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Quality Assurance Program Descriptions

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Environmental Restoration And Waste Management

High-Level Waste Processing

DOE/EM/WO/01
DOE/EM/WO/02
DOE/EM/WO/03

Quality Assurance Program Descriptions

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U.S. Department Of Energy
Office Of Waste Operations



U.S. DEPARTMENT OF ENERGY
OFFICE OF ENVIRONMENTAL RESTORATION AND WASTE MANAGEMENT
OFFICE OF WASTE OPERATIONS

DOE-EM
QUALITY ASSURANCE
PROGRAM DESCRIPTION

DOE/EM/WO/01
FOR
HIGH-LEVEL WASTE PROCESSING

Approved: _____

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Oct 31, 1990

WASTE OPERATIONS
Quality Assurance Program Description
For
High-Level Waste Processing

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FOREWORD

This document describes the U. S. Department of Energy (DOE) Office of Environmental Restoration and Waste Management (EM) Quality Assurance Program for High-Level Waste (HLW) Processing. This program is being implemented to ensure the acceptability of high-level radioactive canistered waste forms for disposal in a licensed Federal Repository. The unprocessed waste, which has resulted from national defense programs, is presently being stored in DOE facilities at Savannah River, Hanford, Idaho, and West Valley.

The high-level waste at each DOE site will ultimately be processed into a canistered waste form suitable for repository disposal. DOE is responsible for processing this waste at each DOE site into acceptable canistered waste forms. A waste form producer organization, which is a composite of DOE organizations and their contractors, will be established at each of the DOE sites that currently store defense waste. The composite waste form producer organization for a given site will normally consist of the following major participants:

- DOE Headquarters
- DOE Operations Office
- DOE Project Office (If separate from an operations office)
- Operating Contractor

Major participants will be associated through organizational, administrative, or contractual arrangements such that a vertical tier relationship exists among the participants. For example, the waste form producer organization for defense high-level waste at Savannah River is an organization that connects downward from the DOE Director, Environmental Restoration and Waste Management, through the DOE Office of Waste Operations (Waste Operations) in Headquarters to the DOE Operations Office, High-Level Waste Division (HLWD) at Savannah River (SR), and to the Defense Waste Processing Facility (DWPF), operating contractor, Westinghouse Savannah River Company (WSRC), for waste form production.

In this arrangement, Waste Operations executes overall responsibility for production of canistered waste forms. The DOE Office of Civilian Radioactive Waste Management (OCRWM), also referred to as RW, is the licensee of the National High-Level Waste Repository and the recipient for the canistered waste forms from the waste form producer. RW is responsible for establishing the Waste Acceptance Specification, for taking custody of the canistered waste form and its production record at the production site, and for transporting the canistered waste form to and disposing of it in the repository.

The specific organizational units of DOE and the operating contractors will vary, depending upon which of the waste form producers, (Savannah River, Hanford, Idaho, or West Valley) is involved.

The waste form producer organization and RW are pursuing an integrated strategy for ensuring that canistered waste forms are acceptable for disposal in a licensed Federal Repository. This four-step strategy, referred to as the Waste Acceptance Process (WAP), involve the following activities:

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- (1) The first step is to prepare an initial specification, called the Waste Acceptance Preliminary Specification (WAPS), to be met by each canistered waste form. Updated versions of this specification will be issued at key points in the Civilian Radioactive Waste Management Program. In this foreword, it will be referred to as the Waste Acceptance Specification (WAS).
- (2) The second step is for each waste form producer to prepare and implement a plan that ensures the processes, methods, and techniques developed for waste form production provides canistered waste forms that meet each requirement of the WAS. This plan is called the Waste Form Compliance Plan (WCP).
- (3) The third step is to collect the information and data that result from executing the WCP, and to prepare a composite report which demonstrates that canistered waste forms can meet all aspects of the WAS. This report is called the Waste Form Qualification Report (WQR). Further, the WQR will demonstrate that high-level waste form production can be accomplished with confidence that the final canistered waste forms will meet the WAS in all respects.
- (4) The last step in this process is to collect the information and data that result from actually producing canistered waste forms, and to assemble a Production Records (PR) package for each canister of waste. This PR ultimately demonstrates conformance with the WAS.

The overall quality assurance program of a particular waste form producer organization, (Savannah River, Richland, Idaho, or West Valley) is comprised of the constituent quality assurance programs of each major participant in that composite organization. In most cases, the major participants already have quality assurance programs in place that may be providing satisfactory results for other DOE projects and programs. To the extent that these programs meet the requirements defined for them, and the participant chooses to apply these programs to WAP activities, they are expected to be acceptable. Programs or portions of programs will be developed in those cases where no previous program exists, or where the participant chooses not to extend its present program to cover Waste Acceptance Process Activities. In either case, participant programs will implement the quality assurance requirements specified for waste form producer organizations in the DOE-OCRWM specification of "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program" (DOE/RW-0214).

Ultimately, the quality assurance programs, program descriptions, and program results of each major participant in the waste form producer organizations will support the acceptability of the product to RW and lead to RW ultimately disposing of that product in the licensed Federal Repository. RW is expected to concur in these quality assurance programs, program descriptions, and program results related to the WAP activities.

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To facilitate RW's repository licensing activities, each major participant in a composite waste form producer organization will prepare its quality assurance program description in a format and with contents that RW can incorporate in the repository safety analysis report when preparing its repository license application. At that time the U. S. Nuclear Regulatory Commission (NRC) is expected to evaluate these program descriptions against the applicable criteria of the NRC Review Plan for Quality Assurance Programs for High-Level Nuclear Waste Repositories (HLNWR).

The objective of this quality assurance program description is to provide Waste Operations with a HLW quality assurance program-defining document that doubles as a quality assurance plan for guiding and directing program implementation; and as a program description with which Waste Operations can satisfy RW's needs in repository licensing activities with regard to canistered waste forms. To accomplish these objectives this description has been prepared in three parts:

- Part 1 - Overview and applications document
- Part 2 - Development and qualification of the canistered waste form
- Part 3 - Production of the canistered waste forms

Part 1 describes the background, strategy, application, and content of the Waste Operations HLW quality assurance program applicable to high-level waste processing by the waste form producer organizations. It further identifies the constituent quality assurance programs that have limited applications to WAP activities, both during development and qualification of the waste form production process and the waste form, and during actual waste form production. It also identifies the waste form producer organizations and how they interface to jointly accomplish the overall high-level waste processing activity.

Part 2, which covers the development and qualification of the canistered waste form, is intended to accompany the WCP. It is specifically focused to cover the quality assurance activities applicable to WCP-identified work activities (Waste Acceptance Process Activities) and the initial preparation of the WQR.

Part 3 is to be applied during production operations and subsequent updatings of the WQR. The described quality assurance program is specifically focused to cover the quality assurance activities applicable to certify canistered waste form (as the final waste form product), including the preparation of its PR.

Both Parts 2 and 3 have been prepared in the format and with the contents required by DOE/RW-0214. Specifically, they have been structured to directly parallel the 18-part format of ASME NQA-1 as is defined in the introduction of DOE/RW-0214. Each section of the description has been subdivided to address the quality assurance activities that Waste Operations has chosen to implement through its Vitrification Projects Branch (Part 2) or through its Division of Site Operations (Part 3), and then to address those activities that Waste Operations has chosen to assign to another organization for implementation. In the latter case, the requirements for those assigned activities are identified.

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The program description parts are internal documents of Waste Operations and they are to be used for developing and implementing the overall quality assurance program for defense high-level waste processing. Although these description documents identify the quality assurance activities to be assigned to other participating organizations to implement, this assignment must be accomplished through contractual actions or other appropriate means.

The Vitrification Projects Branch will implement their quality assurance activities with internal working level plans, schedules, and procedures. Other organizations will implement their assigned activities in accordance with their own internal working level plans, schedules, and procedures. Furthermore, each organization to whom activities are assigned will have the option of implementing those activities with its own staff, or further assigning a portion of those activities to yet another organization for implementation (i.e., other contractors or suppliers).

Both Parts 2 and 3 are suitable for use in support of RW's repository licensing application if needed; however, Waste Operations expects that only Part 3 will be needed for this purpose. Part 3 of the description applies to the production of the canistered waste forms. The canistered waste form and its PR package will be covered under the repository license as a component of the waste package to be placed in the repository.

At the appropriate time, Part 3 will be assembled with similar Part 3 descriptions from other major participants in the composite waste form producer organization. These Part 3 descriptions will make up an overall quality assurance program description for a given waste form producer organization, and will in turn be made available to RW to use in the repository licensing process. This concept is illustrated in the attached Figure 1. To facilitate this concept, this program description has been closely coordinated with the descriptions of other major participant organizations. The format and contents of each description are similar, and each has been prepared to interface and integrate so that they provide an overall quality assurance program description for a composite waste form producer organization.

This program description reflects a quality assurance program applicable to a manufacturing process (much like that of a major component fabricator in a nuclear power project), rather than a more traditional quality assurance program that applies to designing, constructing, and operating facilities. The latter is typical to the two-step licensing process which NRC uses for licensing nuclear power plants. The approach used in this description, which is significantly different, focuses on the identifiers and terminology that describe the quality assurance activities necessary in developing and qualifying the canistered waste form and the production process, and actually producing the canistered waste forms.

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It is expected that the canistered waste form will be identified as a component important to safety and waste isolation, and that it will be classified as a quality Level One component in the repository classification system. While that classification system is meaningful within the repository's quality assurance program, it is not a part of the waste form producer's quality assurance program. However, the waste form producer's quality assurance program is designed to provide a level of confidence in the integrity of the canistered waste forms that is equivalent to quality Level One items under the repository quality assurance program.

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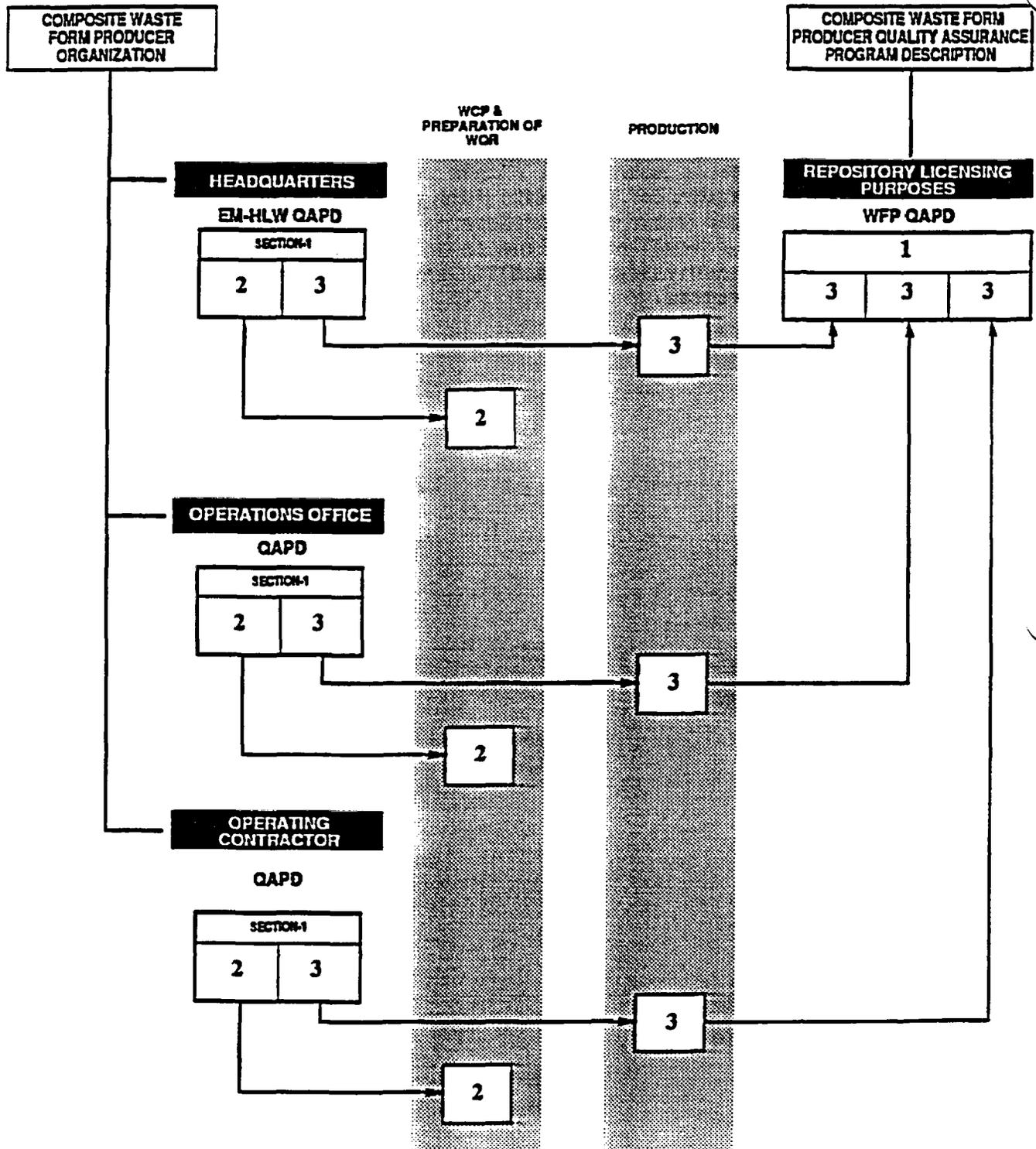


FIGURE 1

TYPICAL COMPOSITE WASTE FORM PRODUCER ORGANIZATION'S QUALITY ASSURANCE PROGRAM DESCRIPTIONS AND THEIR USES

DOE/EM
OFFICE OF ENVIRONMENTAL RESTORATION AND WASTE MANAGEMENT

QUALITY ASSURANCE PROGRAM
FOR
HIGH-LEVEL WASTE PROCESSING

1.0 INTRODUCTION

This document describes the quality assurance program of the United States Department of Energy (DOE) Office of Environmental Restoration and Waste Management (EM) for high-level waste processing. It identifies and describes the planned activities that constitute the required quality assurance program.

The program applies to the development, qualification, and production of waste forms used for the safe, acceptable disposal of high-level radioactive waste. These wastes are the result of activities at DOE sites in support of national defense and other programs.

