizations to produce element #1: a viable Waste Acceptance Preliminary Specifications (WAPS), OGR/B-9. This period also includes the preparation of element #2: a Waste Form Compliance Plan (WCP), WVNS-WCP-001, by the waste form producer.

2. Qualification Period - The qualification period encompasses the essential test and verification activities that will culminate in element #3 which is the Waste Form Qualification Report (WQR). The WQR will provide documented evidence that the canistered waste form meets the specifications of the WAPS and will certify compliance with the WCP.

3. Production Period - The production period will begin with the production of the first high-level waste canister and will finish when the last waste canister is accepted by the designated federal repository. The basis for acceptance of the waste forms is the Production Records (PR), element #4.

The strategy includes provisions to assure that all Waste Acceptance Process Activities are performed according to an effective Quality Assurance Program. The provisions are set forth in OGR/B-14, Quality Assurance Requirements for High-Level Waste Form Production.

0.5 Requirements

The requirements referenced and contained in OGR/B-14 for the Quality Assurance Program are DOE Order 5700.6B, "Quality Assurance"; DOE Order 5000.3, "Unusual Occurrence Reporting System; Guidelines for Application of Readiness Reviews to Department of Energy Activities"; and ANSI/ASME NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities". Other requirements for the Project Quality Assurance Program listed in OGR/B-14 are: a) a set of fourteen supplemental and illuminated requirements, and b) a requirement for each waste form producer to provide a QAPD that can be used to support the licensing application for the federal repository.

Although documenting the Project QAPDs is required in preparation for the production period, the WVNS Quality Assurance Program has been implemented far enough in advance of production to assure that Waste Acceptance Process activities, such as testing and analysis occurring during the developmental and qualification periods, meet the requirements of the WAPS.

0.6 Application

The elements of the overall Project Quality Assurance Program being performed by WVNS are those identified by OGR/B-14 and NQA-1 as the 18 criteria:

1. Organization
2. Quality Assurance Program
3. Design Control
4. Procurement Document Control
5. Instructions, Procedures, and Drawings

6. Document Control
7. Control of Purchased Items and Services
8. Identification and Control of Items
9. Control of Processes
10. Inspection
11. Test Control
12. Control of Measuring and Test Equipment
13. Handling, Storage, and Shipping
14. Inspection, Test, and Operating Status
15. Control of Nonconforming Items
16. Corrective Action
17. Quality Assurance Records
18. Audits

and the supplemental requirements of OGR/B-14 as applied to the 18 criteria. Further, these Quality Assurance Program elements shall be applied to all essential Waste Acceptance Process activities through which documentation and data are collected and prepared to support compliance with the WAPS. Examples are testing and analysis activities associated with research and development that is essential to qualification of the waste form; including control of materials, equipment, facilities, processes, and processing activities that are essential to the certification of canistered waste.

0.7 Terms and Definitions

For a glossary of terms used in this document, refer to Appendix II. The meanings of acronyms used in this document are displayed in Appendix III.

1.0 EXISTING WVNS QUALITY ASSURANCE PROGRAM

1.1 Background

The West Valley Demonstration Project Act was passed in 1980 for the purpose of decommissioning the abandoned West Valley Nuclear Plant and cleaning up its radioactive waste. This includes the conversion of 600,000 gallons of high-level nuclear waste to a durable borosilicate glass for transport to a federal repository. To control early decommissioning activities at the West Valley Nuclear Plant, the WVNS Quality Assurance Program was implemented at the WVDP in 1982. It was written to satisfy NQA-1, 1979, which was the contemporary consensus standard. Since then it has been periodically reviewed and upgraded to meet illuminated requirements. Milestones concurrent and subsequent to WVNS' Quality Assurance Program implementation at the WVDP are listed below.

1. The enactment in 1982 of the Nuclear Waste Policy Act (NWPA) which mandates that all high-level nuclear waste will be sent to a federal repository for disposal.

2. Following President Reagan's ratification in 1985 of the decision to send defense high-level waste to a civilian repository, the DOE devised its strategy the--Waste Acceptance Process--to assure that high-level canistered waste products are acceptable to both a federal repository operator and regulatory authorities. This landmark decision led to the release of:

   a) the preliminary version of the Waste Acceptance Preliminary Specifications (WAPS), OGR/B-9, in April 1987, and,

b) in response to the WAPS, the Waste Compliance Plan (WCP), WVNS-WCP-001, in April 1989.

3. Quality Assurance requirements for High-Level Waste Form Production, OGR/B-14, was released in February 1988 and revised in March 1989, establishing the Quality Assurance Program requirements for both civilian and defense waste form producer organizations.

4. In response to OGR/B-14, the WVNS Quality Assurance Program is being updated to meet the supplemental requirements that are applicable to Waste Acceptance Process Activities for production of high-level waste canisters at the WVDP.

1.2 Current WVNS QA Program

The operating WVNS Quality Assurance Program at the WVDP during the developmental period is shown in table 1, which is a list of the 18 criteria in a matrix of implementing procedures. The program is substantially the same as described in section 2.0 of this document. It complies with the 18 criteria of NQA-1 and the other requirements listed in section 0.5 of this document, except for six supplemental requirements of OGR/B-14 that will be established prior to the qualification period of the waste form. These six requirements are to be implemented by procedures according to the schedule in Appendix A at the end of this section. They are:

1. Effectiveness Evaluation
2. Control of Computer Software
3. Qualification of Existing Data
4. Peer Review
5. Control of Experiments and Developmental Data
6. Archival of Samples

The core document for the program is the Quality Management Manual (QMM). Its purpose is to iterate the requirements for program quality assurance and to identify the internal organizations responsible for implementing them. Each section of the QMM is approved by the president of WVNS. Subsequently, it is approved by WVPO.

The WVNS Quality Management Manual sections and the WVNS organizational procedures that implement the present requirements for Quality Assurance Programs for Waste Acceptance Process Activities are shown in table 1, WVNS QA Program Procedure Matrix.

2.0 WVNS QUALITY ASSURANCE PROGRAM DURING PRODUCTION

2.0.1 The WVNS Quality Assurance Program described below is based on the requirements, supplements, and applicable appendices of NQA-1, 1986, "Quality Assurance Program Requirements for Nuclear Facilities"; DOE Order 5700.6B, "Quality Assurance"; ID Order 5700.6C, "Quality Assurance"; DOE Order 5000.3, "Unusual Occurrence Reporting System"; "Guidelines for Application of Readiness Reviews to Department of Energy Activities"; and the 14 supplemental requirements of OGR/B-14, "Quality Assurance Requirements for High-Level Waste Form Production". In addition, the WVNS Quality Assurance Program complies with the applicable portions of 10 CFR 60, subpart G, which implements the criteria of 10 CFR 50, Appendix B.

2.0.2 The Quality Assurance Program is arranged into 18 elements, based on the 18 criteria of 10 CFR 50, Appendix B, and of NQA-1. Each supplemental requirement of OGR/B-14 has been distributed to the criterion best suited to its topic. The requirements and supplemental requirements are individually addressed in the 18 subsections that follow and they are shown in tables 2 and 3. NQA-1 requirements are shown in table 2. The table shows how the major participants' Quality Assurance Programs: a) implement the requirements at their level; b) flow-down the requirements to the next level; and c) perform overview of the elements at lower levels. OGR/B-14 supplemental requirements are the topic of table 3. It shows the same information as table 2, but for the supplemental requirements.

WHS QUALITY ASSURANCE PROGRAM MATRIX

NQA-1 SERVICE ORGANIZATION	SECTION	GENERAL PROCEDURE	D&C	TECH. DIR. CONST.	TECH. DIR. ANAL. CHEM.	D&D OPNS	AGES SSE	AGES RES	FACILITIES ENGINEERING	FACILITIES OPER/MAINT	PROJ CONT	ADMIN SERVICES PUR/CONT	ADMIN SERVICES ADMIN SPT	Q.A.
ORGANIZATION	QM 1	WM-110	>>	>>	PRO 1.0 *2 >>	>>	>>	>>	>>	>>	>>	>>	>>	>>
QUALITY ASSURANCE PROGRAM TRAINING AND QUALIFICATION REQUIREMENTS FOR INSPECTION AND TEST PERSONNEL QUALIFICATION OF AUDITORS	QM 2 QM 2-1 QM 2-2	WM-330 *3 WM-220 WM-360 *3	>>	>>	PRO 2.0, 3.0 ACP 3.1 *2	>>	>> EM101	>>	>> SOP-001 SOP-001, 002, 003	>> SOP-001, 002, 003	>>	>>	>>	QAP 2-1 >>
DESIGN CONTROL COMPUTER SOFTWARE CONTROL QUALIFICATION OF DATA	QM 3 *2 QM 3-1 *2 QM 3-2	EP-3-001 THRU EP-3-010	>>	>>	N/A	>>	>> WM-006	>>	>> SOP-001, 002, 003	>>	>>	>>	>>	>>
PROCUREMENT CONTROL QUALITY PROGRAM REQUIREMENTS FOR PROCUREMENT ACTIVITIES	QM 4 QM 4-1	WM-610 EP-3-007	>>	EP-7-001 >>	>>	>>	>>	>>	>> WM-161	>>	>>	PURCH. MANUAL >>	>>	QAP 4-1 >>
INSTRUCTIONS, PROCEDURES, AND DRAWINGS PEER REVIEW	QM 5 *2 QM 5-1	WM-100	EP-3-005 EP-3-001 EP-11-001 SOP-002 >>	EP-3-005 EP-3-001 EP-11-001 SOP-002 >>	PRO 4.0 ACP 4.1, 4.2 *2 >>	SOP-001 SOP-002 >>	EM-100 EP-3-005 EP-3-011 >>	NC-ADM-1 >>	SOP-001 SOP-002 >>	SOP-001, SOP-002 >>	>>	PURCH. MANUAL >>	>>	QAP 5-1 QAP 5-1 >>
DOCUMENT CONTROL	QM 6	WM-105 WM-107	EP-3-005 EP-3-011 >>	EP-3-005 EP-3-011 EP-7-002 >>	PRO 4.0, 5.0 ACP 4.1, 4.2 *2 >>	SOP-001 SOP-002 >>	EM-100, 102 EM-11 >>	NC-ADM-1 >>	SOP-001 SOP-002 >>	SOP-001 SOP-002 >>	WM-105, WM-130 >>	201.02 >>	>>	QAP 6-1 >>
CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES CONSTRUCTION AND INSTALLATION	QM 7 QM 7-1	WM-601 WM-630 *	EP-7-001 EP-7-002 >>	EP-7-001 EP-7-002 >>	>>	SOP-003 >>	>>	>>	67-008, 012 SOP 003 *3 >>	>>	>>	201.01, 02 03 203.01 204.00 >>	301.01 - WM-633, 112, 430 >>	QAP 7-1 THRU 7-5 >>
IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS	QM 8	N/A	EP-3-001	>>	PRO 7.0 ACP 7.1, 7.2 7.3, 7.4 ACMs *2	>>	EM-101 EM-11	>>	SOP 01-0,001 002 WM-632 EP-8-001	>>	>>	>>	>>	QAP 8-1 >>
PROCESS CONTROL	QM 9	WDP-001	>>	>>	PRO 1.0, 5.0 9.0 ACP 9.1 ACMs *2	>>	EM TEST PROCEDURES	N/A	SOP 01-0	>>	>>	>>	>>	QAP 9-1, QAP 9-2 >>
INSPECTION	QM 10	QAP 10-1 QAP 10-2	>>	>>	PRO 7.0 >> *2	>>	>>	WDP 010 MANUAL	SOP-001,002 003, 041 WM-654 >>	>>	>>	>>	>>	QAP 10-1 THRU 10-3 >>
TEST CONTROL CONTROL OF EXPERIMENTS	QM 11 *2 QM 11-1	N/A	EP-11-001	>>	>>	EP-11-001	>>	>>	EP-11-001 SOP-002	EP-11-001 SOP-002	>>	>>	>>	QAP 11-1 >>
MEASURING AND TEST EQUIPMENT CONTROL	QM 12	N/A	>>	>>	PRO 1.0, 5.0 ACP 5.1, 5.1 ACP 6.1, ACMs *2	SOP 9-8	EM-8, 9 EM-101, 506	NC PROCEDURES	SOP 01-0 SOP-002	SOP 01-0	>>	>>	>>	QAP 12-1 >>
PRESERVATION, PACKAGING, MARKING, STORAGE AND SHIPPING	QM 13	WM-650, 652, 660 OM-001 WDP-010 WDP-011	>>	>>	PRO 7.0 ACP 9.1, 9.0 >> *2	SOP-001 SOP-002 >>	>>	>>	>>	>>	>>	201.01 201.02 202.01 >>	>>	QAP 13-1 >>
INSPECTION, TEST AND OPERATING STATUS	QM 14	>> SOP 00-6 *2	EP-11-001	EP-7-001	PRO 1.0, 5.0 ACP 7.1, 7.3 ACP 8.1, 8.2 ACMs >> *2	SOP-001 SOP-002	>>	NC-10C-1	SOP-001,002 003	SOP-001, 002, 003	>>	>>	>>	QAP 14-1 >>
NONCONFORMANCE CONTROL	QM 15	QAP 15-1 QAP 15-2 WM-222	>>	>>	PRO 7.0 ACP 9.1 ACMs >> *2	>>	>>	>>	>>	>>	>>	>>	>>	>>
CORRECTIVE ACTION	QM 16	WM-661 QAP 16-1	>>	>>	PRO 9.0 ACP 9.1 >> *2	>>	>>	>>	>>	>>	>>	>>	>>	>>
QUALITY RECORDS	QM 17	WM-730	EP-11-001 EP-11-001 EP-7-002 >>	>>	PRO 5.0, 8.0 ACP 9.1 >> *2	>>	>>	>>	>>	>>	WM-105, 180 >>	>>	>>	QAP 17-1 >>
AUDITS	QM 18	QAP 18-1	>>	>>	PRO 9.0 >> ACP 9.1 *2	>>	>>	>>	>>	>>	>>	>>	>>	>>
GLOSSARY	QM 19	>>	>>	>>	>>	>>	>>	>>	>>	>>	>>	>>	>>	>>

NOTES:
*1 THESE PROCEDURES APPLY TO ALL DEPARTMENTS
*2 PROCEDURES ARE REQUIRED TO BE DEVELOPED
*3 PROCEDURES ARE REQUIRED TO BE REVISED
THOSE >> BLOCKS IMPLEMENT PROGRAM AS DEFINED BY THE WHS QUALITY MANAGEMENT MANUAL AND THE GENERAL PROCEDURES

REV. 3
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TABLE 1

MAJOR PARTICIPANT NQA-1 ACTIVITY TABLE

NQA-1 Element and Supplement	DOE/NE	DOE/ID	WVPO	WVNS
1. Organization	I D O	I D O	I D O	I D O
2. Program (inc QAPD)	I D O	I D O	I D O	I D O
2A. Qualification of Personnel	I D O	I D O	I D O	I D O
3. Design Control	D O	D O	D O	I D O
4. Procurement Doc. Control	D O	D O	D O	I D O
5. Procedures and Drawings	D O	I D O	I D O	I D O
6. Document Control	D O	I D O	I D O	I D O
7. Control of Purchased Items	D O	D O	D O	I D O
8. Identification of Items	D O	D O	D O	I D O
9. Process Control	D O	D O	D O	I D O
10. Inspection	D O	D O	D O	I D O
11. Test Control	D O	D O	D O	I D O
12. Measuring and Test Equipment	D O	D O	D O	I D O
13. Storage/Shipping	D O	D O	D O	I D O
14. Operating Status	D O	D O	D O	I D O
15. Cntrl of Nonconforming Items	D O	D O	I D O	I D O
16. Corrective Actions	D O	D O	I D O	I D O
17. Quality Assurance Records	D O	I D O	I D O	I D O
18. Audits	I D O	I D O	I D O	I D O

I = Implementation of Element by Participant's Program
D = Delegation of Element to Next Participant Level (NE->ID,etc)
O = Oversight of Element at All Lower Participant Levels

Table 2

MAJOR PARTICIPANT OGR/B-14 ACTIVITY TABLE

OGR/B-14			DOE/NE	DOE/ID	WVPO	WVNS
5.1	UOR's	(15)	D O	D O	I D O	I D O
5.1	Readiness Review	(2)	D O	D O	I D O	I D O
5.2.1	Software	(3)	D O	D O	D O	I D O
5.2.2	Peer Reveiw	(3)	D O	D O	D O	I
5.2.3	Experiments	(11)	D O	D O	D O	I D O
5.2.4	Data Qualification	(3)	D O	D O	D O	I D O
5.2.5	Archival Samples	(8)	D O	D O	D O	I D O
5.2.6	Special Processes	(9)	D O	D O	D O	I D O
5.2.7	Product Certification	(17)	D O	D O	D O	I D O
5.2.8	Readiness Review	(2)	D O	D O	D O	I
5.2.9	Quality Level	(2)	D O	D O	D O	I
5.2.10	Personnel Training	(2)	D O	D O	I D O	I D O
5.2.11	Overview	(2)	I D O	I D O	I D O	I
5.2.12	Records	(17)	D O	D O	D O	I D O
5.2.13	Modification	(3)	D O	D O	D O	I D O
5.2.14	Effectiveness Evaluation	(2)	I D O	I D O	I D O	I

( ) = Indicates NQA-1 Criteria
I = Implementation of Element by Participant's Program
D = Delegation of Element to Next Participants Level (NE->ID,etc)
O = Oversight of Element at All Lower Participant Levels

Table 3

2.1 Organization

2.1.1 WVNS is organizationally structured to be both sensitive and responsive to its role as site contractor (SC) at the West Valley Demonstration Project. The intent of the organizational arrangement is to optimize the conduct of the responsibilities and duties delegated to WVNS by DOE through the WVPO. The authority delegated to WVNS is a charter to develop and implement an effective Quality Assurance Program that will assure success of the Project's mission, and to execute Waste Acceptance Process activities in accordance with the Quality Assurance Program. The authority and duties of persons and organizations performing activities affecting Waste Acceptance Process activities for high-level waste form production are established and delineated in program documents.

2.1.2 The portion of the WVDP organization described herein is shown as level 2 in figure 1.3, and in greater detail in figure 3. The Project participants depicted at level 3 in figure 1.3 are also discussed here, because of Project responsibilities and activities that have been delegated to them. They are shown again for clarity in figure 4. Other participants, such as vendors, consultants, subcontractors, and laboratories are a part of this program by virtue of the WVNS Quality Assurance Program elements that provide control of procurement, assuring that incoming items and services are acceptable for Waste Acceptance Process activities. WVNS performs initial approval and scheduled, periodic overview of the organizational structures and Quality Assurance Programs of level 3 participants by audit, surveillance, or other appropriate methods.