The overall quality assurance program for high-level waste processing is made up of constituent programs that are or will be implemented by the organizations that are participating in the work. This program description is intended to define the overall scope and application of those major constituent programs. The program description also provides a means by which the overall program can be managed so that it achieves its objectives. Subsequent parts of this program description will identify the quality assurance program objectives, scope of content and application, and how it is structured and managed for implementation.

2.0 PROGRAM OBJECTIVES

The objectives to be achieved through implementation of this quality assurance program are:

1. To ensure that the objectives of high-level waste processing are attained with a level of quality that is commensurate with EM's responsibility for protecting the health and safety of government employees, contractors, and the general public; for protecting the environment and the government's investment; and for efficient and effective use of national resources
2. To ensure that research and development activities; production processes, facilities, equipment, and services; and products produced by or for the government conform to defined requirements

3.0 PROGRAM APPLICATION

The quality assurance program for high-level waste (HLW) processing is being or will be applied to a broad scope of quality-affecting activities. These activities are performed by or for DOE at a number of its contractor-operated facilities, including the Savannah River, Hanford, Idaho, and West Valley sites. A portion of the quality-affecting activities are those defined as Waste Acceptance Process (WAP) activities. These are the activities through which documentation and data are collected and prepared to support compliance with the Waste Acceptance Specification (WAS). This includes activities associated with the following:

- 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
- Processing operations that are essential to the certification of canistered waste forms

The Waste Operations Quality Assurance Program Description for High-Level Waste Form Development and Qualification (DOE/EM/WO/02), describes in detail the portion of the quality assurance program that is directly applicable to the WAP activities involving development and qualification of high-level waste forms. The Waste Operations Quality Assurance Program Description for High-Level Waste Form Production (DOE/EM/ WO/03), describes in detail the portion of the quality assurance program that is directly applicable to WAP activities that involve high-level waste form production. Although DOE/EM/WO/02 and DOE/EM/WO/03 apply to the limited scope of WAP activities, their application is extended here to cover the broad scope of quality-affecting activities associated with HLW Programs, Projects, and Activities under the responsibility of the Vitrification Projects Branch.

Subsequent parts of this section are intended to identify and provide understanding of the scope of high-level waste processing and the strategy, structure, and schedule necessary for its accomplishment.

3.1 BACKGROUND

High-level radioactive waste resulting from activities in support of national defense and other DOE programs has been accumulating at DOE sites for many years. In the mid-1970's, however, it was concluded that these wastes needed to be placed in forms acceptable for long-term storage or disposal. This conclusion was supported in the Nuclear Waste Policy Act (NWPA) of 1982, wherein Congress made the present generation responsible for the ultimate disposal of radioactive waste.

Prior to the NWPA, a national technology research and development program had been established. Its aim was to develop acceptable waste forms for the ultimate disposal of high-level radioactive waste. By the time the NWPA was enacted, work toward developing an acceptable waste form product was well on its way.

3.2 SCOPE

High-level waste processing activities are ongoing at Savannah River, Hanford, Idaho, and West Valley, with extensive participation by the Argonne, Pacific Northwest, Los Alamos, Lawrence Livermore, Oak Ridge, and Brookhaven National Laboratories. The Defense Waste Processing Facility (DWPF) at Savannah River is scheduled for the first production processing of high-level waste in 1992. In the DWPF, defense high-level waste is prepared in a borosilicate glass form and canistered in stainless steel containers for ultimate disposal in the federal high-level waste repository. The federal high-level waste repository will be available for waste storage early in the next century.

The West Valley Demonstration Project (WVDP) at West Valley New York will be the next facility scheduled for production processing of HLW waste. The Hanford Waste Vitrification Project (HWVP) in Hanford, Washington will follow WVDP. Activities are now being planned for processing the defense high-level waste stored on the Idaho site. Significant developmental work will be proceeding during the next several years in developing and qualifying the waste form and production process, and readying the facilities for production processing there.

Extensive work is continuing at Savannah River, Hanford, Argonne, Pacific Northwest Laboratory, and other locations in support of the development and qualification of acceptable waste forms.

3.3 STRATEGY

Waste Operations is also proceeding with its technology development program activities in parallel with waste form development and qualification activities. The canistered high-level waste form product and its production process will be fully developed and qualified, and production processing will begin at Savannah River in 1992. By this plan, Savannah River will have canistered waste forms ready for delivery to the repository several years prior to its scheduled operation. This condition is expected to still exist when the HWVP is ready to go into production in the late 1990s and may still exist when the high-level waste processing facilities go into production in Idaho early in the next century. This condition has mandated that DOE devise and execute a strategy where the high-level canistered waste forms produced in its high-level waste processing facilities are acceptable

to the repository operator and regulatory authorities when the repository is able to accept waste packages for long-term disposal.

The WAP identifies the DOE strategy (see Figure 3.3-1) for ensuring the acceptability of high-level waste forms produced in its facilities for disposal in the federal repository. The four elements of the WAP are:

- (1) A Waste Acceptance Specification (WAS)
- (2) A Waste Form Compliance Plan (WCP)
- (3) A Waste Form Qualification Report (WQR)
- (4) A Production Record (PR)

The Office of Civilian Radioactive Waste Management (RW, also referred to as OCRWM), Waste Acceptance Committee (WAC) prepared the WAS. This committee consisted of representatives from the repository projects and waste form producers. The WAS was agreed upon at the front end of the Waste Acceptance Process and it was initially issued as a preliminary specification. In its preliminary form, it is identified as the Waste Acceptance Preliminary Specification (WAPS). RW plans to update the WAPS from time to time as information becomes available. The WAPS, referred to as the WAS, includes a Waste Form Specification, a Canister Specification, a Canistered Waste Form Specification, and a Quality Assurance Specification.

The WAS was followed by the development of the WCP. The WCP details the plans and actions to be employed by DOE and its contractors in the development and qualification of the high-level canistered waste form and the process by which it is produced to meet the WAS. This will be followed by the preparation of the WQR, which is a compilation of the data and documentation resulting from implementation of the WCP. The WQR provides proof that the high-level canistered waste form meets all the requirements of the WAS.

The final step in the process will come in the production phase when a PR will be prepared for each high-level canistered waste form. The PR provides proof that the canistered waste forms meet the requirements of the WAS. The PR will then provide the basis for certifying each high-level canistered waste form. Each high-level canistered waste form and its certification, supported by its PR, will be on a site-by-site basis.

The key documentation that supports this strategy is shown in Figure 3.3-2. This figure identifies documentation that exists or that is under development.

Implementing this strategy requires actions on the part of Waste Operations and other DOE organizations, as well as outside organizations that interface with DOE. Figure 3.3-3 illustrates the principal actions and interfaces between EM and other organizations in the work flow of implementing the waste acceptance strategy.

3.4 RESPONSIBILITIES

DOE - The Secretary of Energy is ultimately responsible for processing the high-level waste resulting from national defense and other DOE programs activities. The execution of this responsibility has been delegated to the Director of the Office of Environmental Restoration and Waste Management, and other DOE headquarters and field organizations. Participants in the processing of high-level waste are shown in Figure 3.4-1.

Headquarters Organizations - The Director, Office of Environmental Restoration and Waste Management (EM), has further delegated the execution of the Secretary of Energy's responsibility for processing high-level waste to the Associate Director, Office of Waste Operations. Within Waste Operations, the execution of this responsibility for development and qualification is assigned to the Chief, Vitrification Projects Branch through the Division Director of Waste Management Projects. The responsibility for production facility operation is assigned to the cognizant Branch Chief for Operations through the Division Director of Site Operations. To execute this responsibility, the cognizant Branch Chief uses the resources of DOE operations offices and their contractors, as well as headquarters staff organizations and their support contractors.

The Director, Office of Civilian Radioactive Waste Management (RW), is responsible for executing the Secretary of Energy's responsibilities under the NWPA. In this role, the Director, RW is responsible for establishing and operating a federal high-level waste repository in accordance with NWPA. Since the federal high-level waste repository is the ultimate destination of the high-level canistered waste forms from DOE facilities, the Director, RW interfaces directly with the Director, EM to coordinate requirements for the waste package and to ensure its acceptability for ultimate disposal in the repository. Through this organizational interface, guidance and direction on waste package acceptability is provided to the Vitrification Projects Branch Chief (development and qualification) or cognizant Operations Branch Chief (production).

Field Organizations - A portion of the execution of the Secretary of Energy's responsibility has been further assigned to the managers of DOE Operations Offices. These include the Richland Operations Office (RL), the Savannah River Operations Office (SR), the Chicago Operations Office (CH), and the Idaho Operations Office (ID). Through these operations offices and their contractors, the technology, research, and development program is being accomplished and the processing facilities are being made ready for high-level waste form production.

In addition, the Projects Technology Support Office within RL provides overall program management and coordination assistance in the technology,

research, and development program. The Materials Integration Office within CH provides program management and coordination assistance to EM and RW in the development of standard test methods and data, as well as characterization of materials and the provision of standard testing methods.

3.5 SCHEDULE

Pre-startup developmental work in support of waste form qualification for each of the production facilities is in progress. Developmental work will be considered complete for a site when all activities of the WCP have been satisfactorily accomplished and when the WQR is approved by the Director of EM. The DWPF is scheduled to be the first plant to begin waste form production. The WVDP is scheduled to begin waste form production a few years after DWPF. HWVP is scheduled to begin waste form production operations in about ten years with the Idaho facility to follow.

Work in the development and qualification phase for each processing facility also includes activities in planning, design, fabrication, installation, and testing of the production processes, equipment, and facilities installed for production processing operations. This work will normally progress in parallel with product and process qualification work under a site's WCP. In the DWPF, this work is scheduled to be completed in 1991.

These activities in the DWPF Project will be integrated during the later stages of work under the DWPF WCP. Cold and hot testing for process and product qualification will take place in the DWPF itself. Production operations are scheduled to begin in 1992, with routine waste form production proceeding from that point.

4.0 PROGRAM CONTENT

The quality assurance program for waste processing is intended to cover all quality-affecting work activities of high-level waste processing. The program is to be a composite of all plans and actions established and implemented to ensure that quality is achieved in high-level waste form development, qualification, and production. Subsequent parts of this section are intended to identify and provide a general understanding of quality-assuring activities that make up the quality assurance program, the requirements for those activities, and how those activities are organized and applied to the high-level waste processing work over which Waste Operations is responsible.

4.1 PROGRAM REQUIREMENTS

The requirements for quality assurance program activities applicable to high-level waste form development, qualification, and production are shown

in Figure 4.1-1, which identifies requirements that are imposed internally by DOE and externally by other organizations.

The Department of Energy Organization Act of 1977 authorized DOE to establish a system of internal directives to guide DOE activities. DOE Orders 5700.6 and 4700.1 are the directives that establish quality assurance policies for DOE projects, programs, and activities, and designate responsibilities for preparing quality assurance plans and implementing quality assurance activities. As guided by DOE Order 5700.6, DOE quality assurance policy for high-level waste processing flows through EM to Waste Operations. The Associate Director, Waste Operations has stated quality assurance policy as shown in Figure 4.1-2. The policy commits Waste Operations to implement the quality assurance program described herein. The Vitrification Projects Branch Chief will review the program description periodically and revise it as necessary to keep it current. As indicated in Figure 4.1-2, the policy is executed by implementing the Waste Operations HLW Quality Assurance Program.

To meet the provisions of the NWPA, Waste Operations incorporates the quality assurance requirements of other DOE and non-DOE organizations. The NWPA established RW to research, design, construct, and operate a national repository for HLW. In addition, it authorized the NRC to license and regulate the national repository. RW and NRC were empowered to issue requirements and guidance sufficient to execute their assigned responsibilities.

To that end, NRC has issued 10 CFR Part 60 and 10 CFR Part 71, which contain requirements for quality assurance activities. NRC guidance documents, such as Regulatory Guides, NUREGS, and Generic Technical Positions, also guide quality assurance policies and requirements. RW quality assurance requirements pertaining to high-level waste processing are detailed in DOE/RW-0214, Quality Assurance Requirements Document. DOE/RW-0214 calls for the mandatory implementation of ASME NQA-1.

The requirements established in DOE/RW-0214 and/or adopted by Waste Operations include ASME NQA-1; Guidelines for Application of Readiness Reviews to Department of Energy Activities; DOE Order 5000.3, Unusual Occurrence Reporting System; DOE/RW-0260, Waste Acceptance Preliminary Specifications for the Defense Waste Processing Facility High-Level Waste Form; and DOE/RW-0261 Waste Acceptance Preliminary Specifications for the West Valley Demonstration Project High-Level Waste Form.

Following are specific requirements that apply to the quality assurance program for high-level waste form development, qualification, and production:

- DOE Order 5700.6, Quality Assurance
- DOE Order 5000.3, Unusual Occurrence Reporting System
- DOE Order 4700.1, Project Management System
- Guidelines for Application of Readiness Reviews to Department of Energy Activities, January 1987
- ASME NQA-1, Quality Assurance Program Requirements for Nuclear Facilities, Sections I, II, III and IV (2A-1 only)

Indexes indicating these requirements and Waste Operations requirement implementing documents are included in DOE/EM/WO/02, High-Level Waste Form Development and Qualification; and DOE/EM/WO/03, High-Level Waste Form Production.

4.2 PROGRAM PARTICIPATION

Program participation has been organized into a three-level structure as shown in Figure 4.2-1. The Owner (DOE) is responsible for the overall program and its adequacy. The Owner's portion of the program is at the third level of the structure and is primarily a management-type program with overview, interface coordination, and program integration functions. The second level of the overall program includes the qualifier and the operator (operating contractors that have a direct interface with the owner). These portions of the overall program are also primarily management-type programs with overview, interface coordination, and lower-tier program integration functions. The second and third level participants are referred to hereafter as major program participants.

The first level of the overall program includes a multitude of suppliers for systems, components, materials, and services and their lower-tier suppliers. First-level quality assurance programs are primarily work practice-oriented programs concerned with direct control and verification through inspection, examination, and testing.