WVNS Organizational Chart

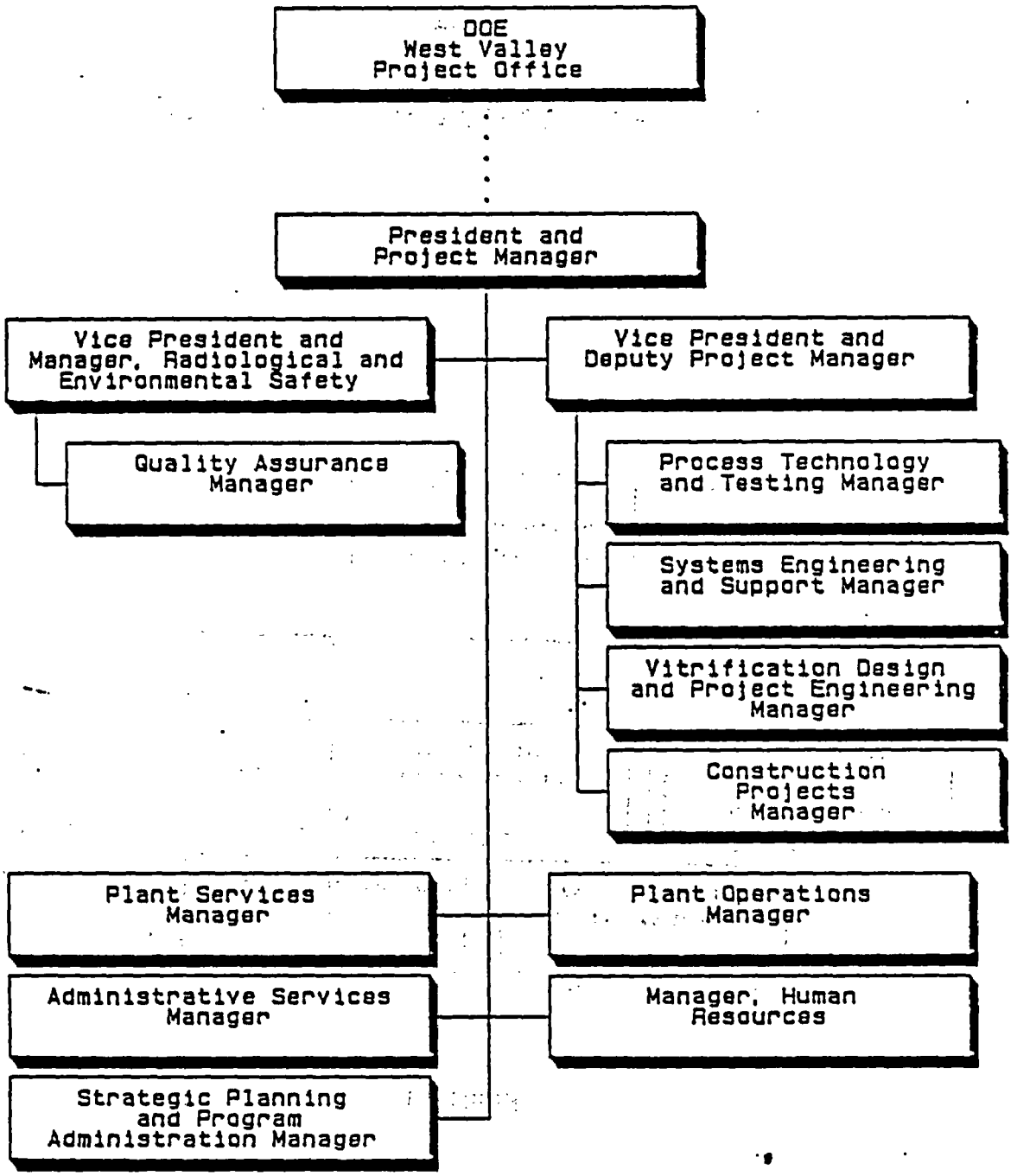

Figure 3

WVNS - Participants Chart

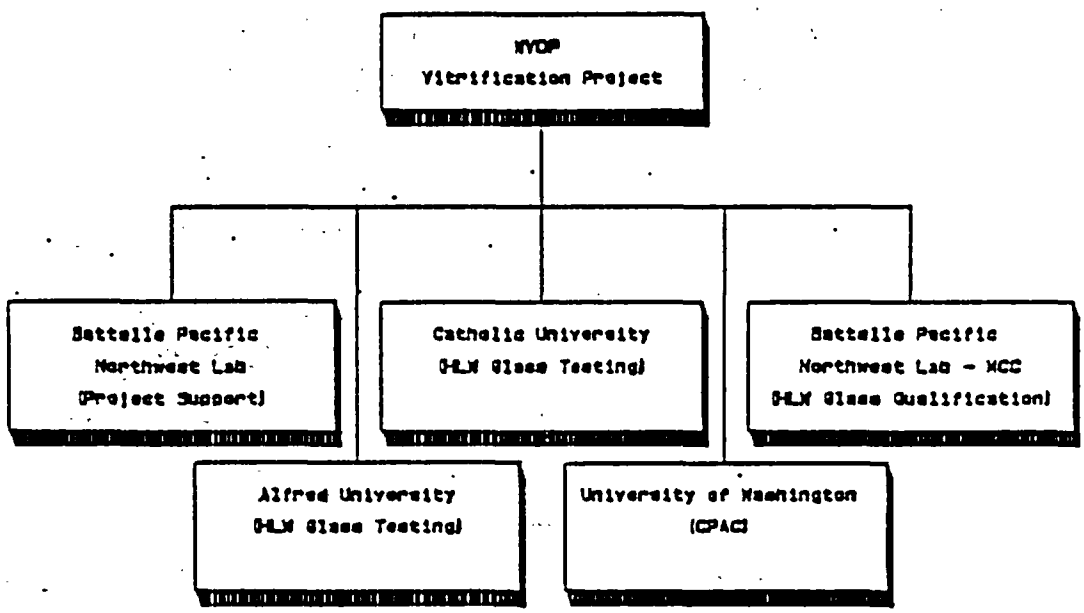

FIGURE 4

2.1.3 The responsibilities and authority of persons and organizations performing the functions of assuring that the Quality Assurance Program is established and conducted and of verifying that activities have been correctly performed are documented. A brief summary follows:

1. The President of WVNS is responsible for all functions of WVNS, including establishment and implementation of the Quality Assurance Program policies and procedures. The President may delegate authority to carry out these policies. The President is also responsible for reviewing the Quality Assurance Program and for causing corrective action, when necessary, to be taken by the responsible West Valley Nuclear Services organization.

2. The WVNS Quality Assurance Department is responsible for development, maintenance, and verification of effective implementation of the Quality Assurance Program. The Quality Assurance Manager is in charge of the Quality Assurance Department. The Quality Assurance Manager position has the following characteristics.

   A. It is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality and is sufficiently independent from cost and schedule to assure impartiality.

B. It has established effective communication channels with other senior management positions.

C. It has the authority to approve quality assurance manuals, changes thereto, and interpretations thereof.

D. It has no other duties or responsibilities unrelated to quality assurance that would prevent full attention to quality assurance matters.

3. Other Departments within WVNS are responsible for compliance with the Quality Assurance Program as documented in the Quality Management Manual (QMM), and for implementing the portions of the QMM applicable to them. Referring again to figure 3, the WVNS departments are structured to effectively administer the Waste Acceptance Process and production activities while assuring compliance with the Project Quality Assurance Program. Their authorities and duties are described in program documents.

2.2 Quality Assurance Program

2.2.1 The WVNS Quality Assurance Program is documented by written policies and procedures and carried out by qualified personnel in accordance with the program documents. Appendix B at the end of this section shows the requirements, documents, and paragraphs applicable to the corresponding WVNS implementing procedures.

2.2.2 The WVNS Quality Assurance Program is a graded approach using quality levels (Q-levels) that relate to the safety and service classifications of items and activities. The Q-level system of classes, A, B, C, and N, is consistent with the provisions of NUREG-1318, "Technical Positions on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements," and reflects safety- and service-related objectives. These are based on the activity required to achieve an adequate level of confidence in equipment, items, and systems. The Quality Assurance Program covers all four levels with N (the lowest) being the responsibility of the performer to document quality achievement. The target of the Quality Assurance Program in Waste Acceptance Process activities is the items and activities that are essential to canistered waste form certification and acceptance as defined in the WAPS. These are listed in Appendix I.

2.2.3 The WVNS Quality Assurance Program is operative at all periods of Waste Acceptance Process activities, including waste form development, design, testing, qualification, and production. Quality Assurance Department involvement occurs early enough in these activities to provide for planning of the quality requirements for the activity. For example, Quality Assurance reviews design and procurement specifications to design criteria for the inclusion of quality requirements. Quality Assurance participates with the organization performing purchasing and engineering activities in the evaluation and selection of suppliers. Inspection planning is developed by Quality

Assurance to assure that technical requirements are met. Frequent contact exists between organizations through reports, meetings, and audits.

2.2.4 The WVNS Quality Assurance Program has estalbished procedures to assure that quality objectives are met. Two examples of quality objectives are; 1) assurance that items important to safety comply with all requirements; and 2) the early detection and correction of conditions that could adversely affect items important to safety. Quality Assurance staff (in concert with line staff, when applicable) perform the following Waste Acceptance Process activities according to procedures and other documents.

A. Maintain liaison on quality matters with WVNS management, the Department of Energy, subcontractors, suppliers, and regulating agencies.

B. Publish and maintain the controlled distribution documents, such as Quality Management Manual, and the Quality Procedures Manual.

C. Verify that training and indoctrination are provided for qualified personnel as required by written procedures.

D. Review and approve other department's policies, procedures, and documents which affect the quality of Waste Acceptance Process and Production activities.

E. Assist other departments and level 3 participants with quality planning.

F. Monitor work by WVNS suppliers and subcontractors to assure that work is performed in compliance with approved requirements. Also review and approve suppliers' quality assurance documents according to written procedures.

G. Identify quality problems and recommend or assist in the development of solutions through the responsible organization.

H. Ensure that any disagreements regarding quality problems or proposed solutions are promptly referred to higher-level management for resolution.

I. Verify implementation of solutions and conformance with established requirements.

J. Assure that items or services important to safety, that do not conform to specifications, are controlled to prevent inadvertent use until disposition is authorized and implemented.

K. Stop work whenever continuation of work could result in a violation of approved work requirements, product damage, or personal injury. Cognizant management shall be notified immediately of any stop-work decision. During production, this stop-work authority does not apply to systems essential to operation of the plant; anomalous conditions detected on such systems will immediately be brought to the attention of the responsible manager of the affected operation(s) for safe and orderly correction of the condition. They will also

be reported to the Quality Assurance Manager for follow-up to affirm that adequate and timely corrective action is taken.

L. Coordinate procurement quality requirements-- such as hold points, inspection, and documentation-- for verification of compliance to requirements and specifications.

M. Verify by audit surveillance, test, or inspection that quality requirements are met for processes and items that are important to safety.

N. Ensure that appropriate technical and quality requirements are invoked on items based on the assignment of quality level (Q-level).

O. Document and report nonconforming activities and items according to written procedures.

P. Ensure that corrective actions are documented and effectively implemented in a timely manner.

Q. Provides analysis support for sample analysis of glass composition.

2.2.5 Procedures are established for resolving allegations of inadequate quality regardless of whether the allegations originate within the responsible organization or from outside of it.

2.2.6 Procedures are established that control the use of software that is essential to meeting the WAPS. A documenting system that includes software summaries, users manuals, and continuing documentation assures authenticity and repeatability of results obtained from software. Documenting the identification and verification of codes, mathematical models, numerical methods, software in analysis, usable software, as well as the identification of personnel and organizations responsible for control and support of software is the method for control. The overall essential software Quality Assurance Program establishes controls for development, acquisition, verification, validation, configuration management, problem resolutions, change control, storage, custody, and transfer methods.

2.2.7 Procedures are established to provide documented formal indoctrination and training of personnel performing activities affecting quality in Waste Acceptance Process activities of high-level waste form production to assure that suitable proficiency is achieved and maintained. The purpose of the indoctrination and training program is to 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 by annual employee appraisals to determine the need for retention, retraining, or replacement.

2.2.8 Personnel who perform quality verification activities that require qualification-- such as auditors, inspectors, nondestructive examiners, etc.-- are certified in accordance with the detailed requirements of the applicable supplements and appendices of NQA-1, 1986 and applicable referenced codes and standards. The requirements for other personnel who perform quality-related activities for which they must be qualified are documented. This includes the task description and the qualifications required for the task, including minimum education and experience requirements. Employees are appraised annually by management to assess the need for retention, retraining, or replacement.