4.3 TRANSFER OF REQUIREMENTS TO PARTICIPANTS

The Waste Operations' Program Execution Guidance initially specifies to the Operations Offices the quality assurance program activities that are required to be implemented on high-level waste processing activities. The contracts issued by the cognizant Operations Office specify the requirements to be implemented by participating contractors. These contracts include the appropriate requirements of the documents listed in Section 4.1. Requirements may be specified directly in contract scope of work statements or the appropriate requirements document may be referenced as applicable. Participants may already have programs in accordance with ASME NQA-1 or other nationally recognized codes or standards. These programs are recognized to the maximum extent possible as acceptable methods of complying with the specified requirements.

4.4 PROGRAM BREAKDOWN

The Waste Operations HLW quality assurance program is an overall integrated program applied to the DOE WAP activities of high-level waste processing activities under its cognizance. In this application, illustrated in Figure 4.4-1, the Waste Operations HLW quality assurance program will interface with RW's quality assurance program in DOE headquarters and the quality assurance programs of the various DOE field organizations that are involved in WAP activities of HLW processing.

DOE/EM Office of Waste Operations Quality Assurance Program Description for High-Level Waste Form Development and Qualification (DOE/EM/WO/02), describes in detail that portion of the overall Waste Operations HLW Quality Assurance Program being applied to waste form development and qualification. The program described will be appropriately implemented on all high-level waste technology development activities under the cognizance of Waste Operations. Within Waste Operations, the Vitrification Projects Branch has the lead responsibility for program implementation. The program will include WAP activities of high-level waste form development and qualification and other activities determined to be appropriate by the Vitrification Projects Branch.

DOE/EM Office of Waste Operations Quality Assurance Program Description for High-Level Waste Form Production (DOE/EM/WO/03), describes in detail the portion of the overall Waste Operations HLW quality assurance program being applied to waste form Production work. The program described will be appropriately implemented on all high-level waste operations and projects under the cognizance of Waste Operations. Within Waste Operations, the cognizant Operations Branch has the lead responsibility for program implementation. The program will include WAP activities of high-level waste form production, and other activities determined to be appropriate by the Operations Branches.

4.5 PROGRAM DOCUMENTATION BREAKDOWN STRUCTURE

Figure 4.5-1 shows the quality assurance program-defining documentation of the major participants in the SR waste form producer organization. This documentation falls into three types: existing program documentation, additional program documentation required for high-level waste processing activities, and additional documentation for repository licensing support. Existing documentation, shown on the left side of the figure, includes the organization's basic program documents that are generically applicable to their activities. Additional program description documents, shown in the middle of the figure, are those required to meet the requirements of DOE/RW-0214. The right side of the figure illustrates how program descriptions applicable to high-level waste form production are assembled and provided to RW for use in repository licensing activities.

Existing program documentation includes quality assurance program descriptions, manuals, and plans covering the waste form producers' general operations. These documents include:

- DOE/EM Waste Operations HLW Quality Assurance Program Descriptions
- DOE/Operations Office Quality Assurance Program Manuals
- Operating Contractor's Quality Assurance Plans

Additional program documentation for defense high-level waste processing builds upon the existing program documentation. Documents guiding defense high-level waste processing activities at SR include:

- DOE/EM Waste Operations QAPD for High-Level Waste Processing (DOE/EM/WO/01) and its associated documents, High-Level Waste Form Development and Qualification (DOE/EM/WO/02), and High-Level Waste Form Production (DOE/EM/WO/03)
- DOE/SR/High-Level Waste Division QAPD for Defense Waste Processing (DOE-SR-2006-1) and its associated documents, High-Level Waste Form Development and Qualification (DOE-SR-2006-2), and High-Level Waste Form Production (DOE-SR-2006-3)
- The Operating Contractor's QAPD for Defense Waste Processing, SW-4, and its associated documents

The production quality assurance program descriptions, DOE/EM/WO/03, DOE-SR-2006-3, and SW-4 are combined under an umbrella program description to support repository licensing. This umbrella program description is the SR Waste Form Producer Quality Assurance Program Description.

4.6 PROGRAM OVERVIEW

Waste Operations, through the Vitrification Projects and Operations Branches, will establish and implement a systematic overview of quality assurance activities performed by other program participants over which Waste Operations has contractual or administrative overview responsibilities. This overview practice will include an appropriate combination of the following:

- The review and acceptance of participant quality assurance program descriptions (or plans)
- Surveillance of participant activities affecting quality to verify compliance with requirements
- Performance of quality assurance audits to verify the adequacy and effectiveness of participant quality assurance program activities

These activities will be planned and performed in accordance with appropriate procedures. The results will be reported to appropriate DOE and contractor management.

Waste Operations will also be subject to overview by EH as a part of their routine overview of DOE activities for the Secretary of Energy. EH overview actions may include high-level waste processing activities as a constituent part of Waste Operations activities.

In addition, the HLW activities of Waste Operations will be subject to overview by RW (in conjunction with the NRC) in its role of canistered waste form receiver and licensee for the federal repository. The scope of RW/NRC overview actions may include HLW activities by Waste Operations, DOE field organizations, and contractors participating in high-level waste processing.

Joint overview efforts will be encouraged where practical, and where timing permits. Such efforts will minimize the adverse impacts of overview actions and maximize government resources. In any event, arrangements for overview actions will be made through appropriate administrative channels for governmental program management and division interfaces, and through appropriate contractual channels with contractors.

5.0 REFERENCES

- ASME NQA-1, Quality Assurance Program Requirements for Nuclear Facilities (Sections I, II, III and 2A-1 of IV)
- DOE Order 5000.3, Unusual Occurrence Reporting System (7/15/85)
- DOE Order 5700.6B, Quality Assurance (9/23/86)
- DOE Order 4700.1, Project Management System (3/6/87)
- Guidelines for Application of Readiness Reviews to Department of Energy Activities, January 1987
- Office of Civilian Radioactive Waste Management Quality Assurance Requirements Document (DOE/RW-0214, Rev. 2)
- Waste Acceptance Preliminary Specifications for the Defense Waste Processing Facility High-Level Waste Form (DOE/RW-0260, formerly OGR/B-8)
- Waste Acceptance Preliminary Specifications for the West Valley Demonstration Project High-Level Waste Form (DOE/RW-0261, formerly OGR/B-9)

6.0 ACRONYMS

ANL	- Argonne National Laboratory
ANSI	- American National Standards Institute
ASME	- American Society of Mechanical Engineers
CH	- DOE - Chicago Operations
CWFD	- Canister and Waste Form Description
DHLW	- Defense High-Level Waste
DOE	- Department of Energy
D&Q	- Development and Qualification
DuPont	- E. I. duPont de Nemours and Company
DWPF	- Defense Waste Processing Facility
EH	- DOE-Environment, Safety, and Health
EM	- DOE Office of Environmental Restoration and Waste Management
ESAAB	- Energy System Acquisition Advisory Board
HLW	- High-Level Waste
HLCWF	- High-Level Canistered Waste Form
HLNWR	- High-Level Nuclear Waste Repositories
HWVP	- Hanford Waste Vitrification Plant
ID	- DOE - Idaho Operations
MCC	- Materials Characterization Center
MIO	- Materials Integration Office
MRB	- Materials Review Board
MSC	- Materials Steering Committee
NEPA	- National Environmental Policy Act

NRC - Nuclear Regulatory Commission
NWPA - Nuclear Waste Policy Act of 1982
OCRWM - DOE - Office of Civilian Radioactive Waste Management
OGR - DOE - Office of Geologic Repositories
ORR - Operational Readiness Review
PNL - Pacific Northwest Laboratories
PR - Production Records
QAPD - Quality Assurance Program Description
RL - DOE - Richland Operations
RW - DOE - Office of Civilian Radioactive Waste Management
SR - DOE - Savannah River Operations
WAC - Waste Acceptance Committee
WAP - Waste Acceptance Process
WAPS - Waste Acceptance Preliminary Specification
WAS - Waste Acceptance Specification
WCP - Waste Compliance Plan
WHC - Westinghouse Hanford Company
WINCO - Westinghouse Idaho Nuclear Company, Inc.
WSRC - Westinghouse Savannah River Company
WQR - Waste Qualification Report
WVDP - West Valley Demonstration Project
WVNS - West Valley Nuclear Services

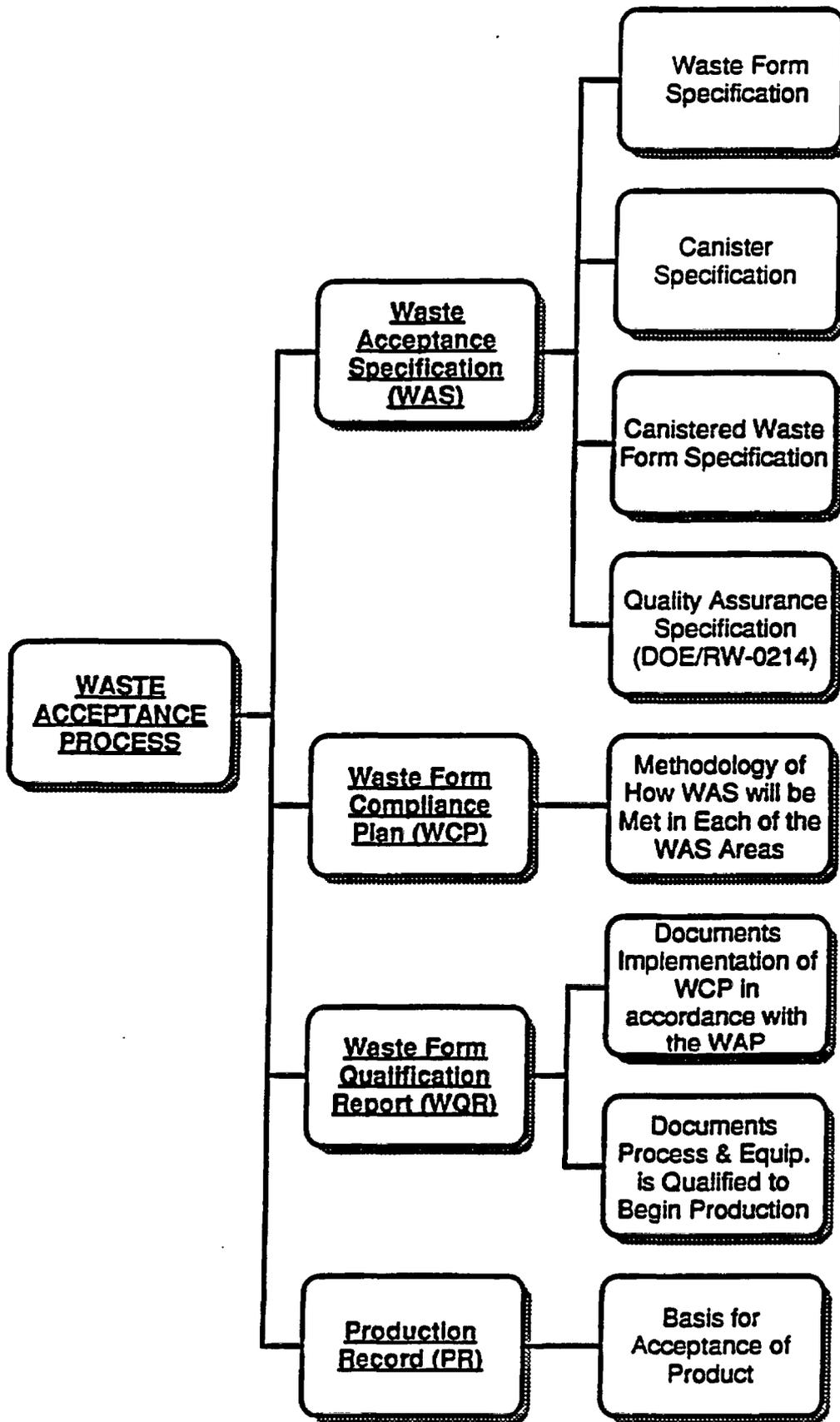
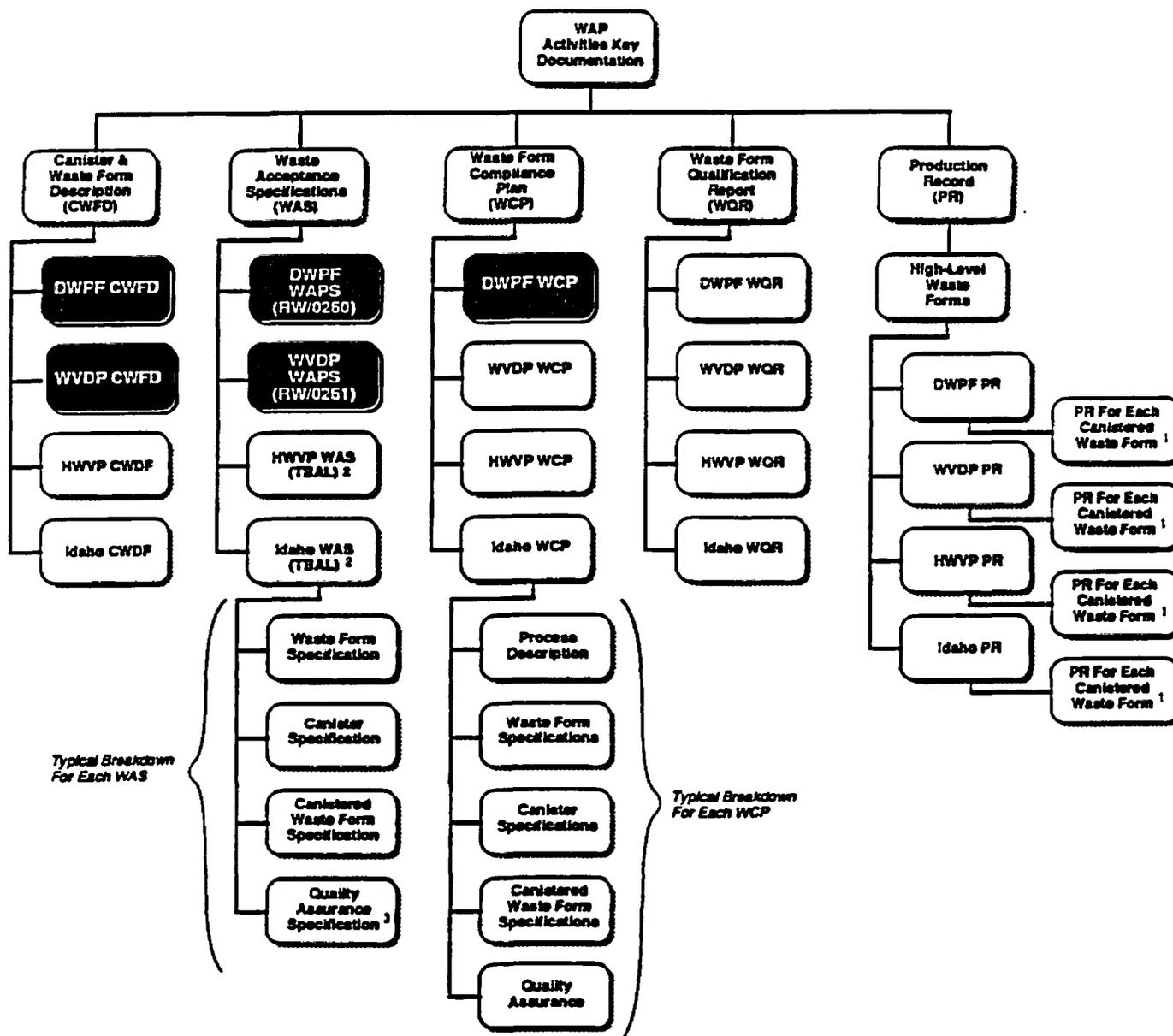