2.2.9 Procedures are established for readiness reviews to assure that all prerequisites have been met for activities important to safety. Readiness reviews are accomplished in accordance with DOE guidelines at significant transitional events in Waste Acceptance Process activities.

2.2.10 Procedures are established to assure that activities affecting quality are accomplished under suitable controlled conditions, including: 1) the use of

appropriate equipment; 2) a suitable environmental for accomplishing the activity, e.g., adequate cleanliness, and 3) compliance with necessary prerequisites for the given process or activity.

2.2.11 A preplanned, documented system is established for measuring the Quality Assurance Program's effectiveness at meeting the WAPS. Program quality goals are established. Feedback collected from surveillances, audits, and other quality reporting activities is compared to the program quality goals and a measurement of effectiveness is obtained and reported. Corrective action is identified and tracked.

2.2.12 The QAPD as well as the QMM will be updated should any changes impacting the WVNS Quality Assurance Program occur.

2.3 Design Control

2.3.1 The documented WVNS Quality Assurance Program for design control, which was implemented prior to the inception of Waste Acceptance Process activities will continue during the development, qualification, and production periods of high-level waste canisters. Design work is performed by WVNS or under the control of WVNS by architect/engineers, suppliers, and development laboratories. The design control criterion is consistent with 10 CFR 60 and enfolds the requirements for:

1. Control of essential software as stated in paragraph 2.2.6.

2. Peer reviews and technical reviews.

3. Control of experiments and developmental activities.

4. Qualification of data.

5. Modification control.

2.3.2 Essential WVNS engineering Waste Acceptance Process activities are accomplished in accordance with documented and approved procedures which provide for the basic elements of planned systematic control including:

1. Establishment and implementation of scientific and engineering criteria.

2. Establishment or identification of engineering procedures for control.

3. Identification of input requirements.

4. Development of data and designs and performance of analysis.

5. Performance of qualification and/or verification of data and designs.

6. Control of changes and modifications.

7. Control of interfaces among organizations.

8. Development and maintenance of documentation and records.

9. Test control and verification testing, when required.

10. Peer review and Technical review.

11. Qualification of existing data.

12. Verification and certification of computer codes.

2.3.3 WVNS Engineering initiates and maintains schedules for preparation of documents, review of interface requirements, verification of materials suitability, preparation of changes in the descriptions of system designs, qualification testing, conduct of reviews, and release of documents.

2.3.4 Procedures are established for the definitions and control of WVNS codes, data, and designs. These procedures are directly applicable to WVNS scientific and engineering activities and to the approval by WVNS of designs and data developed by other participants. In addition, WVNS invokes Section 3 of NQA-1 on the other organizations and participants, as applicable, to assure their use of adequate design control systems.

2.3.5 The importance to safety, performance objectives, and other basic criteria of new designs are reflected in the description of system designs. The criteria include, but are not limited to, materials, processes, interfacing characteristics, and operating parameters.

Any changes to these criteria are also incorporated into the description of system designs. These changes are approved by WVNS according to established procedures.

2.3.6 Standards, code classifications, and regulating agency requirements, that are incorporated into the design of new or replacement items are in accordance with system design requirements. Standards are used for items on which plant safety or operability depends, except where industrial standards have been determined to be fully adequate. Designs incorporate the latest revisions of the applicable codes, standards, and regulating agency requirements in effect on the date of design approval.

2.3.7 Whenever possible, new and revised specifications and designs use materials, components, and processes already in use and proven at WVNS. Material properties are based on the nationally accepted standards. Applicable data and documentation are provided to validate all changes requested and establish requirements for any design verification testing necessary for validation.

2.3.8 The engineering and scientific activity reviews original drawings and specifications for applicability when authorizing procurement of spares or replacements. Approval from applicable WVNS departments is required in this review, and the original documents are upgraded, if necessary.

2.3.9 Drawings and specifications for new and redesigned items are reviewed prior to approval for inclusion of applicable requirements for materials, quality assurance, safety, fabrication, constructability,

interchangeability with original equipment, and measures to protect the items against damage or deterioration. These include requirements for cleanliness control, handling, storage, packaging, shipping, and preservation.

2.3.10 All drawings and specifications applicable to the Vitrification Project or its operation are controlled by the WVNS organization(s) responsible for this activity.

2.3.11 An identification system has been established in which each piece of equipment and instrument in the WVDP has been assigned a unique identifying number. This system is extended as necessary to include equipment spares and new equipment. Spare parts are identifiable to the components and systems in which they are to be used.

2.3.12 Design documents specify traceability of parts and components to manufacturing lot, batch, or heat numbers, including item identification, as required. Such requirements are as stringent as those of applicable codes and standards. When marking methods could be detrimental to component function or integrity, provisions to prevent adverse consequences are included in the design documents.

2.3.13 Design descriptions for spares, experiments, and for new or redesigned equipment and facilities are reviewed by the Quality Assurance Department to assure that acceptance criteria have been included for all specified requirements. Deviations from these standards are controlled.

2.3.14 The established system for the review and approval of WVNS design descriptions and changes is also applied to the review and approval of documentation from supplier's information, such as inspection and test plans and manufacturing procedures. Under this system, a procedure or description is first submitted to the WVNS cognizant engineer. The cognizant engineer confirms the final approval level required and determines the list of reviewers and approvers in accordance with established procedures. Classification criteria for the final approval levels of changes including nonconformances are based on the impact of the change on the existing design.

2.3.15 Procedures identify the various organizations and disciplines that must review or approve technical content. These criteria provide for appropriate reviews and approvals by Quality Assurance, Safety, and other organizations. Quality Assurance reviews such aspects as the completeness and adequacy of acceptance criteria, provisions for item protection, clarity and completeness of technical requirements, quality assurance requirements including the selection and application of quality assurance standards, and documentation requirements. Documented comments, approvals, and disapprovals are collected and reconciled by the cognizant engineer, who then obtains final approval of the document.

2.3.16 WVNS Document Control maintains the engineering documents that define all new or revised designs, including approval records.

2.3.17 Following final approval of the design criteria it is signed and released for Project use.

2.3.18 Suppliers, users, and contractors are required to establish and implement systems which assure that WVNS approval of specified documents and changes thereto is obtained prior to implementation.

2.3.19 A centralized print control system is used to assure that drawings used are current. Only specially stamped prints may be used for construction.

2.3.20 Lists of approved drawings for the WVNS plant are kept current by WVNS Project Engineering for reference and for use during spares procurement and design or modification of new or revised equipment. Architect/engineers and suppliers of design-and-build items for plant modifications are required to maintain complete drawing lists.

2.3.21 At the start of each design, the cognizant engineer or manager specifies the types of necessary design reviews (formal or informal) and at what stages of design evolution these will be conducted. The design reviews are systematic evaluations to assure agreement with design criteria and elimination of errors.

2.3.22 For items important to safety, the WVNS procedure for formal design review and/or verification provides for the appointment of a qualified design review chairman and establishes his authority for organizing and conducting the review, and for the resolution of resulting action items. It establishes the criteria for

the method of review, identifies the organizations or functions to be represented, and establishes the qualifications and the responsibility of the participants to review the data packages prior to the meeting and to resolve action items in a timely manner. For formal design reviews, the majority of the design review committee was not directly involved in the development of the design. Agenda checklists are used for all reviews. Action items resulting from the reviews are documented, scheduled, and followed up. Formal design reviews typically include representatives of all technical disciplines involved in the design and are applicable to the entire design. Verification and/or validation are completed prior to release for procurement or use.

2.3.23 Informal design reviews are typically aimed at specific design problems and involve only those personnel specifically needed to resolve the problem.

2.3.24 For design or modification/change activities, which use untried or beyond-the-state-of-the-art testing and analysis elements, a peer review in compliance with NUREG-1297, "Peer Review for High-Level Nuclear Waste Repositories," is conducted as part of the review/verification process. Peer review is also applied when detailed technical criteria and requirements do not exist.

2.3.25 Based on assigned quality level, Quality Assurance maintains an overview of the design review program through participation in the reviews and through audits. In the reviews, Quality Assurance concentrates

on such aspects as completeness of design criteria, consistency of detailed design with the criteria, control of interfaces, acceptance criteria, interchangeability, and resolution of previous problems. Quality Assurance also overviews design review preparation, participation by appropriate disciplines, and follow up.

2.3.26 WVNS design verification testing is specified in test plans. Test plans are prepared by Engineering and identify test objectives, test parameters, the item or process to be tested, the tests to be performed, and the facility to be used. They identify the test articles and their disposition. They also specify requirements for data acquisition and reduction, pre-test and post-test examinations, any readiness reviews, and documentation. The quality assurance requirements for the test programs are also included.

2.3.27 Procedures for conducting WVNS design verification tests are defined in the test plans. These procedures identify the prerequisites for conducting tests and define the detailed test evolution and data requirements. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verification processes, it includes suitable qualification testing of a prototype under the expected ranges of design conditions.

2.3.28 WVNS maintains or archives the record copies of approved drawings and specifications, evidence of their approval, the descriptions of system design, and official correspondence. The responsible WVNS technical organizations initially maintain record copies of design

reviews and follow ups, "Holds" and "To Be Determined" reports, drawing lists, engineering studies, Approvals-In-Principle, test requests, and test plans.

2.4 Procurement Document Control

2.4.1 WVNS has established procedures for Procurement Document Control which provide assurance that applicable design bases and other requirements necessary to assure adequate quality of Waste Acceptance Process activities are included or referenced in documents for procurement of items and services. The procedures delineate the actions to be accomplished in the preparation, review, approval, and control of procurement documents.

2.4.2 To the extent of an item's importance to safety, procurement documents require suppliers to have Quality Assurance Programs consistent with the requirements contained in the purchase documents. The requirements are commensurate with the Q-Level of the item or activity.

2.4.3 Suppliers are surveyed and evaluated to assure that sufficient and appropriate systems, procedures, and personnel are available to meet the programmatic and technical requirements of the order. Records are maintained on all suppliers surveyed to show those quality assurance attributes available within their Quality Assurance Program. The WVNS Purchasing organization obtains approval from engineering and quality assurance management of potential suppliers.

2.4.4 Procurement quality requirements are specified in procurement documents.

2.4.5 The procurement documents are reviewed and approved by quality assurance and others based on the quality level of the procurement action. The review and approval are documented prior to release.

2.5 Instructions, Procedures, and Drawings

2.5.1 WVNS has established procedures that define the requirements for preparation, review, approval, issuance, and changes to instructions, procedures, and drawings. These procedures insure that documents generated to support Waste Acceptance Process activities such as processing, equipment maintenance, testing, inspection, and product handling are prescribed in sufficient detail to insure appropriate controls and verifications are accomplished.

2.5.2 Procedures list each specific step required to finalize instructions, procedures, and drawings. Review by technical specialists and Quality Assurance is required. Methods to insure resolution of comments by reviewing organizations prior to the document being released are specified.

2.5.3 Documented instructions, procedures, and drawings include appropriate acceptance criteria for verification that prescribed quality has been achieved.

2.5.4 Work Instructions for melter and related equipment testing and facility work are prepared, reviewed, approved, and issued in accordance with procedures.

2.6 Document Control

2.6.1 WVNS has established procedures to control the issuance of documents such as instructions/work orders, procedures, and drawings that define Waste Acceptance Process activities. These procedures also describe how changes are made to documents and how obsolete or suspended documents are removed from use.

2.6.2 WVNS uses a review process that includes qualified, technical specialists to insure that the documents are adequate, are approved by authorized personnel, and are issued for use to the area where the prescribed work will be performed prior to starting the work.

2.6.3 Master document lists for WVNS documents are maintained to assure that only the current document revision is listed and available for use.

2.6.4 All document changes are reviewed and approved by the same organization that performed the original review.

2.6.5 The types of documents controlled are identified with the organization responsible for obtaining review, approval, and issuance.

2.7 Control of Purchased Items, and Services

2.7.1 WVNS has established procedures for control of purchased material, equipment, and services to ensure compliance to technical and waste acceptance requirements. Evaluation and selection of sources of supply prior to award of the purchase order are defined by procedure.

2.7.2 Qualified personnel proposed suppliers of quality-related services and items, as required, based on the Q-level of the item being procured. The survey is documented. Quality Assurance concurs with the proposed supplier list prior to issuing the procurement package for supplier quotations. For specific major or critical procurements, Quality Assurance will participate in the entire supplier selection process.

2.7.3 Upon award of a procurement action, suppliers are required to submit Quality Assurance Program documents to show how the quality assurance requirements of the procurement action are being met.

2.7.4 Procurement documents define requirements for specific WVNS inspection hold points beyond which a supplier may not proceed until released, in writing, by WVNS Quality Assurance. Suppliers are required to flow-down the applicable purchase order requirements to sub-tier suppliers.

2.7.5 Surveillance at supplier's facilities is planned and conducted during the life of the contract by WVNS Quality Assurance or a representative of the WVNS Quality Assurance Department. These surveillances are performed to verify compliance with the procurement quality assurance requirements. Surveillances may include source inspection and release of items at the supplier prior to shipment.

2.7.6 Upon receipt of items at WVNS, receipt inspection is performed in accordance with procurement documents and documented when required by the purchase order.

2.7.7 Upon acceptance of all procurement actions by Quality Assurance, a Quality Release is issued to permit the item to proceed with further processing. Hold or conditional release tags are used by Quality Assurance to prevent the release of items that have not met all procurement requirements. Items fully acceptable and released by Quality Assurance are tagged with an "Accept" tag or otherwise identified.

2.7.8 Supplier quality assurance documents, including a copy of the supplier's final Certificate of Compliance are reviewed by qualified personnel and maintained in the WVNS Quality Assurance inspection working file.

2.7.9 Nonconformances are processed as described in section 2.15 of this QAPD. Audits of suppliers are described in section 2.18 of this QAPD.

2.8 Identification and Control of Items

2.8.1 WVNS has established procedures for the identification and control of materials, parts and components for Waste Acceptance Process activities. Procedures provide detailed instructions for the preparation of equipment and material specifications, including the designation of quality level and the resulting review and approval cycle. Quality Assurance reviews the specification for the incorporation of applicable quality requirements. This review includes for example material identification, material and equipment test reports, shelf life, manufacturing and inspection requirements and special shipping and handling requirements.

2.8.2 After approval of material/equipment specifications, a procurement package and purchase requisition is prepared. Quality Assurance reviews the package for incorporation of proper quality requirements.

2.8.3 WVNS specifies to the vendor, per the purchase order and related specifications, necessary material controls such as equipment identification numbers, heat and lot or batch numbers for raw materials or any other unique identification to assure positive control of WVNS material and associated test, inspection and acceptance reports.

2.8.4 Upon receipt at WVNS, a Quality Assurance receiving inspector verifies the identification of the item and its documentation. Acceptable items are then released to controlled stores for issue. Procedures require that items important to safety be listed for the purpose of maintaining control and traceability of an item to its point of use.

2.8.5 The shelf life of an item is identified, if required, to assure that it will function as originally intended.

2.9 Control of Processes

2.9.1 WVNS has established procedures to control special processes at WVNS as well as at WVNS' suppliers to ensure quality consistent with design requirements. Controlled processes include, but are not limited to, welding, NDE, heat treating and glass processing. Control procedures are developed for processes which specify preparatory steps, personnel qualification requirements, processing details, test conditions and the requirements for records.

2.9.2 Records are required which provide objective evidence that special processes were performed in compliance with approved process control procedures, by qualified personnel using qualified equipment. Quality Assurance verifies that requirements for procedures, personnel and equipment, qualification and control requirements are adequately specified to subcontractors on Purchasing documents and equipment specifications.

2.9.3 Quality Assurance Procedures provide a system for evaluation of supplier abilities to comply with special process control requirements prior to contract award and confirmation of adequate control during contract performance.

2.9.4 Quality Assurance reviews and approves internal work documents such as standard operating procedures and work orders for adequate incorporation of process control requirements.

2.9.5 For work performed at WVNS requiring control of special processes, Quality Assurance Procedures provide for in-process verification of WVNS work activities for compliance to process control conditions and requirements as specified in approved work packages.

2.9.6 Characteristics of items that are important to safety, which cannot be readily verified by test or inspection of final product, require process control including documented procedures for performance, personnel training and qualification, procedure qualification.

Areas which require process control during waste canister production are melter feed, pouring, glass melting, canister cooling, transfer and storage of canisters.

2.9.7 Process control requirements are part of the vitrification operations procedures reviewed and approved by Quality Assurance. The areas covered by the procedures may include for example the following:

1. Identification of required equipment and instrumentation,
2. Identification of control parameters and operating limits for those parameters,
3. Environmental conditions and requirements,
4. Instrument calibration frequency,
5. Reference to applicable codes, standards and specifications.

2.10 Inspection

2.10.1 Procedures are established for classifying items and for identifying significant quality characteristics to be measured to verify conformance to specifications. Inspections are performed according to documented instructions, procedures and drawings such as Inspection Instruction Data Sheet (IIDS) and the results are documented.

2.10.2 The performance of inspections is planned and includes: 1) identification of characteristics or activities to be inspected; 2) required M&TE,

documents, and revisions; and 3) appropriate acceptance and rejection criteria. The frequency and methods of inspection are selected to assure that the required quality is obtained. Inspection instructions and plans are prepared from drawings and specifications by Quality Assurance prior to performing the inspection.

2.10.3 Inspection activities are performed by personnel other than those who performed to actual work activity.

2.10.4 Inspectors are qualified by appropriate training or experience to perform the required inspection. Nondestructive Examination (NDE) personnel are certified in accordance with the American Society for Nondestructive Testing Standard SNT-TC-1A, "Recommended Practice for Nondestructive Testing Personnel Qualification and Certification." Inspector personnels' qualifications or certifications are kept current.

2.10.5 Contractor and vendor inspection programs are evaluated by Quality Assurance to ascertain compliance with contract requirements.

2.10.6 The types of inspections performed are source inspections, receiving inspection, in-process inspection, testing, and process monitoring. Inspections performed for each work operation or process activity to verify quality of equipment, materials products or process are direct. If direct inspection is impossible or disadvantageous, indirect control by process monitoring methods is used. Both inspection and process monitoring are used when control is inadequate without both.

2.10.7 Nonconformances detected during performance of quality-specified inspections or process monitoring are documented and processed in accordance with procedures. Replaced, modified, or reworked items are inspected by methods that are equivalent to the original inspection method.

2.10.8 When mandatory sampling or inspection hold points are identified in design and test documents, the work may not proceed without the authorization of Quality Assurance. This is accomplished by including hold points in work documents, test procedures and operating procedures during preparation.

2.11 Test Control

2.11.1 WVNS has established a test control program that provides for assuring that testing required to demonstrate that items and services conform to the WAPS. Personnel performing tests are trained and appropriately qualified. Tests are performed in accordance with written test procedures that incorporate or reference the requirements and acceptance limits contained in applicable design documents.

2.11.2 The test control program includes testing that will be performed in the process qualification and production phases. Acceptance testing is specified, approved, and controlled through the use of test requests, test plans, test matrixes and test procedures.

2.11.3 Acceptance of test results is performed through test reports and test report summaries. Mandatory evaluations and approvals by qualified personnel are required where appropriate throughout the test control program to verify that design criteria, safety analysis report and quality requirements are met.

2.11.4 The WVNS test program establishes measures to assure that test procedures have provisions for including prerequisites and verifying that they have been established and performed. Instrumentation and equipment required for testing is specified to satisfy test requirements. Environmental conditions are reviewed for adequacy for the tests being performed.

2.11.5 The test control program establishes requirements by which test results are documented and evaluated to assure that test requirements have been satisfied. The WVNS testing control procedures require that management define the requirements for review, approval and acceptance of test data. Where appropriate, test review teams are established for the review, evaluation and acceptance of data.

2.11.6 Items tested are identified, controlled, and ultimately dispositioned.

2.12 Control of Measuring and Test Equipment

2.12.1 WVNS has established procedures for the control of measuring and test equipment (M&TE). Quality Assurance Procedures require that all measuring and test equipment used at WVNS for accepting material or

equipment, controlling special processes, verifying critical operation of the facility, or obtaining test data be identified and calibrated against certified standards having traceability to nationally recognized standards. If no nationally recognized standard exists, the basis for calibration is required to be documented.

2.12.2 Calibrations are required to be performed at planned intervals which will provide confidence in the reliability of the M&TE. Also required are traceable records of M&TE calibrations. Each organization possessing M&TE is responsible for issuing, approving, and implementing a calibration program.

2.12.3 Calibration implementing procedures require review, evaluation and disposition by Plant Operations Support and Quality Assurance to verify that equipment and materials accepted or checked with discrepant equipment is evaluated and/or rechecked to verify that no adverse condition exists.

2.13 Handling, Storage, and Shipping

2.13.1 WVNS has established procedures for the preservation, packaging, handling, shipping, and storage (PPHSS) of items important to safety which are purchased, fabricated, shipped, or stored by WVNS. The objective of the procedures is to prevent damage, loss or deterioration of items essential to meeting the WAPS and to provide safety to personnel performing quality-related tasks for the Vitrification Project.