FIGURE 3.3-1
BREAKDOWN STRUCTURE OF DOE STRATEGY FOR WASTE
ACCEPTANCE

DOE WASTE ACCEPTANCE PROCESS

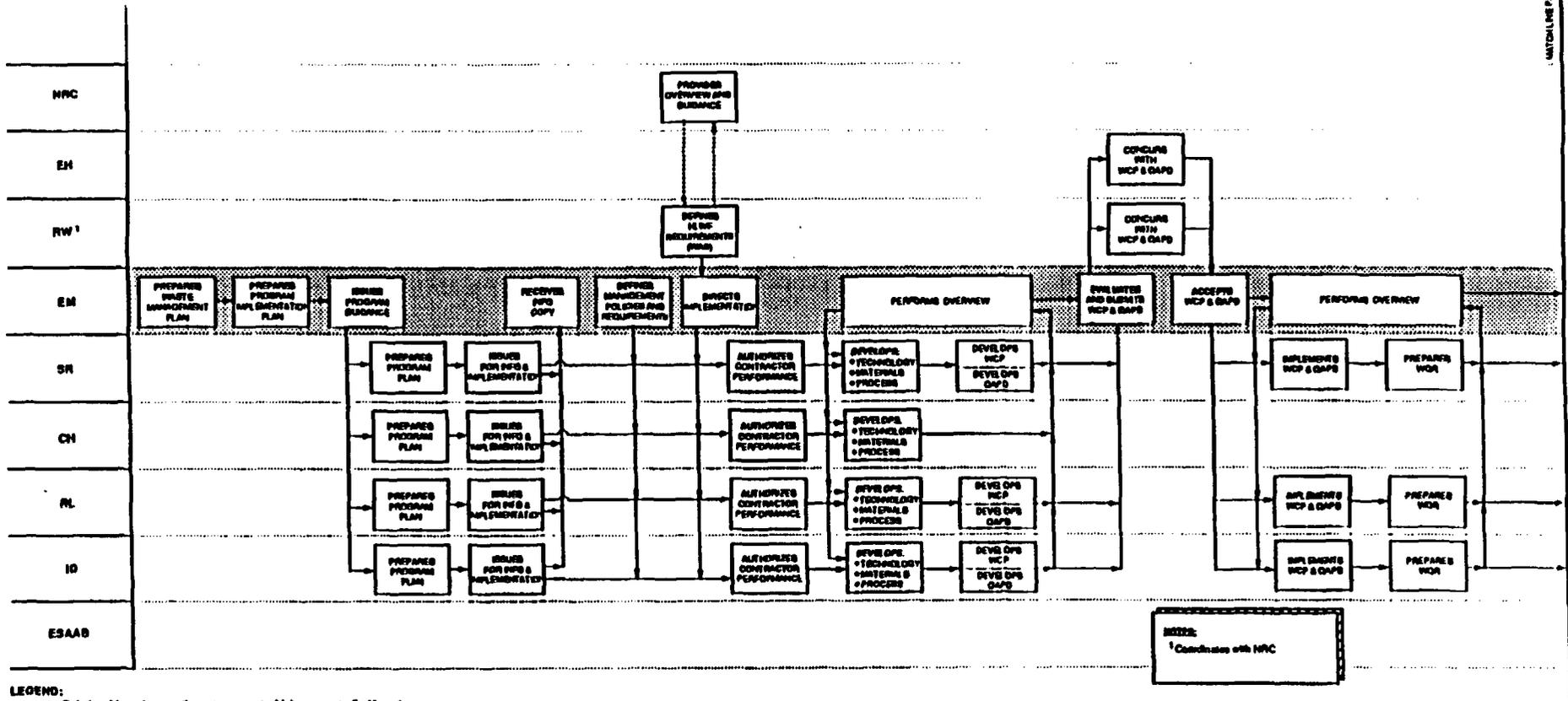
DOE/EMWO/01
Page F-2
Rev. 0
10/09/90



█ INDICATES COMPLETION

¹ Individual Production Records for each Canistered Waste Form (each individual canister of waste) is the Basis for Waste Form Certification
² To be added later
³ Invokes DOE/RW-0214 as the Quality Assurance Specification

FIGURE 3.3-2
WASTE ACCEPTANCE PROCESS DOCUMENTATION



LEGEND:
 - - - - - Relationships where actions may occur which are controlled by other organizations and activities of DOE outside EM

FIGURE 3.3-3
 HIGH-LEVEL WASTE ACCEPTANCE PROCESS WORK FLOW

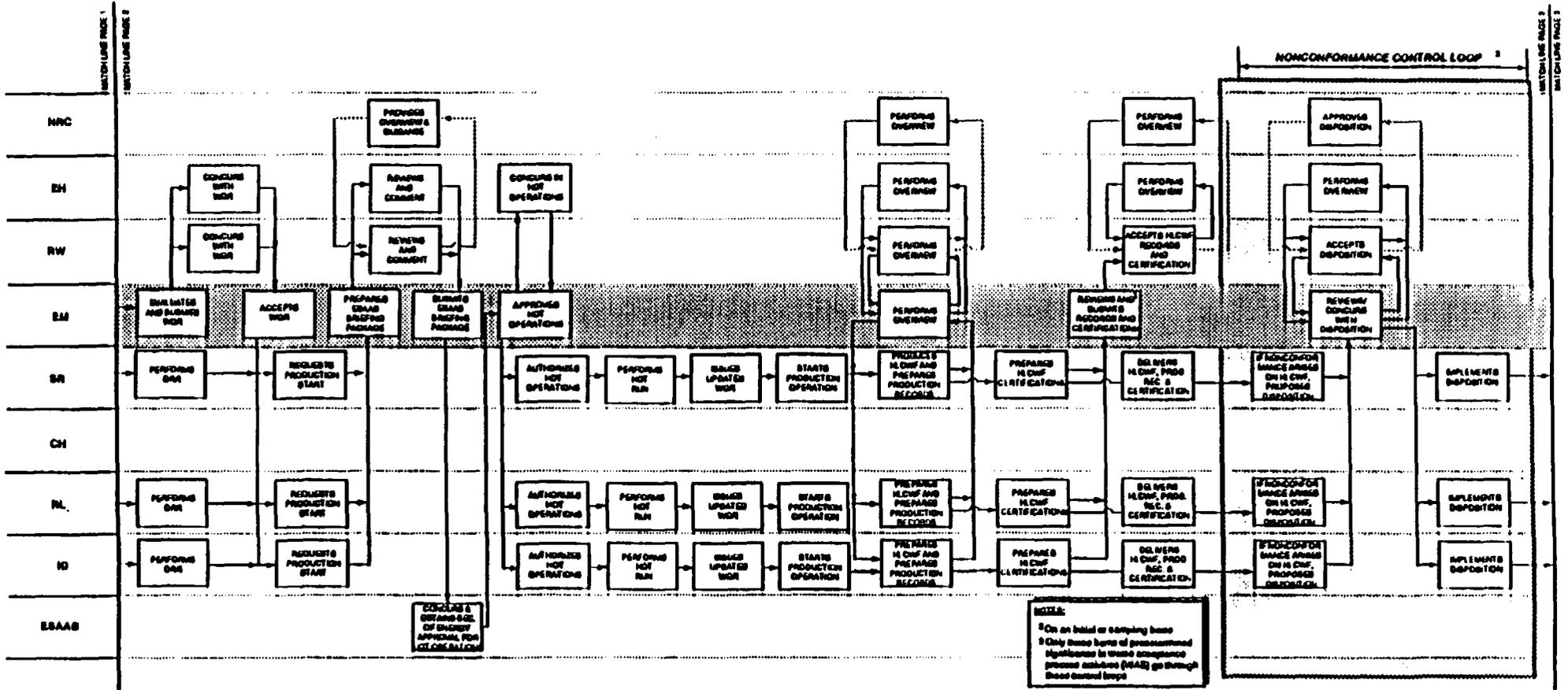
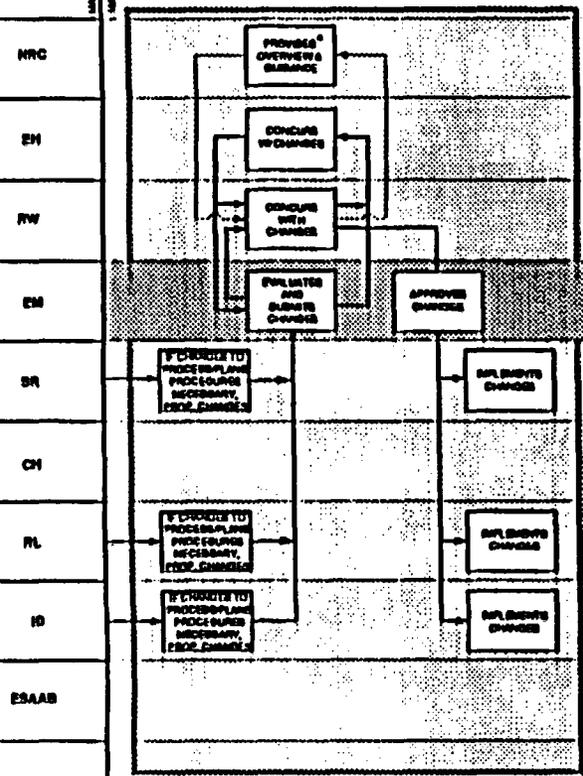


FIGURE 3.3-3
 HIGH-LEVEL WASTE ACCEPTANCE PROCESS WORK FLOW

ATTACHED AND PAGE 2
 ATTACHED AND PAGE 3

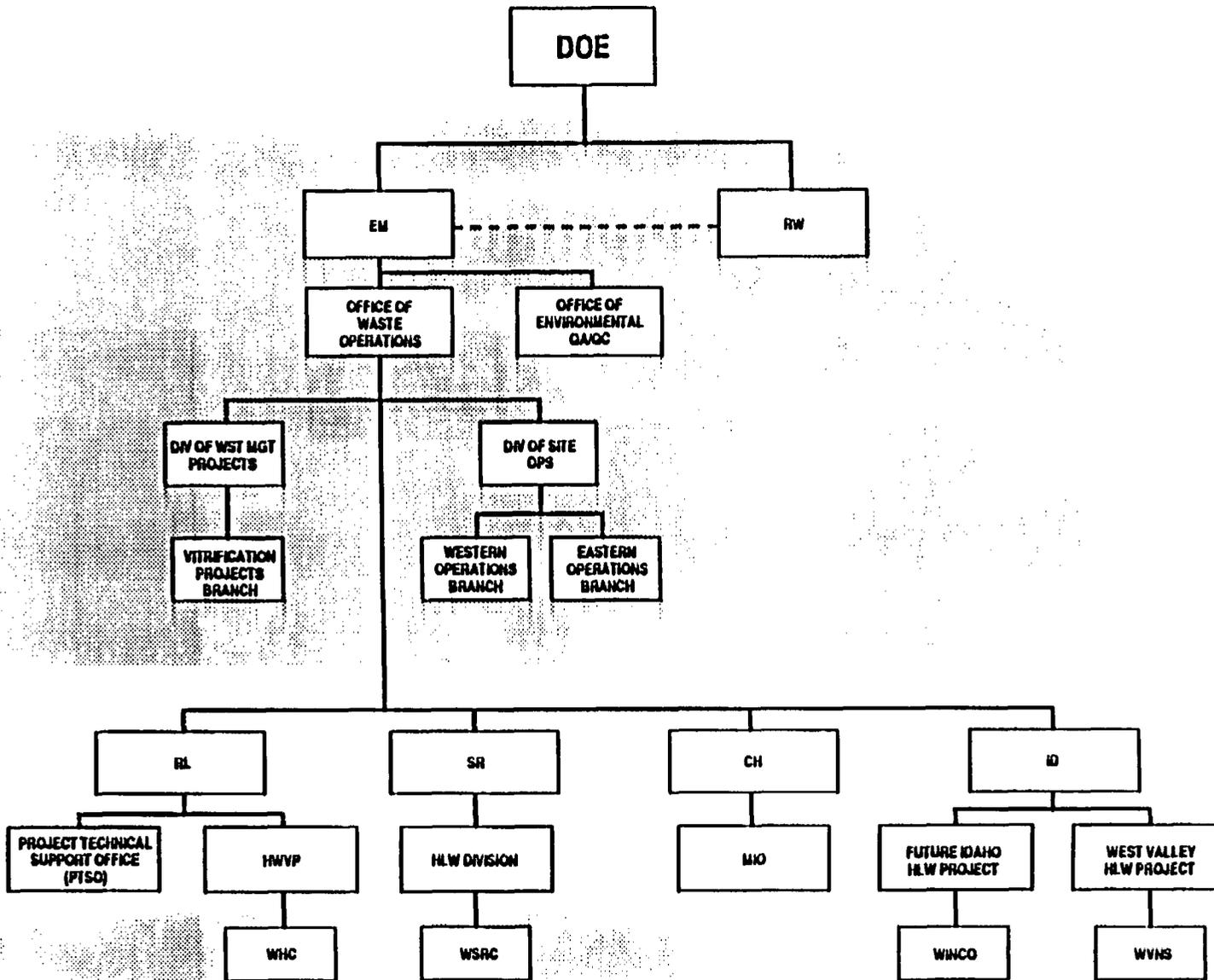
CHANGE CONTROL LOOP



NOTE:
 Only those items of predetermined significance to waste acceptance process activities (WAP) go through these defined steps
 • Items of standing significance will require NRC approval

FIGURE 3.3-3
 HIGH-LEVEL WASTE ACCEPTANCE PROCESS WORK FLOW

DOE HEADQUARTERS ORGANIZATIONS



DOE OPERATIONS OFFICES

CONTRACTOR

———— = Program Guidance And Funding
 - - - - = Major Program Interfaces

FIGURE 3.4-1 PARTICIPANTS IN HIGH-LEVEL WASTE PROCESSING

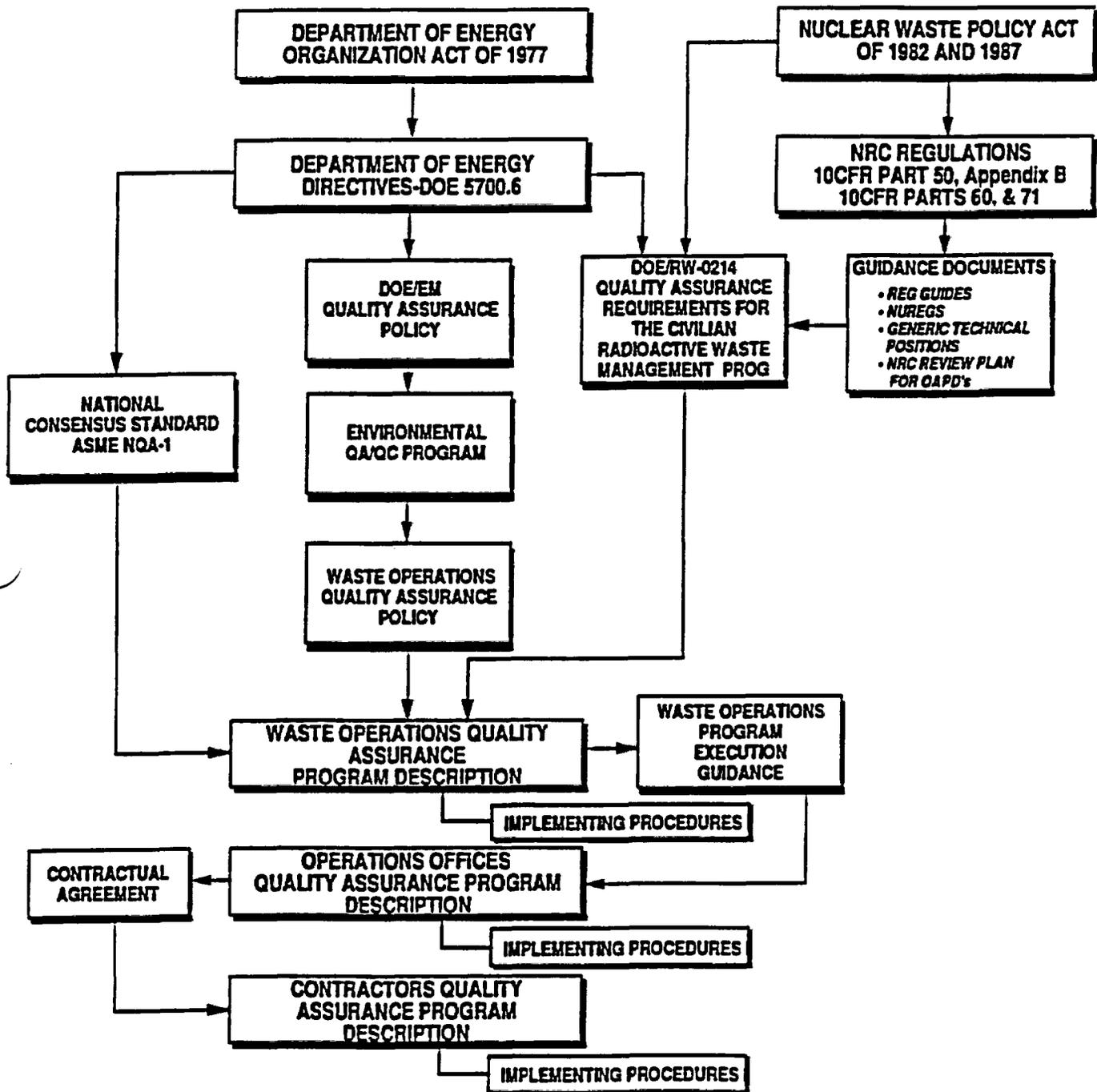


FIGURE 4.1-1
 HIGH-LEVEL WASTE QUALITY ASSURANCE REQUIREMENTS

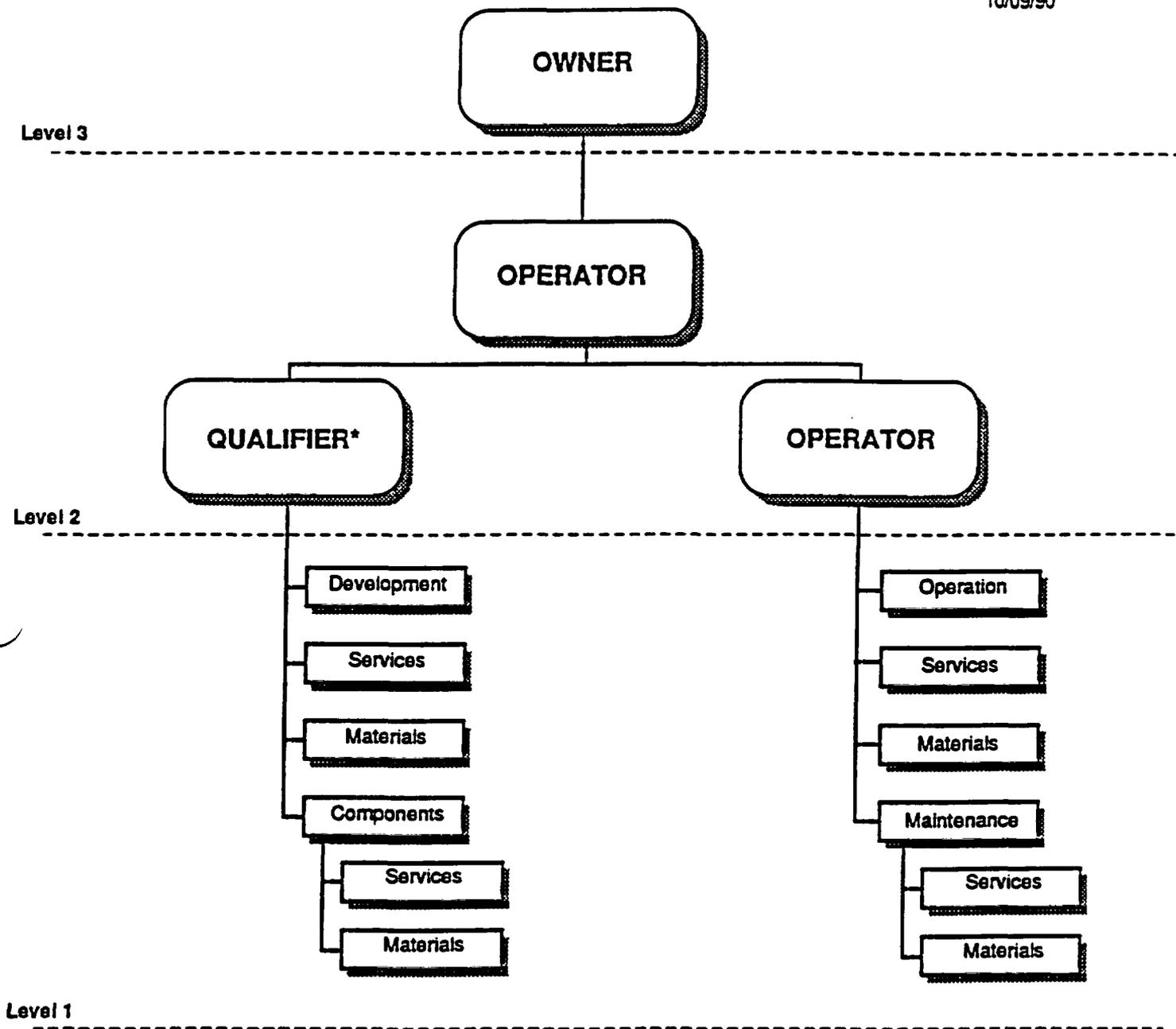
U. S. DEPARTMENT OF ENERGY
OFFICE OF WASTE OPERATIONS
QUALITY ASSURANCE POLICY

It is the policy of the Office of Waste Operations to develop, implement, and maintain a Quality Assurance Program to fulfill the requirements of the Department's orders and to be consistent with applicable Federal, State, and Local regulations and requirements. This policy is to ensure that the principles of quality assurance are implemented for the programs, projects, and activities of the Office to achieve high quality and success in meeting its goals and objectives, including protection of health, safety of workers and the general public, and the protection of the environment.



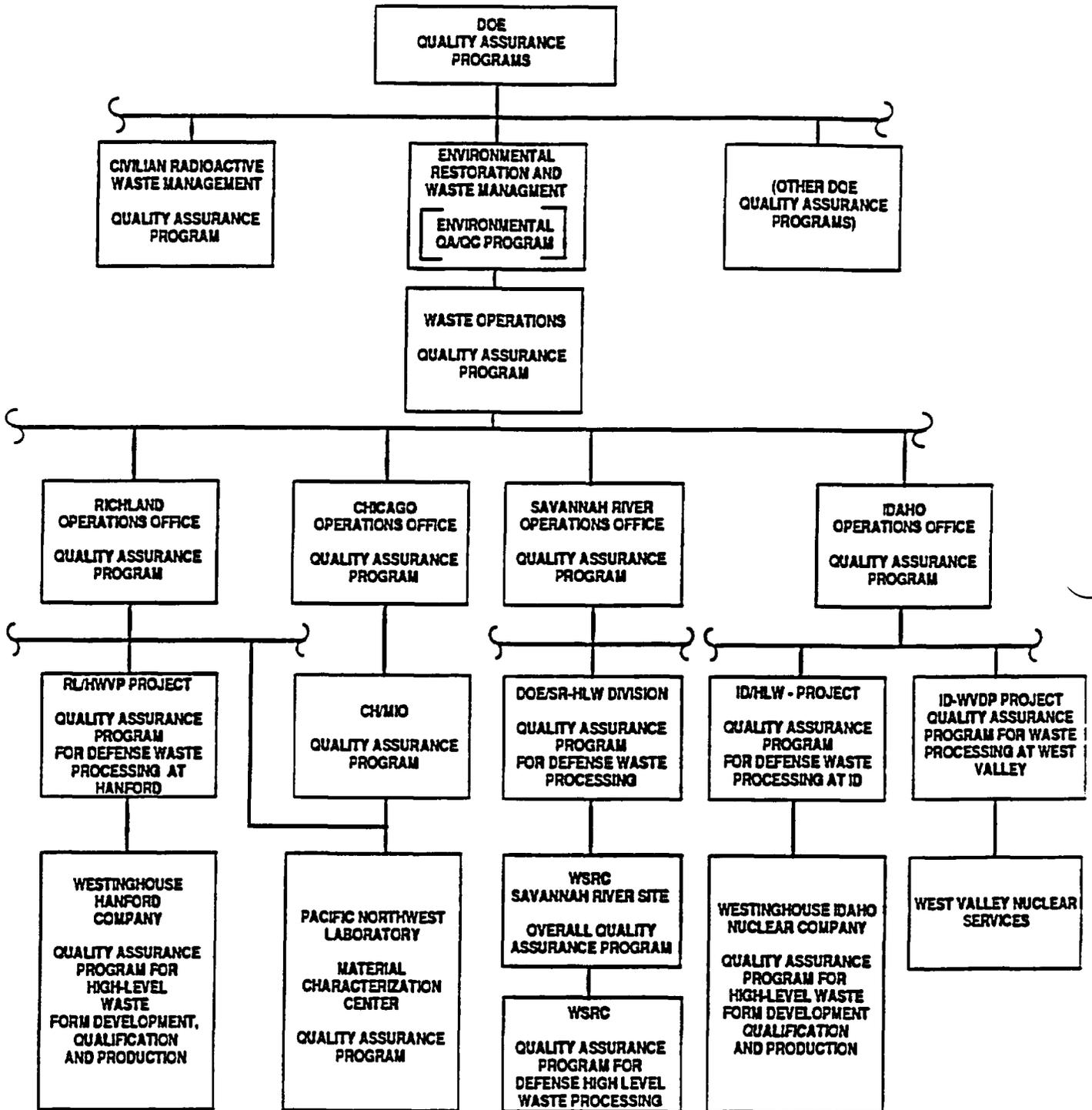
Jill Lytle
Associate Director
Office of Waste Operations

Date: Oct. 31, 1990



* Includes program responsibility for any developmental activities associated with qualification.