2.13.2 Activities related to PPHSS are performed to established procedures, work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents.

2.13.3 Cognizant organizational managers are responsible for:

1. Incorporating any PPHSS requirements into design, procurement, contractual, and instructional documents.

2. Preparing and obtaining approval of procedures for critical lifts, components, handling operations, and other high value or critical items, as applicable.

3. Identifying requirements for trained operators for special handling and lifting equipment.

4. Establishing requirements to ensure safe and adequate handling for particular items, special tools and equipment (such as containers, shock absorbers, and accelerometers), and special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels). These items shall be specified, provided, and their existence verified at specified intervals through inspection and tests.

5. Instructions for marking and labeling for packaging, shipment, handling, and storage of items are required to be established as necessary to identify, maintain, and preserve the item, including indication of the presence of special environments or the need for special controls.

2.13.4 Quality Assurance performs surveillances and audits to verify compliance to PPHSS program requirements.

2.14 Inspection, Test, and Operating Status

2.14.1 WVNS has established procedures for the identification of the status of inspection and test activities on items, or documents traceable to the item, to insure that required tests have been performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used or operated.

2.14.2 Procedures exist for a facility status control system. The procedures address the status of items and require the operating status of facilities to be identified, documented, approved and controlled.

2.14.3 The test status of individual items important to safety, and the operational status of quality-related structures, systems, and components shall be indicated by utilizing tags, stamps, labels, logs, or other suitable documentation.

2.14.4 WVNS incorporates the status of inspection and test activity requirements into procurement, contractual and instructional documents to assure that these requirements are implemented by vendors and subcontractors.

2.14.5 The status of high-level waste processing equipment readiness to operate will be evaluated, prior to operation, by readiness reviews.

2.15 Control of Nonconforming Items

2.15.1 WVNS has established procedures which define the measures required to control computer codes, materials, parts, components or equipment that do not conform to requirements in order to prevent their inadvertent use or delivery. Procedures include organizational responsibilities and authority.

2.15.2 Internal nonconforming items are identified on Nonconformance Reports (NRs). The NR describes measures that provide for, as appropriate, identification, documentation, segregation, disposition, and notification to affected organizations. NRs are reviewed and dispositioned by the cognizant engineer, using organization, and Quality Assurance.

2.15.3 Corrective actions are identified to prevent a recurrence of the nonconformance.

2.15.4 Hold tags are affixed to the items identified on the nonconformances. These hold tags are replaced with either "accept," "conditional" or "scrap" tags depending on the disposition of the NR.

2.15.5 Contractors report nonconformances to WVNS, identifying deviations from procurement requirements, on a Supplier Nonconformance Report (SNR) according to procedure. Prior to items being shipped to WVNS, all SNRs must be dispositioned by WVNS. Suppliers list all SNRs on their final Certificate of Compliance which is provided

to WVNS with the items being shipped. Procurement packages define the supplier's responsibility when detecting a SNR condition and his method of reporting the nonconformance to WVNS.

2.15.6 WVNS performs periodic analysis of nonconformance documents to detect adverse quality trends and reports the results of such analyses to WVNS management.

2.16 Corrective Action

2.16.1 WVNS has established procedures for the identification and correction of the causes of conditions adverse to quality, such as deficiencies, failures, deviations, equipment defects and nonconformances in processes. UORs and critiques are included in the procedures. Other systems that further support the identification and resolution of adverse conditions are Trouble Records Reporting, Operating Plant Deficiencies and Test Exceptions.

2.16.2 When significant conditions adverse to quality are discovered through inspection, test, evaluation, audit or other means, it is the responsibility of the identifying organization to select the most appropriate reporting mechanism, such as UOR, RCA or Critique.

2.16.3 WVNS procedures govern the reporting and investigation to determine the root cause(s), identification of the actions to correct the problem and prevent its recurrence and the requirements for reporting the condition to the appropriate levels of management and the other major participants when required. Solutions are followed up to verify implementation.

2.16.4 Quality Assurance collects key information about UOR and critique events and inputs this information into a data base. From this data base, evaluations are done to determine event root cause(s) and establish a course of action for correction.

2.17 Quality Assurance Records

2.17.1 Procedures are established to ensure that records which furnish documentary evidence of quality shall be specified, prepared, and maintained. Records are protected against damage, deterioration, or loss. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition are established and documented. Other systems which cover activities affecting quality-related records, including those generated by subcontractors, vendors, engineering, and experimental contacts and testing activities are described in applicable sections of this document.

2.17.2 Permanent storage of WVNS quality-related records is accomplished through the Master Records Center (MRC). The MRC, in compliance with procedures, indexes, stores, microfilms and transmits WVNS records to archival storage. The records are retained until canister shipment, at which time the records will be provided to the repository.

2.17.3 Procedures governing the handling of quality-related records are approved by Quality Assurance and comply, as applicable, with the Quality Management Manual.

2.17.4 Procedures impose additional requirements for records administration, records receipt, storage, preservation, retrieval, and disposition, as required.

2.17.5 Production records required to furnish evidence of quality of the high-level Waste Acceptance Process activities will be processed according to procedures, with new procedures being generated as required. Documentation sufficient to demonstrate canistered waste form compliance with the WAPS and implementation of this compliance plan will be prepared and maintained as quality records. These records will be collected and maintained as follows:

1. Documentation will be collected and maintained as lifetime quality records by WVNS. Copies of these records will be made available to the federal repository operating at the time the repository is ready to begin accepting canistered waste forms from the waste form producer. Such records will be maintained by the federal repository operator to satisfy any repository requirements. Other documentation generated during preparation and implementation of the WCP will be collected and maintained as nonpermanent quality records.

2. Documentation sufficient to support preparation of the WQR will be collected and maintained as lifetime quality records. Copies of these records will be made available to the federal repository operator at the time the repository is ready to begin accepting canistered waste forms from the waste form

producer. Other documentation generated during preparation and maintenance of the WQR will be collected and maintained as nonpermanent quality records.

3. Production records will be identified in a manner that facilitates positive-direct correlation between documents and canistered waste forms to which they relate through the canister ID number.

4. Production records will be declared lifetime quality records and transferred to the federal repository operator with the canistered waste forms to which they relate.

5. Copies of production records will be kept and maintained as nonpermanent quality records. These records will be kept for a minimum of 10 years after the canistered waste forms they represent are transferred to the federal repository operator or as otherwise directed by DOE.

2.17.6 Product certification records necessary to provide evidence of the acceptability of the canister and waste form which includes the canistered waste form will be developed and retained as lifetime records in accordance with procedures. The WCP and/or WQR will identify the types of records that will be developed during the waste form production process. The WQR will identify the quality records required to be a permanent part of the overall canistered waste form product certification package.

2.18 Audits

2.18.1 WVNS has established a program 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.

2.18.2 A semiannual audit schedule is published which lists the organization to be audited with a WVNS qualified lead auditor identified. These audits are planned and scheduled to assure that they are conducted on the basis of the importance to safety of the activities being performed and are initiated early enough to assure effective quality during installation, equipment maintenance, modification, inspection, testing, processing and storage of the canistered waste form.

2.18.3 Audits are conducted in accordance with written checklists prepared by appropriately trained personnel under the direction of a qualified lead auditor. Audit personnel do not have direct responsibility in the area being audited.

2.18.4 Audit findings and observations are documented, reviewed by management responsible for the area audited, and issued to the audited organization for corrective action implementation and a documented reply stating corrective actions taken or to be taken.

2.18.5 Follow up actions are taken by Quality Assurance personnel until all corrective actions have been closed out. A formal audit closeout letter is then issued.

APPENDIX A

SUPPLEMENTAL REQUIREMENTS IMPLEMENTATION SCHEDULE

OGR/B-14 REQUIREMENT	ELEMENT SUBJECT	IMPLEMENTATION DATE
5.2.1	Control of Essential Software	September 1989
5.2.2	Peer Review	September 1989
5.2.3	Control of Experiments	September 1989
5.2.4	Qualification of Data	September 1989
5.2.5	Archival of Samples	Not Scheduled
5.2.14	Effectiveness Evaluation	September 1989

APPENDIX B
MATRIX TABLE - OF IMPLEMENTING PROCEDURES

OGR/B-14 QA REQUIREMENTS FOR HLW FORM PRODUCTION	ANSI/ASME NQA-1 BASIC REQUIREMENT	QAPD-4 SECTION	REQUIREMENT	CONTROLLING DOCUMENT
5.2.1	3	2.2	Computer Software Control* Control of Computer Software Quality Assurance Verification of Computer Software Programs	QM (TBAL) EP QAP (TBAL)
5.2.2	3	2.3	Peer Review Control of the Peer Review Process	QM (TBAL) QAP (TBAL) EP- (TBAL)
5.2.3	11	2.11	Control of Experiments Development Test Control	QM (TBAL) EP-11-003
5.2.4	3	2.3	Qualification of Data Data Qualification Control	QM (TBAL) EP- (TBAL)
5.2.5	17	2.17	Later	QM (TBAL)
5.2.9	2	2.2	Quality Assurance Program (Quality Levels)	QM-2
5.2.14	12	2.2	Effectiveness Evaluation	QM (TBAL)

* TBAL - to be added later

MATRIX TABLE - OF IMPLEMENTING PROCEDURES (CONTINUED)

OGR/B-14 QA REQUIREMENTS FOR HLW FORM PRODUCTION	ANSI/ASME NQA-1 BASIC REQUIREMENT	QAPD-4 SECTION	REQUIREMENT	CONTROLLING DOCUMENT
17.2.1	1	2.1	Organization	QM 1
			Quality Assurance	WV-120
17.2.2	2	2.2	Quality Assurance Program	QM 2
5.2.8			Organization	QM 1
5.2.9			WVNS Training	QM 2-1
5.2.10			QA Training	QM 2-2
5.2.11			Auditor Training	QM 2-3
			Training	WV-538
17.2.3	3	2.3	Design Control	QM 3
5.2.13			Safety Review Program	WV-906
			Preparation of Functional and Operational Requirements	EP-3-001
			Preparation of Design Criteria	EP-3-002
			Design Review	EP-3-003
			Preparation of Engineering Specifications	EP-3-004
			Preparation of Drawings	EP-3-005
			Interface Identification and Control Procedure	EP-3-006
			Engineering Change Notice	EP-3-007
			Configuration Control Board	EP-3-008
			Preparation of Technical Manuals	EP-3-010
			Review, Approval, and Engineering Release	EP-3-011
			Engineering Style Guide	EP-3-012
			Equipment Numbering	EP-8-001
17.2.4	4	2.4	Procurement Document Control	QM 4
			Establishment of Quality Requirements in Purchase Requisitions	QM 4-1
			Control and Preparation of Purchase Requisitions	WV-620