FIGURE 4.2-1
DOE/WASTE OPERATIONS QUALITY ASSURANCE FUNCTIONAL ORGANIZATION OF PROGRAM RESPONSIBILITY



**FIGURE 4.4-1
 QUALITY ASSURANCE PROGRAM-BREAKDOWN STRUCTURE**

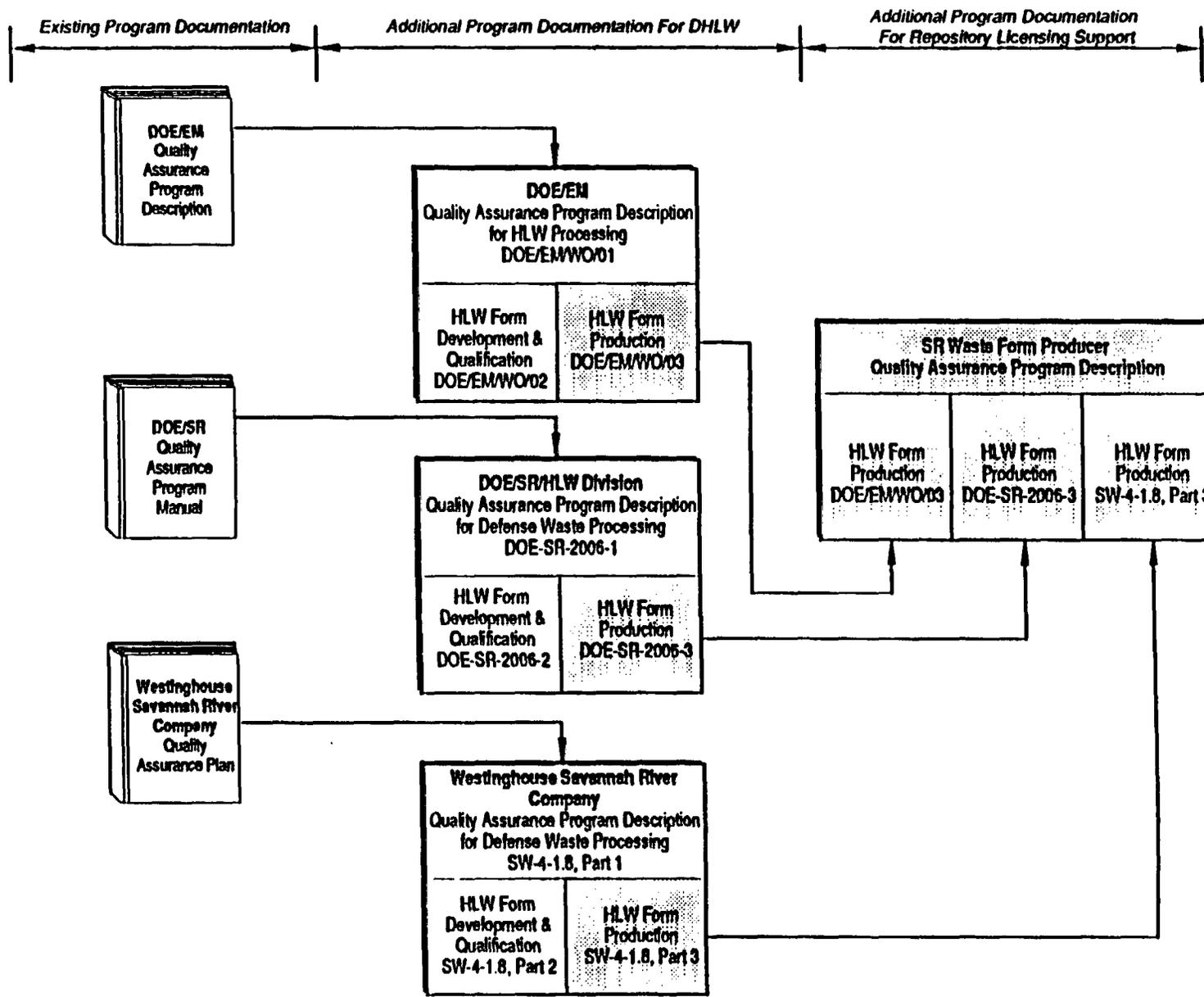


FIGURE 4.5-1
QUALITY ASSURANCE PROGRAM DOCUMENTATION BREAKDOWN STRUCTURE
FOR SAVANNAH RIVER WASTE FORM PRODUCER

QAPD

Quality Assurance Program Descriptions

UNCONTROLLED COPY

Environmental Restoration And Waste Management

High-Level Waste Processing

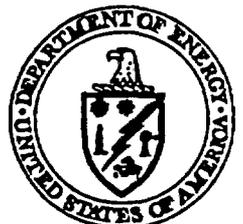
DOE/EM/WO/01
DOE/EM/WO/02
DOE/EM/WO/03

Quality Assurance Program Descriptions

Revision 0
October 1990

DOE/EM/WO/02

U.S. Department Of Energy
Office Of Waste Operations



U.S. DEPARTMENT OF ENERGY
OFFICE OF ENVIRONMENTAL RESTORATION AND WASTE MANAGEMENT
OFFICE OF WASTE OPERATIONS

DOE-EM
QUALITY ASSURANCE
PROGRAM DESCRIPTION

DOE/EM/WO/02
FOR
HIGH-LEVEL WASTE FORM
DEVELOPMENT AND QUALIFICATION

Approved: _____

Stephen P. Cowan

Stephen P. Cowan
Deputy Director
Office of Waste Operations
Environmental Restoration and Waste Management

Date: _____

Oct 31, 1990

DOE/EM/WO/02

HIGH-LEVEL WASTE FORM DEVELOPMENT AND QUALIFICATION

POLICY STATEMENT

In supporting the Office of Waste Operations' goal of excellence, it is the policy of the Division of Waste Management Projects to maintain and utilize an effective quality assurance program in all aspects of its work. Quality will be given equal consideration with cost and schedule in all our activities for waste acceptance process activities for high-level waste form development and qualification.

Each line organization must accept and discharge the responsibility for the quality of all phases of the work. All personnel must participate, as necessary, in the quality assurance program. The EM-34 Managers are responsible for ensuring quality in their programs. Quality assurance specialists are available to provide advice and service to aid the line organization in performing this important responsibility, as well as to ensure that the objectives of the program are being carried out in an effective and efficient manner.



Stephen P. Cowan
Deputy Director,
Office of Waste Operations
Environmental Restoration and Waste Management

Oct 31, 1990

Date

WASTE OPERATIONS
Quality Assurance Program Description
For
High-Level Waste Processing

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DOE/EM/WO/02

**SUMMARY OF EVENTS IN THE DEVELOPMENT
AND REVIEW OF THE PROPOSED
QUALITY ASSURANCE PROGRAM DESCRIPTION
FOR HIGH-LEVEL WASTE FORM DEVELOPMENT AND QUALIFICATION**

Revision 0 of DOE/DP-0062 was issued on November 10, 1988 and was based on the requirements contained within Revision 0 of OGR/B-14.

In February 1989, the Nuclear Regulatory Commission (NRC) issued its review comments on Revision 0 of OGR/B-14. As a result of these comments, OGR/B-14 was revised to Revision 1. The Quality Assurance Program descriptions were revised to Revision 1 as a result. The descriptions were then submitted to the DWTM Working Group for Waste Acceptance (WGWA) for review. WGWA review comments have been dispositioned, and Revision 1 of the descriptions were submitted for DWTM review and approval in May 1989.

Revision 2 of DOE/RW-0214, Quality Assurance Requirements Document was issued in January 1990. This revision of DOE/RW-0214 replaced/superseded OGR/B-14, Quality Assurance Requirements for High-Level Waste Form Production. This program description replaces DOE/DP-0062, Quality Assurance Program Description - Defense High-Level Waste Form Development and Qualification. This program description is based on Revision 1 of DOE/DP-0062, which was changed to reflect the current DOE organization and program, and Revision 2 of DOE/RW-0214.

DOE/EM

OFFICE OF ENVIRONMENTAL RESTORATION AND WASTE MANAGEMENT
QUALITY ASSURANCE PROGRAM DESCRIPTION
FOR
HIGH-LEVEL WASTE FORM DEVELOPMENT AND QUALIFICATION

0.0 INTRODUCTION

0.1 SCOPE

This Quality Assurance Program Description describes the plans and actions of the United States Department of Energy (DOE), Office of Environmental Restoration and Waste Management (EM), to ensure that quality is achieved in developing and qualifying an acceptable high-level canistered waste form product from DOE high-level waste (HLW) processing facilities at the Savannah River, Hanford, Idaho, and West Valley sites. The description also covers development and qualification activities through which documentation and data are collected and prepared to support compliance with the Waste Acceptance Specification. The production activities will be described separate from development and qualification. Section 0.3 defines in more detail the application of this program. Hereafter, this program, which consists of the specific quality assuring plans and actions referenced in this document, is referred to as the "development and qualification (D&Q) quality assurance program."

0.2 BASIS

The quality assurance program described in this document has been developed to fulfill EM's responsibility for the adequacy and effectiveness of the D&Q quality assurance program for high-level waste processing. The D&Q quality assurance program described herein is an element of the overall EM quality assurance program. Although responsibility for establishing and executing portions of the D&Q quality assurance program has been assigned to others participating in the program, EM retains ultimate responsibility for the adequacy of their performance.

0.3 BACKGROUND

The development and qualification of the final waste forms, to be produced at DOE high-level waste processing facilities, has been underway for many years. This section briefly describes the work that preceded the current phase of HLW processing work and the quality assurance program applied to that work. This description of the development and qualification

background is divided into the following three elements of the Waste Acceptance Process (WAP):

The WAP identifies the DOE strategy for ensuring the acceptability of high-level waste forms produced in its facilities for disposal in the federal repository. The four elements of the WAP are:

- (1) A Waste Acceptance Specification (WAS)
- (2) A Waste Form Compliance Plan (WCP)
- (3) A Waste Form Qualification Report (WQR)
- (4) A Production Record (PR)

The WAS, WCP, and WQR are development and qualification, the RR is covered in the production quality assurance program.

WASTE ACCEPTANCE SPECIFICATION

Waste Acceptance Specification (WAS) identifies the properties and requirements the high-level waste form must meet in order to be accepted for disposal in a Federal Repository. Each HLW processing facility will have a WAS.

The WAS was initially issued as a Waste Acceptance Preliminary Specification (WAPS), to be updated from time-to-time as significant progress was made in the Waste Acceptance Process. Since that time, it has been maintained under the DOE Office of Geologic Repository (OGR) configuration management process. Within the WAS, quality assurance activities were covered by reference to the DOE Office of Civilian Radioactive Waste Management (OCRWM) specification OGR/B-14, Quality Assurance Requirements for High-Level Waste Form Production. OGR/B-14 implemented DOE Order 5700.6 and its referenced American National Standard on Quality Assurance Program Requirements for Nuclear Facilities, ANSI/ASME NQA-1. OGR/B-14 has been superseded and replaced by OCRWM's DOE/RW-0214, Quality Assurance Requirements Document.

West Valley Demonstration Project (WVDP) were initially approved and issued in 1986. Before being issued as OGR/B-8 of the federal repository baseline documentation, they were prepared by the RW Waste Acceptance Committee, and reviewed and approved by involved DOE organizations.

WASs will be developed in a similar way for the Hanford Waste Vitrification Plant (HWVP) on the Hanford Site at Richland, Washington, and the future high-level waste processing facilities to be built in Idaho. These WASs will be specific to the types of high-level waste at these sites.

WASTE FORM COMPLIANCE PLAN

The Waste Form Compliance Plan (WCP) describes the producer's plan for demonstrating compliance with each requirement in the WAS. The WCP includes descriptions of the tests, analyses, and process controls to be performed by the producer. Each HLW processing facility will have a WCP.

The DWPf WCP and the WVDP WCP were developed in draft form in 1986 and 1987. These WCPs outline the planned activities in each of the following four areas of the WAS: the waste form, the canister, the canistered waste form, and quality assurance.

Before actually preparing and issuing the DWPf WAS and the DWPf WCP, research and development in support of the Waste Acceptance Process had begun during the 1970's, and progressed in several DOE national laboratories. This work was planned, conducted and reported according to the accepted practices for such work under DOE and its predecessor organizations (U. S. Energy Research and Development Administration and the U. S. Atomic Energy Commission), and performed in its national laboratories.

These principal investigators were accomplished scientists and engineers, who were selected for their assignments on the basis of their expert qualifications (education and experience). Their experiments and experimental installations were planned and designed under the laboratories' management control systems which were developed and applied to routine research and development activities. Experiments were conducted, data taken and managed, and results reported according to standard laboratory procedures. These procedures were supplemented by special waste management program procedures for certain aspects of the work such as rock cup leach testing of waste form samples. Early work relating to waste form development was subjected to several independent peer reviews and to public scrutiny through the National Environmental Policy Act (NEPA) process.

During the early research and development work, the DOE laboratories were in the process of developing and implementing a more formal quality assurance program which was being developed to implement DOE Order 5700.6. This order referenced ANSI/ASME NQA-1 and the predecessor standard ANSI/ASME N45.2. The program was supplemented by a group of activities defined in the specification, "Quality Assurance Requirements for High-Level Waste Form Production" (OGR/B-14), which was issued by DOE in late 1987.

OGR/B-14 was subsequently replaced by OCRWM's Quality Assurance Requirements document, (DOE/RW-0214). DOE/RW-0214 is a portion of the WAS.

WASTE FORM QUALIFICATION REPORT

The Waste Form Qualification Report (WQR) is a compilation of the results from waste form testing and analysis which develops in detail the case for compliance with each Waste Acceptance Specification. Each processing facility will have a WQR.

A Waste Form Qualification Report (WQR) will be prepared for DWPF, WVDP, HWVP, and the future HLW facility at Idaho. The documentation and data contained in these reports will be collected, prepared, and maintained under the provisions of the D&Q Quality Assurance Program. All WQRs will be approved by DOE and issued to the RW baseline of repository documentation. This documentation is under configuration control in the repository quality assurance program.

1.0 ORGANIZATION

The ultimate responsibility for processing the high-level waste that results from national defense programs and other DOE activities rests with the Secretary of Energy. The execution of this responsibility has been delegated to the Director, Office of Environmental Restoration and Waste Management (EM), and other DOE headquarters and field organizations. The organization chart for EM is shown in Figure 1.0-1.

The execution of the Secretary of Energy's responsibility for processing high-level waste has been further delegated by the Director, EM to the Associate Director, Office of Waste Operations (Waste Operations). Within Waste Operations, the execution of this responsibility for development and qualification is assigned to the Vitrification Projects Branch Chief through the Director, Division of Waste Management Projects. The Waste Operations organization for development and qualification is shown in Figure 1.0-2. Waste Operations is an off-site organization.

One facet of the Director, EM's responsibility is to ensure that the canistered high-level waste forms, to be produced in DOE waste processing facilities, are developed and qualified in such a way as to provide adequate confidence that they will satisfy all requirements of each facility-specific WAS. To provide this assurance, the Associate Director of Waste Operations has directed that the D&Q quality assurance program, as described in this document, be established and conducted.

1.1 FUNCTION

- 1.1.1 Functions that the Vitrification Projects Branch will perform in order to achieve the stated objectives of the D&Q Quality Assurance Program and fulfill its ultimate responsibility for program adequacy are as follows:

- (1) Develop an overall plan for conducting the D&Q Quality Assurance Program.
- (2) Identify portions of program execution responsibility for assignment to appropriate Operations Offices, including Richland (RL), Savannah River (SR), Chicago (CH), and Idaho (ID).
- (3) Develop working plans and procedures to conduct program activities.
- (4) Organize and staff appropriately, or contract work as appropriate, to implement program functions.
- (5) Implement the program activities.
- (6) Interface Operations Office's programs with the Waste Operations D&Q program.
- (7) Integrate, coordinate, evaluate, and accept Operations Offices' quality assurance programs.
- (8) Where Waste Operations elects to retain execution responsibility in lieu of assigning it to another organization, develop and implement programs.

1.1.2 Those quality assurance functions which have been assigned to other organizations are explained in Section 2.3.3.

1.2 RESPONSIBILITY AND AUTHORITY

1.2.1 The Vitrification Projects Branch uses its own organization as well as other DOE organizations, committees, and contractors, to fulfill its quality assurance role for development and qualification in the Waste Acceptance Process. The relationships between Waste Acceptance Process participants are illustrated in Figure 1.2.1-1, and the responsibilities and areas of authority for those participants under the scope of this program description are listed as follows:

(1) Office of Waste Operations

The Office of Waste Operations develops and directs programs for ensuring that nuclear waste is safely handled, treated, stored, and packaged for disposal, with no adverse effects to the safety and health of the public.

The Office of Waste Operations is a major office of DOE-EM. The Associate Director of Waste Operations is responsible for providing HLW forms that are acceptable for ultimate disposal in the geologic repository, according to the specifications established by RW.

The Associate Director of Waste Operations is supported by the Division of Waste Management Projects, the Vitrification Projects Branch, designated DOE Operations Offices, and their contractors. The formal interface between the waste form producers and RW is through the Vitrification Projects Branch. Informal coordination and cooperation between the waste form producers and the repository operator are encouraged.

The Office of Waste Operations is responsible for management of HLW from defense and other DOE programs. Waste Operations programs address the following:

- Minimizing waste generated
- Storing waste awaiting treatment
- Transporting from place generated to place of treatment
- Treating and packaging waste
- Developing and qualifying canistered waste forms
- Producing canistered waste forms
- Storing canistered waste forms, and eventually transferring them to RW for transportation and disposal

The implementation of this quality assurance program will enhance the safety function and the waste isolation function of the entire program. For the purposes of this program, the term "waste isolation" is equivalent to "safety."

(2) Vitrification Projects Branch

The Vitrification Projects Branch is primarily responsible for development and qualification activities for high-level waste. The Vitrification Projects Branch Chief reports to the Director of the Waste Management Projects Division, who reports to the Associate Director, Waste Operations. The Branch Chief, who serves as the general manager, is responsible for cost, schedule, and technical requirements, as well as quality and quality assurance. Detailed descriptions of the Branch Chief's assigned duties are given in Sections 1.2.2 and 1.2.3. The organizations above, below, and related to the Vitrification Projects Branch are shown in Figure 1.2.1-1.

The Vitrification Projects Branch Chief is assisted by technical evaluators, engineers, and quality assurance specialists in carrying out his or her primary responsibilities. One of these serves as the HLW Quality Assurance Program Manager. Some of the assistants who support the Branch Chief are members of the Vitrification Projects Branch. Others are members of the Project Offices associated with the Operations Offices. Some of the Quality Assurance Specialists are contract consultants obtained

through contracts or subcontracts, but they work directly with the Branch Chief. These persons who assist the Branch Chief, even though they are under the Operations Office or are provided through a contract or subcontract, receive programmatic direction and instruction from the Vitrification Projects Branch Chief.

These project office personnel and contract consultants perform quality-achieving and quality-assuring tasks using instructions or procedures approved by the Vitrification Projects Branch Chief. The quality-assuring tasks may include preparing procedures, descriptions, directives, and instructions; performing evaluations such as audits, surveillances, reviews, and assessments; recommending dispositions and corrective actions; and reviewing and concurring with proposed corrective actions, dispositions, and solutions. These are defined in detail in Section 1.3.

(3) Working Group on Waste Acceptance (WGWA)

The WGWA assists the Vitrification Projects Branch in identifying and describing its role in Waste Acceptance Process activities, including identifying and documenting the Waste Acceptance Process-related mission; preparing and describing a Waste Acceptance Process-related organization; characterizing the Waste Acceptance Process-related work flow; preparing a documentation structure to help Waste Operations fulfill its role in Waste Acceptance Process-related activities; and preparing a Waste Operations quality assurance program.

The WGWA is responsible to the Vitrification Projects Branch Chief. The WGWA is composed of technical personnel closely associated with the high-level waste technology program, and is chaired by a DOE representative.

(4) Operations Offices and Project Offices

Operations Offices [Richland (RL), Savannah River (SR), Chicago (CH), and Idaho (ID)] are assigned specific responsibilities in the D&Q quality assurance program. Operations Offices provide the normal administrative and technical support, and have primary responsibilities for cost and schedule. They are also the primary contact with the operating contractor.

Within the Operations Offices there are Project Offices, Divisions, or other designated organizations. Project Offices are staffed with Operations Office personnel. There are communication links between the Vitrification Projects Branch and the Operations Office.

RL, in addition to its other responsibilities, assists the Vitrification Projects Branch Chief in a technical support role. In conjunction with other contractors, RL arranges for specific HQ technical support services to meet its quality-assuring and quality-achieving responsibilities. These support functions include performing audits, reviews, evaluations, and other normal quality assurance personnel duties. RL also performs specific technical and quality-assuring assignments made by the Vitrification Projects Branch Chief.

Assignments to Operations Offices are by program guidance letters, work authorization letters, memoranda of understanding, or similar documents. These assignment documents are treated as Vitrification Project Branch procurement documents.

(5) Materials Steering Committee (MSC)

The MSC functions as a coordinating center among DOE organizations that have a role in high-level radioactive waste management. It coordinates DOE radioactive waste activities at the waste form producer/repository interface, and recommends establishment of the Waste Acceptance Process. The MSC coordinates the preparation and review of documents relating to the acceptance standards for defense waste, and reviews Materials Integration Office (MIO) activities at its regular meetings.

The MSC is composed of members from RW, EM, MIO, and each cognizant Operations Office. The chairman is appointed by the Director, RW. The secretary is appointed by EM. The chairman and primary committee members appointed by RW and EM make up the MSC Executive Committee. This committee provides direction to the Waste Acceptance Committee (WAC).

Operating Contractors [Westinghouse Hanford Company (WHC), Westinghouse Savannah River Company (WSRC), Pacific Northwest Laboratory (PNL), Argonne National Laboratory, (ANL), Westinghouse Idaho Nuclear Company (WINCO)], and West Valley Nuclear Services (WVNS) provide on-site and off-site quality assurance activities.

(6) Waste Acceptance Committee

The WAC implements the Waste Acceptance Process. The WAC was established to focus contractor resources on developing waste acceptance documentation, to advise the MSC, and to assist in coordinating the needs and requirements of the repository providers and waste form producers.

The WAC is composed of DOE-selected representatives from the repository project, the waste form producers, and the Materials Characterization Center (MCC).

The chairman is selected by the Director of RW with the concurrence of Director of EM. The WAC is directed by the Executive Committee of the MSC.

(7) Materials Integration Office (MIO)

The MIO, centered at CH, serves as the DOE administrative manager for the MCC. It guides the MCC in developing programs to respond to the needs of RW, EM, and their contractors. The MIO provides administrative support for special groups to study or coordinate special projects. It also prepares monthly progress reports to DOE headquarters and the Operations Offices. MIO supports a peer group to conduct engineering and peer reviews as needed. MIO activities are reviewed by the MSC.

(8) Materials Characterization Center (MCC)

The MCC, organized with the concurrence of the MSC and located at the Pacific Northwest Laboratory, provides standard test methods and reference and testing materials; characterizes spent fuel; performs confirmation testing; and establishes confidence limits and test data. It serves as a central source of accurate, reliable data for use in waste management systems design, integration, and licensing. It reports to the MIO.

MCC receives guidance and funding from the EM, RW, the repository projects, and the waste form producers. There is a waste form producer organization for each defense waste processing facility; each organization is a composite of elements of DOE and its contractors. The MCC prepares a program plan to accomplish the work to be performed, and prepares monthly reports that become part of the MIO report to DOE headquarters and the Operations Offices.

- 1.2.2 The Vitrification Projects Branch Chief has general management responsibilities, including quality assurance, and is therefore responsible for devising, developing, and ensuring that the overall HLW Quality Assurance Program applied to vitrification projects is effectively executed. The Vitrification Projects Branch Chief is assisted in managing and directing HLW quality assurance programs by support services contractors, who provide a HLW Quality Assurance Program Manager and appropriate Quality Assurance Specialists.

The individual serving as the Vitrification Projects Quality Assurance Program Manager:

- (1) Is at a level equivalent to the other positions reporting to the Vitrification Projects Branch Chief
- (2) Has knowledge and experience in quality assurance and management
- (3) Has the authority and resources to do the following:
 - Verify that the organization's and sub-tier organizations' quality assurance programs are effectively implemented and adequate.
 - Identify quality problems; initiate, recommend, or provide solutions; and verify implementation of solutions.
 - Ensure that further processing, delivery, installation, or operation is controlled until a nonconformance, deficiency, or unsatisfactory condition is properly dispositioned, or recommend stop work to the Vitrification Projects Branch Chief.
 - Review and recommend approval or disapproval of quality assurance programs, revisions to programs, and the interpretations of the programs.
- (4) Does not have other duties or responsibilities that could prevent full attention to quality assurance program matters
- (5) Has freedom from cost and schedule considerations when they are opposed to quality considerations
- (6) Has access to the Vitrification Projects Branch Chief and the Director of Waste Operations when necessary to identify and resolve unresolved quality concerns

The support services contractor who provides the Quality Assurance Specialist is responsible for the following specific tasks:

- (1) Recommending the organization of the HLW Quality Assurance Program and the assignments for execution responsibility as appropriate
- (2) Recommending the organization and staffing plan and level for conducting the quality assurance practices necessary to fulfill DOE's responsibility for establishment and adequacy of the Program
- (3) Administratively controlling the Quality Assurance Specialists

1.2.3 The Vitrification Projects Branch Chief has general responsibilities, including quality assurance, and is therefore responsible for devising,

developing, and ensuring that the overall HLW Quality Assurance Program applied to vitrification projects is effectively executed. Support services contractors who provide a Quality Assurance Program Manager and Quality Assurance Specialists assist the Vitrification Projects Branch Chief in managing and directing the HLW quality assurance programs. The individual serving as the Quality Assurance Program Manager and the Quality Assurance Specialists have the authority to do the following:

- (1) Gain access to work areas and identify quality problems
- (2) Initiate, recommend, or provide solutions to quality problems through designated channels
- (3) Verify implementation of solutions
- (4) Determine the adequacy of facilities and equipment provided to carry out approved procedures and instructions
- (5) Issue special instructions necessary to execute his or her responsibilities
- (6) Notify responsible management of unsatisfactory work or unapproved practices, and if necessary, stop unsatisfactory work or control further processing, delivery, or installation of nonconforming materials

1.2.4 The Vitrification Projects Branch Chief is responsible for the following specific tasks:

- (1) Organizing the D&Q Quality Assurance Program and assigning execution responsibility as appropriate
- (2) Ensuring that each Operations Offices' organization gives the person responsible for quality assurance sufficient authority to assess and identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions
- (3) Arranging for the support and assistance needed to implement the D&Q Quality Assurance Program
- (4) Maintaining technical and administrative control of individuals under his or her supervision that perform quality assurance-related activities

1.3 ORGANIZATIONAL ARRANGEMENTS

1.3.1 The organization responsible for executing the quality-related activities of the D&Q program is the Vitrification Projects Branch. The

Quality Assurance Program Manager and Quality Assurance Specialists from contract organizations, arranged through RL, assist the Branch Chief. The Quality Assurance Specialists provide technical and quality assurance support to the Quality Assurance Program Manager. The Quality Assurance Program Manager and the Quality Assurance Specialists have the authority and the organizational freedom to do the following:

- Verify that the organization's and sub-tier organizations' quality assurance programs are effectively implemented and adequate.
- Identify quality problems; initiate, recommend, or provide solutions; and verify implementation of solutions.
- Ensure further processing, delivery, installation, or operation is controlled until a nonconformance, deficiency, or unsatisfactory condition is properly dispositioned, or recommend stop work to the Vitrification Projects Branch Chief.
- Review and recommend approval or disapproval of quality assurance programs, revisions to programs, and the interpretations of the programs.

The Quality Assurance Specialists are involved in portions of the waste acceptance process activities for development and qualification of the high-level waste form. The extent of quality assurance controls is determined by the Quality Assurance Program Manager, assisted by the Quality Assurance Specialists. The extent of controls is based on the specific activity, its complexity, and its importance to waste acceptance process activities for high-level waste form development and qualification of the canistered waste form. The Quality Assurance Program Manager, assisted as needed by Quality Assurance Specialists, will perform quality-assuring functions determined to be appropriate to the Branch Chief's assigned scope of work. Control of unsatisfactory conditions, including issuing and lifting stop work orders, is addressed in procedures.

Typically, these functions include the following:

- (1) Quality Verification - This function monitors internal D&Q Quality Assurance Program activities to verify overall adequacy. Quality verification involves conducting surveillance of Operations Offices' quality assurance programs and verifying quality achievement in their work performance. Following are the types of activities performed as a part of quality verification:

- Review

Checking the adequacy and acceptability of sub-tier organizations' quality assurance program descriptions and implementing

procedures. This is the principal method for ensuring that programs start out with the correct focus, scope, and level of detail.