MATRIX TABLE - OF IMPLEMENTING PROCEDURES (CONTINUED)

OGR/B-14 QA REQUIREMENTS FOR HLW FORM PRODUCTION	ANSI/ASME NQA-1 BASIC REQUIREMENT	QAPD-4 SECTION	REQUIREMENT	CONTROLLING DOCUMENT
17.2.5	5	2.5	WVNS Requirements for Instructions, Procedures and Drawings	QM 5
			Instructions, Procedures and Drawings	
			Drawing Preparation	EP-3-005
			Engineering Procedure Administration	EP-5-001
17.2.6	6	2.6	Requirements for Control of WVNS Documents	QM 6
			Requirements for Distribution of Controlled Documents	WV-103
			Engineering Document Control	EP-6-001
			Requirements for Preparing Engineering Documents	EP-3-005
			Requirements for Release of Engineering Documents	EP-3-011
17.2.7	7	2.7	Requirements for Submittal of Supplier Approval Requests	WV-602
			Control Purchased Material; Equipment and Services	QM 7
17.2.8	8	2.8	Identification and Control of Materials, Parts and Components	QM 8
			Purchase Requisitions and Changes	WV-620
17.2.9 5.2.6	9	2.9	Control of Special Processes	QM 9
17.2.10	10	2.10	Design Control	QM 3
			Inspection and Test Control	QM 10
17.2.11	11	2.11	Test Control	QM 11
			Development Test Control	EP-11-003
17.2.12	12	2.12	Control of Measuring and Test Equipment	QM 12

MATRIX TABLE - OF IMPLEMENTING PROCEDURES (CONTINUED)

OGR/B-14 QA REQUIREMENTS FOR HLW FORM PRODUCTION	ANSI/ASME NQA-1 BASIC REQUIREMENT	QAPD-4 SECTION	REQUIREMENT	CONTROLLING DOCUMENT
17.2.13	13	2.13	Requirements for Handling, Storage and Shipping	QM 13
17.2.14	14	2.14	Inspection, Test and Operating Status WVNS program for Review and Approval Process of Operational Readiness of Site Systems	QM 14 WV-368
17.2.15			Nonconformances	QAP 15-1
17.2.16	16	2.16	Corrective Action Reporting of Unusual Occurrences	QM 16 WV-187
17.2.17 5.2.12 5.2.7	17	2.17	Quality Assurance Records Records Management and Storage Engineering Quality Record	QM 17 WV-730 EP-7-001
17.2.18	18	2.18	Audits	QM 18

APPENDIX I

UNCONTROLLED

Waste form production items and activities essential to certification and acceptance of canistered waste forms that require control in accordance with the quality assurance program will include the following, as appropriate:

1. Qualification of the Production Process - Included are those items and activities that shall be established, controlled, or accepted for waste form qualification in accordance with quality assurance program and engineering requirements. Individual items and activities will be identified by waste qualification documentation. General categories include:

   - essential process control specifications and limits;
   - essential system equipment, material, fabrication, and construction acceptance criteria;
   - essential equipment and system configuration;
   - qualification of production procedures;
   - criteria for qualification of production personnel;
   - feed composition specifications and limits;
   - process chemical specifications (frit, etc.); and
   - product measurement and acceptance criteria.

2. Control of Production - Included are those items and activities to be controlled or accepted in accordance with quality assurance program requirements. Individual items and activities, including associated acceptance criteria, will be determined and documented in accordance with the items and activities identified by the waste form qualification program. A readiness review program will be established and conducted to assure readiness and adequacy of identified production controls. General categories include:

- feed composition parameters;
- procurement and control of feed chemicals (frit, etc.);
- calibration and control of process instrumentation;
- procedure control and procedure compliance (process control);
- personnel qualification and correct job assignment;
- procurement and control of canister and canister materials;
- identification and handling of essential items and materials;
- canister closure welding;
- product and production records;
- plant and equipment maintenance and modification; and
- handling and storage of finished product.

3. Acceptance of the Final Product - Included are inspection and test activities and associated items that are necessary for final product acceptance. Criteria for this acceptance will be established and identified as early as the qualification of the production process and revised subsequently as required. General categories include:

   - inspection and product acceptance test planning;
   - in-process test and inspection;
   - non-destructive examination and finished product inspection (seal test, etc.);
   - qualification and correct job assignment of inspection and acceptance test personnel;
   - calibration and control of measuring and test equipment; and
   - measurement, test, and inspection records.

4. Documentation of Specific Requirements - The applicable points shall be specified in the Waste Form Qualification Report submittals, process control plans, and/or operating schedules, as appropriate.

APPENDIX II

GLOSSARY

UNCONTROLLED

WEST VALLEY NUCLEAR SERVICES COMPANY, INC.

QUALITY MANAGEMENT

Acceptance Criteria - specified limits placed on characteristics of an item, process or service defined in codes, standards, or other requirements documents. (NQA-1)

Activities Affecting Quality - include siting, designing, purchasing, fabricating, bundling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, modifying, and decommissioning. (NUREG 1318, 10 CFR 60)

Audit - a planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and effectiveness of implementation... (OGR/B-14).

Barrier - any material or structure that prevents or substantially delays movement of water or radionuclides (10 CFR 60.2).

Calibration - the process of comparing an instrument or device to a (nationally recognized) appropriate standard, and:

a) adjusting the instrument so that the accuracy of its readings is within approved tolerances, or

b) recording the corrections in properly identified calibrations reports. (QM-19)

Canister - the metal vessel into which borosilicate waste glass is poured during waste form fabrication. (OGR/B-9)

Canistered Waste Form - the waste form and the surrounding canister as well as any secondary canisters applied by the producer. (OGR/B-9)

Causative Process - an exercise of management authority that causes an action to be performed through the issuance of an order, a letter, and/or a purchase contract. The causative process takes precedence over procedures by causing them at lower levels to be; 1) brought into being, 2) performed at specific times, 3) superseded, and 4) changed to become more effective. (QAPD)

Certificate of Conformance - a document signed or otherwise authenticated by an authorized individual certifying the degree to which the items or services meet specified requirements. (NQA-1)

Certification - the act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements. (NQA-1)

Characteristic - any property or attribute of an item, process or service that is distinct, describable, and measurable. (NQA-1)

Computer Code (Scientific and Engineering) - instructions written in a computer language for the processing of mathematical models developed for use in scientific and engineering analysis, design, safety analysis, process or equipment control and other activities dependent upon a computer for solution or control. Computer code development includes preparation of instructions for the input data format and use of the code. (See Essential Software for Waste Acceptance Process Activities.) (OGR/B-14)

Condition Adverse to (Required) Quality - an all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one which, if uncorrected, could have a serious effect on safety or operability. (QM-19)

Containers (Radioactive Shipments)

Type A - meet WVNS approved design and performance specifications (in compliance with Department of Transportation Specification), and are certified by the builder. These containers are quality level C.

Type B - are engineered to meet DOT design and performance specifications; hypothetical accident conditions as specified in 49 CFR 173.398, and are reviewed by USDOE with approval evidenced by a "Certificate of Compliance." These containers are quality level A or B, depending on the end use. (QM-19)

Contractor - the individual or organization entering into a contract, subcontract or purchase order issued by the purchaser. (QM-19)

Controlled Work Area - an area to which the access of personnel, tools, and materials is limited and physically controlled. (QM-19)

Contamination - material that is not an inherent part of the components such as grit, metal particles, oil, grease, slag, scale, residual films, soil and unspecified preservative or paint. (QM-19)

Corrective Action - measures taken to rectify conditions adverse to (required) quality and, where necessary, to preclude repetition. (NQA-1)

Design Change - measures taken to rectify conditions adverse to required quality and, where necessary, to preclude repetition. (NQA-1)

Design Input - those criteria, parameters, bases, or other design requirements upon which detailed final design is based. (NQA-1)

Design Output - documents, such as drawings, specifications, and other documents, defining technical requirements of structures, subsystems, and components. (NQA-1)

Design Process - technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents. (NQA-1)

Design Review - the process consisting of examination, comment, evaluation, resolution, and documentation which ensures that any given design clearly, accurately, and completely describes the technical requirements of the product in sufficient detail for the appropriate phase. (QM-19)

Development Testing - the testing of material, components, features, subassemblies, systems or processes to obtain quantitative data for use in the establishment of design process parameters. (QM-19)

Deviation - a departure from specified requirements. (NQA-1)

Document - any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. (QM-19)

Effectiveness Evaluation - a documented system for measuring the Quality Assurance Program's effectiveness at meeting the WAPS. Program quality goals are established. Feed-back collected from surveillances, audits, and other quality reporting activities is compared to the program quality goals and a measurement of effectiveness is obtained. (QAPD)

Essential Software - scientific and engineering computer codes used in applications essential to meeting the Waste Acceptance Preliminary Specification (WAPS). (QAPD)

External Audit - an audit of those portions of another organization's Quality Assurance Program not under the direct control or within the organizational structure of the auditing organization. (NQA-1)

Failure - the inability of an item to perform within specified limits. (QM-19)

Final Cleaned Surface - the surface condition after all surface finishing and cleaning operations have been performed prior to placing the surface in service. (QM-19)

Final Design - approved design output documents and approved changes thereto. (NQA-1)

Guideline - a suggested practice that is not mandatory in programs intended to comply with a standard. The word "should" denotes a guideline; the work "shall" denotes a requirement. (NQA-1)

High-Level Waste - high-level radioactive waste is:

a) Irradiated reactor fuel.

b) Liquid wastes resulting from the operation of the first cycle solvent extraction system, or equivalent, and the concentrated wastes from subsequent extraction cycles, or equivalent, in a facility for reprocessing irradiated reactor fuel.

c) Solids into which such liquid wastes have been converted (10 CFR 60.2).

Hold Point - a point in the work sequence, designated by WVNS beyond which work may not proceed without their consent. (QM-19)

Inaccessible Area - areas or openings in a component that are not readily accessible for cleaning or inspection during or after fabrication, and where dirt, liquids, foreign articles, or other contaminants may be trapped. (QM-19)

Independent (Personnel) - a condition characterizing an individual or group of individuals who are qualified to analyze, review, inspect, test audit, or otherwise evaluate activities and work results because:

a) they had no direct responsibility for or involvement in performing the activity or work,

b) they are not accountable for the activity or work result, and

c) they do not report directly to the immediate supervisor who is responsible for performing the activity of work being evaluated. (OGR/B-14)

Indoctrination - to instruct in fundamentals so as to provide understanding of principles involved. (OGR/B-14)

Inspection - the examination or measurement to verify whether an item or activity conforms to specified requirements. (NQA-1)

Inspector - a person who performs inspection activities to verify conformance to specific requirements. (NQA-1)

Interface - the identifiable point of connection or coordination between two or more defined entities, which must be properly coordinated for successful operation. Entities may be either physical items or organizations. (QM-19)

Internal Audit - an audit of those portions of an organization's Quality Assurance Program retained under its direct control and within its organizational structure. (NQA-1)

Item - an all-inclusive term used in place of any of the following: appurtenance, assembly, component, computer code, equipment, material, module, part, structure, subassembly, subsystem, system, or unit. (NQA-1)

Items Important to Safety - those engineered structures, systems, and components essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area at any time until the completion of permanent closure of the repository (10 CFR 60.2 and NUREG 1318)

Items Important to Waste Isolation - natural and engineered barriers which are relied on for achieving the postclosure performance objectives in 10 CFR 60 subpart E. (NUREG-1318)

Low-Level Waste (LLW) - those low-level radioactive wastes containing sources, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as in the Low-Level Waste Policy Act. That is, radioactive waste not classified a high-level radioactive waste, transuranic waste spent nuclear fuel, or byproduct material as defined in section 11 e.(2) of the Atomic Energy Act (uranium and thorium tailings and waste) of 10 CFR 61. (was "waste" in QM-19)

Maintainability - the combined features of equipment design and installation which facilitate the accomplishment of inspection, test, checkout, services, repair, and overhaul. (QM-19)

Major Participant Organizations - those organizational units of DOE and the Operating Contractor that are associated through organizational, administrative, or contractual arrangements and together form a waste form producer organization. (OGR/B-14)

Measuring and Test Equipment (M&TE) - devices or systems used to calibrate, measure, gage, test, or inspect in order to control or to acquire data to verify conformance to specified requirements. (NQA-1)

Nonconformance - a deficiency in characteristics, documentation, or procedure which renders the quality of an item or activity unacceptable or indeterminate. (NQA-1)

Objective Evidence - any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests which can be verified. (NQA-1)

Overview - an analysis and assessment by management of the scope, status, adequacy, and effectiveness of quality achievement and assurance activities. Overview encompasses effectiveness assessments, technical reviews, readiness reviews, audits, and surveillances, as appropriate. (OGR/B-14)

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 that needed to perform 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 material or data contained in a report which generally includes elements that go beyond the existing state of current technology. (OGR/B-14)

Procedure - a document that specifies or describes how an activity is to be performed. (NQA-1)

Procurement Document - purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase. (NQA-1)

Production Records (PR) - the documentation, provided by the producer, that describes the actual canistered waste forms and certifies compliance with the Waste Acceptance Preliminary Specification (WAPS) (OGR/B-14).

Program - activities not directly related to the construction or modification of a facility, such as research and development, manufacturing, production, and testing. (ID 5700.6)

project - activities related to the construction or modification of a facility and its associated safeguards and utilities. (ID 5700.6)

Project, the - the West Valley Demonstration Project. (QAPD)

Purchaser - the organization responsible for establishment of procurement documents. (NQA-1)

Q-List - the document(s) that identify items important to safety...(10 CFR 60, subpart G)

Qualification (Personnel) - the characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function. (NQA-1)

Qualified Procedures - an approved procedure that has been demonstrated to meet the specified requirements that an item will perform satisfactorily in service. (NQA-1)

Quality Assurance - all of the planned and systematic actions necessary to provide adequate confidence that canistered waste forms will comply with the Waste Acceptance Preliminary Specification (WAPS), OGR/B-9. (QAPD)

Quality Assurance Program Description (QAPD) - a document which identifies the requirements that are applicable to a particular program or project, and provides an index, matrix, or description of the procedures that implement these and any necessary supplementary requirements. The document also includes specific responsibilities and authorities for its implementation. (QAPD)

Quality Control - the quality assurance actions that control the attributes of the material, process, component, system or facility in accordance with predetermined quality requirements. (QM-19)

Quality Record - a completed document that furnishes evidence of the quality of items and/or activities affecting quality...(OGR/B-14)

Readiness Review - a structured method of determining that an activity is ready to operate or proceed to the next phase, and includes, as a minimum, a comprehensive review of the readiness of the plant and hardware, personnel, and procedures. The review includes a determination of compliance with all requirements. (OGR/B-14)

Receiving - taking delivery of an item at a designated location. (NQA-1)

Reject - a decision that a nonconforming item cannot be accepted as-is, reworked, or repaired. Rejected items are either scrapped or returned to the suppliers, as appropriate. (QM-19)

Repair - the process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirement. (NQA-1)

Rework - the process by which an item is made to conform to original requirements by completion or correction. (NQA-1)

Right of Access - the right of a purchaser or designated representative to enter the premises of a supplier for the purpose of surveillance, inspection, or quality assurance audit. (NQA-1)

Secondary Canister - a sealed metal vessel that is applied by the producer and completely surrounds the waste form and its canister. (OGR/B-9)

Service - the performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation. (NQA-1)

Software - see computer code.

Special Process - a process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified equality cannot be readily determined by inspection or test of the product. (NQA-1)

Supplier - any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and subtier levels. (NQA-1)

Surveillance - the act of monitoring or observing to verify whether an item or activity conforms to specified requirements. (OGR/B-14)

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 that needed to perform the original work. Technical reviews are in-depth critical reviews, analyses, and evaluation of documents, material, or data that require technical verification and/or validation for applicability, correctness, adequacy, and completeness that are within the existing state of current technology. (OGR/B-14)

Testing - an element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical environmental, or operating conditions. (NQA-1)

Traceability - the ability to trace the history, application , or location of an item and like items or activities by means of recorded identification. (NQA-1)

Training - in-depth instruction to develop proficiency in the application of requirements, methods, and procedures. Such instruction may be internal or external classroom sessions, courses or informal on-the-job assignments. (OGR/B-14)

Use-As-Is - a disposition permitted for a nonconforming item when it can be established that the item is satisfactory for intended use. (NQA-1)

User - the person who uses or installs or instructs the use and installation for its intended purpose of the work under review. (QM-19)

Validation - the documented confirmation of the adequacy (suitability for its intended purpose) of the work under review. (OGR/B-14)

Verification - the act or reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements. Also, the documented determination that work under review conforms to specified requirements. (OGR/B-14)

Verification Point - a point in the work sequence that may be examined at any time after completion of the work; usually verification is after-the-fact while witness is during the operation. (see hold point) (QM-19)

Vitrification Project - the overall activities occurring at or on behalf of the West Valley Demonstration Project that support the Waste Acceptance Process. (QAPD)

Waiver - documented authorization to depart from specified requirements. (NQA-1)

Warehouse - the facility responsible for receiving, maintaining storage, and issuing items. (QM-19)

Waste Acceptance Process Activities - the activities through which documentation and data are collected and prepared to support compliance with the Waste Acceptance Preliminary Specification (WAPS), OGR/B-9. This includes activities associated with: research and development that is essential to qualification of the waste form; control of materials, equipment, facilities, and processes that are essential to the certification of canistered waste forms; and processing operations that are essential to the certification of canistered waste forms. (OGR/B-14)

Waste Acceptance Preliminary Specifications (WAPS) - identifies the properties and requirements the HLW form must meet in order to be accepted for disposal in a federal repository. (OGR/B-14)

Waste Form - the radioactive waste materials and any encapsulating or stabilizing matrix, such as borosilicate glass. (OGR/B-14)

Waste Form Compliance Plan (WCP) - the document that describes the producer's plan for demonstrating compliance with each Waste Acceptance Preliminary Specifications (WAPS) in the WA. The WCP includes descriptions of the tests, analyses, and process controls to be performed by the producer. (OGR/B-14)

Waste Form Qualification Report (WQR) - a compilation of results from waste form testing and analysis which develops in detail the case for compliance with each Waste Acceptance Preliminary Specifications (WAPS). (OGR/B-14)

Witness Point - a point in the work sequence that is identified by WVNS in test procedures, travelers or work instructions. WVNS must be notified to witness inspection, examination, or test. Such points apply to in-process activities for convenience toward assurance that the end item will be acceptable. Work may proceed if WVNS is not readily available, and such written release is not required. (QM-19)

APPENDIX III

ACRONYMS

UNCONTROLLED

ACRONYM	MEANING
ANSI	The American National Standards Institute
ASME	The American Society of Mechanical Engineers
CA	Corrective Action
CFR	Code of Federal Regulations (example: 10 CFR 60)
DOE	U.S. Department of Energy
DOE/ID	U.S. Department of Energy, Idaho Operations Office
DOE/NE	U.S. Department of Energy, Office of Nuclear Energy
DOE/WVPO	U.S. Department of Energy, West Valley Project Office
DOE/RW	Office of Civilian Radioactive Waste Management (also OCRWM)
EP	Engineering Procedure
HLW	High-Level Waste
ID	1) Identification, or 2) Idaho Operations Office
M&TE	Measuring and Testing Equipment
MRC	Master Records Center
NDE	Nondestructive Examination
NR	Nonconformance Report
NRC	U.S. Nuclear Regulatory Commission
NWPA	Nuclear Waste Policy Act
OCRWM	Office of Civilian Radioactive Waste Management
OGR	Office of Geological Repositories
PNL	Pacific Northwest Laboratory (Battelle Memorial Institute)
PPHSS	Preservation, Packaging, Handling, Shipping, Storage
PR	Production Records
Q-Level	Quality Level
QA	Quality Assurance

APPENDIX III (CONTINUED)

ACRONYMS (CONTINUED)

ACRONYM	MEANING
QAP	Quality Assurance Procedure
QAPD	Quality Assurance Program Description
QMM	Quality Management Manual
RCA	Request for Corrective Action
SC	Site Contractor
SNR	Supplier Nonconformance Report
SNT	Society for Nondestructive Testing
TBAL	To Be Added Later
UOR	Unusual Occurrence Report
WAPS	Waste Acceptance Preliminary Specifications (OGR/B-9, original issue)
WCP	Waste Form Compliance Plan
WHC	Westinghouse Hanford Company
WQR	Waste Form Qualification Report
WVDP	West Valley Demonstration Project
WVNS	West Valley Nuclear Services
WVPO	DOE West Valley Project Office