- Surveillance

Monitoring the work and the quality assurance practices applied to that work. It also provides for interface coordination between the Waste Operations quality assurance program and the quality assurance programs of applicable operations offices. Surveillance also includes monitoring inspections by others; monitoring selected civil, structural, electrical, mechanical, and welding inspections; and nondestructive examinations.

- Audit

Planning and conducting internal audits of the Waste Operations' quality assurance activities and external audits of Operations Offices' quality assurance activities. This includes audits of operating contractors' quality assurance programs, and audits of subcontractors, consultants, vendors, and laboratories furnishing equipment or services to the Operating Contractor or DOE. Scheduled and unscheduled audits are conducted.

(2) Quality Engineering - This function consists of planning, defining, and developing the overall quality assurance program for high-level waste form development and qualification and Waste Operations' portion of that program. It also consists of preparing and maintaining the D&Q quality assurance program requirements for high-level waste form development and qualification, and internal plans and procedures. Also included is the responsibility for reporting the progress and status of the quality assurance program, and for quality records management. Following are the three types of activities performed as a part of quality engineering:

- Planning

Planning, program development, and documenting plans and procedures for conducting both the D&Q quality assurance program for high-level waste form development and qualification and Waste Operations' portion of that program. A knowledge of industry and government standards and their appropriate application to the Waste Operations quality assurance program is maintained.

- Reporting

Establishing and maintaining the requirements for reporting the progress and status of the quality assurance program. This

activity includes collecting reports from Operations Offices and preparing quarterly consolidated status reports on development, implementation, and progress for the quality assurance program. These reports are distributed to the Director, Waste Operations by the Branch Chief.

- Collecting and Maintaining Records

Collecting, filing, and maintaining quality records. This includes receiving, routing, and filing quality-related documentation within Waste Operations.

- (3) Quality Improvement - This function consists of providing needed training and indoctrination for personnel (including assigned contract personnel and personnel borrowed from other DOE organizations to perform quality-related functions), and coordinating Waste Operations training and indoctrination activities for personnel performing quality-related functions. This function also consists of dispositioning nonconformances, and correcting program deficiencies to improve quality achievements and to prevent recurrence of nonconforming conditions. The following three types of activities are performed:

- Nonconformance Control

Collecting unusual or abnormal occurrence reports, deviation requests, nonconformance reports, and deficiency citations, and processing them to satisfactory resolution. A log of quality problems and significant conditions adverse to quality identified internally and by operations offices is maintained, and corrective actions are recorded.

- Trend Analysis

Activities, reports (audit, surveillance, inspection, progress, status) and records are monitored through this activity to identify quality problems. Problems identified, including significant conditions adverse to quality, are studied and actions are recommended to correct the problem, to improve quality, and to improve the efficiency and effectiveness of quality assurance activities.

- Training and Indoctrination

Actions to acquaint Waste Operations personnel with the various elements of the quality assurance program and the practices needed to ensure quality achievement. Quality assurance personnel qualifications are certified, and personnel training and

indoctrination within Waste Operations and within Operations Office organizations is monitored.

1.4 QUALIFICATION REQUIREMENTS FOR QUALITY ASSURANCE POSITIONS

1.4.1 Quality Assurance Specialists

The individuals assigned to assist the Branch Chief in carrying out his or her responsibilities for directing, controlling, and verifying the D&Q Quality Assurance Program are the Quality Assurance Program Manager and the Quality Assurance Specialists. The Quality Assurance Program Manager will have the following qualifications:

Education - A four-year degree in either engineering or science from an accredited college or university, or equivalent experience.

Experience - General: A minimum of eight years experience in quality assurance or engineering, construction, or operation activities associated with nuclear facilities or equivalent heavy industry. A minimum of four years experience shall be in quality assurance.

Specialty: A broad knowledge and understanding of industry and government codes, standards, and regulations defining quality assurance requirements and practices.

A broad knowledge and understanding of quality assurance methods and their application.

Experience in planning, defining, and performing quality assurance practices, and applying procedures.

Managerial: Experience in organizing, directing, and administering an overall program of activity, or a major portion of an overall program having broad scope and application.

The qualifications for the Quality Assurance Specialists are similar to those for the Quality Assurance Program Manager. General experience may be less than eight years, and managerial experience is not required for Quality Assurance Specialists.

1.5 COMMUNICATIONS

1.5.1 Effective lines of communication are established to ensure the free and continuous flow of communications, both horizontally and vertically, within organizations as well as among DOE and other program participants. The free exchange of information among responsible

individuals is also essential to the expeditious execution of quality assurance activities.

Parties involved in disagreements or disputes involving quality are encouraged to resolve or attempt to resolve the dispute informally and by directly communicating with their supervisor(s). When adequate resolution cannot be achieved at that level, each party is encouraged to document his or her position and forward it to higher management for resolution. The dispute is progressively elevated until satisfactory resolution is achieved. When resolution is achieved, the resolution is documented, communicated to the involved parties, and a copy is forwarded through channels to the Director, EM.

If the dispute remains unresolved until it reaches the Waste Operations level, the Associate Director of Waste Operations will resolve the issue and document the resolution. A copy of the resolution is forwarded through channels to the Director of EM. Receiving, documenting, investigating, and dispositioning allegations and quality concerns are controlled by procedures.

1.5.2 Official communications between DOE and NRC regarding waste acceptance process activities of high-level waste form development and qualification will flow between DOE/RW and NRC. Within DOE, such communications will flow between DOE/RW and DOE/EM. Vitrification Projects Branch will represent DOE/EM in matters of high-level waste acceptance, and will pass communications to and from the appropriate DOE Operations Office. Communications between DOE and DOE Operating Contractors will pass to and from the appropriate DOE Operations Office to the DOE Operating Contractor, with copy distribution to the Vitrification Projects Branch Chief. The contract organization who provides the Quality Assurance Program Manager and the Quality Assurance Specialist will work directly with the Branch Chief on task assignments and results, but will work administratively through RL.

1.5.3 To promote the flow of communications and to ensure positive attention to quality problems within the D&Q Quality Assurance Program, lines of communication between Waste Operations and the applicable Operations Offices are established as follows:

(1) Communications by Senior Management

These communications will deal with such matters as major changes in the scope of the quality assurance program. Communications will be addressed to the responsible senior management official within EM and at each applicable Operations Office.

(2) Communications by Quality Assurance Program Management

These communications will provide a direct formal or informal exchange of information between the Vitrification Projects Branch Chief, assisted as needed by the Quality Assurance Program Manager and Quality Assurance Specialists, and the Operations Offices' quality assurance personnel. Other quality assurance managers of organizations that interface directly with Vitrification Projects Branch will also assist. Copies of such communications will be distributed to other affected Operations Offices.

(3) Communications by Individuals

These communications are encouraged in order to identify and evaluate quality problems, and to initiate, recommend, or provide solutions. Communications may also be formal or informal, the choice of which shall depend on the significance of the subject and the judgment of the individuals involved.

1.5.4 Communication of quality assurance-related activities within DOE's organization is promoted through the following:

- (1) Briefings at periodic staff meetings by the Vitrification Projects Branch Chief, assisted by the Quality Assurance Program Manager.
- (2) Monthly quality assurance program progress and status reporting to the Branch Chief.
- (3) Informal and formal communications between the Branch Chief and the Operations Offices and Project Offices regarding program direction. Formal communications will normally be in the form of Program Execution Guidance, which is routed to DOE personnel cognizant of the subject.

1.5.5 Communication of quality assurance-related activities among the Headquarters and the organizations of the Operations Offices is promoted through monthly and/or quarterly quality assurance program progress and status reporting by Operations Offices, as requested by Vitrification Projects Branch.

2.0 QUALITY ASSURANCE PROGRAM

2.1 POLICY AND OBJECTIVES

The policy and objectives of the D&Q Quality Assurance Program are as follows:

- 2.1.1 To ensure quality is achieved in the development and qualification of an acceptable canistered high-level waste form product at each of the facilities for processing defense waste
- 2.1.2. To ensure that appropriate quality assurance activities are implemented by or for Waste Operations

2.2 RESPONSIBILITY

2.2.1 Participants

Program participation responsibilities are organized in a three-level structure, as illustrated in Figure 2.2.1-1. The Owner (DOE) portion of the program is at the third level and consists of DOE's headquarters and field organizations as shown in Figure 2.2.1-2.

The other major program participants are the Qualifiers, who are shown at the second level. The major participant having direct interface with DOE is the Qualifier. Generally, the Qualifier is an Operating Contractor.

At the first level are the multitude of subcontractors and suppliers that furnish systems, components, materials, and services.

2.2.2 Office of Environmental Restoration and Waste Management

The Office of Environmental Quality Assurance/Quality Control performs oversight of Waste Operations activities on a broad spectrum. The Waste Operations Quality Assurance Organization (EM-331) performs oversight activities on a very define spectrum of EM-30 project quality assurance activities including Headquarters, Operations Offices and sites.

The Office performs an annual assessment of the scope, status, adequacy, and compliance of the quality assurance program with DOE/RW-0214. The assessment may be performed by the office of Environmental Quality Assurance/Quality Control, the Waste Operations Quality Assurance Organization, or may be assigned to another organization that is independent of the Vitrification Projects Branch. The annual assessment is preplanned and documented. Resultant corrective measures are reported to the affected organizations for completion. The corrective actions are tracked to completion.

2.2.3 Vitrification Projects Branch Chief

- (1) As described in Section 1.0 of this document, DOE's principal manager for the high-level waste program is the Vitrification Projects Branch Chief, who has management overview involvement in the overall D&Q Quality Assurance Program.
- (2) Responsibility for executing the Waste Operations Program, elements detailed in the implementing procedures. The assuring activities are performed by the Quality Assurance Program Manager, who is assisted as needed by the Quality Assurance Specialist(s).
- (3) The technically-related, quality-achieving functions that are performed by the Quality Assurance Program Manager, assisted as needed by staff members and Quality Assurance Specialists, include the following:
 - Participation in multi-discipline audits and reviews
 - Review and acceptance of program plans and procedures
 - Review and concurrence with proposed corrective actions resulting from audit findings of deficiency
 - Execution of certain design control and document control activities
 - Execution of certain contracting control activities
 - Execution of certain development and qualification control activities
- (4) The Branch Chief executes independent management assessments that assess the scope and implementation of the quality assurance program. The purpose of the assessments is to determine:
 - The effectiveness of implementation
 - The adequacy of planning and control
 - The effectiveness of corrective action
 - The adequacy of the organizational structure, staffing, and training
 - The adequacy of the management reporting system

The assessments are either performed by the EM line organization management; or the Branch Chief, with the concurrence of the Division Director, may designate other organizations to perform the evaluations. In either case, the assessments will be performed by persons above or outside the quality assurance organization.

These evaluations, which are conducted at least annually, use the resources and information at their disposal, including previous assessments and reports of surveillance, inspection, and audit

activities; and results from root cause analyses of significant conditions adverse to quality, quality issues, and trends. Any quality problems identified in the assessments are tracked until closure.

- (5) Additionally, the Branch Chief receives the results of 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 Branch Chief reviews these reports and initiates whatever management action is required to improve conditions and further implement the program. The results of the Branch Chief's review are reported to higher management.

2.2.4 Other Participants

- (1) Although the Branch Chief retains the responsibility for adequacy of the overall D&Q Quality Assurance Program, Operations Offices are assigned the execution responsibility for establishing and implementing particular program practices. These assigned program practices are described in Section 2.3.3.
- (2) The operating contractors that serve as the "Qualifiers" are assigned execution responsibilities. The assignment is accomplished by contract. Other contractors providing specialized services or direct assistance are delegated responsibilities by contract. The contract may be direct with an Operations Office or through an operating contractor.

2.3 REQUIREMENTS

2.3.1 D&Q Quality Assurance Program

This QAPD is written to be responsive to the requirements described in DOE/RW-0214, Quality Assurance Requirements Document. DOE/RW-0214 incorporates the applicable requirements from:

- DOE Order 5700.6, Quality Assurance
- 10 CFR 60, Subpart G, Quality Assurance
- 10 CFR 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

DOE's method for performing in accordance with NRC regulations to satisfy the needs of the repository program is to implement a program in accordance with the requirements defined above. It is DOE's position that a program that is established and implemented in accordance with these defined requirements will satisfy the requirements of 10 CFR 60 Subpart G and 10 CFR 50, Appendix B.

2.3.2 Program Elements Executed by Waste Operations

Table 2.3.2-1 contains an index of the plans and procedures and indicates the program elements that will be implemented by the Vitrification Projects Branch in accordance with specific documents. A listing of these procedures with a brief description of each is contained in Attachment II. These documents are contained in the procedure manual, which has been developed to implement the quality assurance policies, goals, and objectives of the D&Q Quality Assurance Program. The procedures are implemented before initiating the activities they control.

2.3.3 Program Elements Assigned to Operations Offices

- (1) The responsibility for executing of various other program elements is assigned to Operations Offices and is applied to their respective scopes of participation as appropriate. This assignment is accomplished through the use of Program Execution Guidance. The Operations Offices may pass along portions of the program functions to operating contractors that serve as Qualifier (see Figure 2.2.1-1) so that each portion of the program functions can be performed by those most qualified. This delegation is accomplished by contract.

Waste Operations retains the ultimate responsibility for adequate implementation and performance by each Operations Office. Waste Operations requires Operations Offices to document their programs in appropriate descriptions, plans, and procedures. These programs are initially evaluated and accepted by the Vitrification Projects Branch. After being implemented, these programs are monitored on a continuing basis through review and audit to assess their adequacy and to verify compliance with program requirements. Subsequently, the Operations Offices' revised or new program plans and procedures are reviewed on an on-going basis. Revised or new plans and procedures are accepted contingent upon verification of their acceptable implementation.

- (2) The Operations Offices review and accept the quality assurance descriptions, plans, and procedures of the operating contractors. In addition, the Vitrification Projects Branch reviews and accepts the portions of the descriptions, plans, and procedures applicable or specific to the waste management projects.

2.4 STAFFING AND TRAINING

Personnel who are assigned responsibility for verifying that Operations Office performance is in accordance with requirements are selected and assigned to their area of responsibility based upon experience, education,

and Vitrification Projects Branch's assessment of their performance capabilities. They are observed for performance evaluation on a continuing basis by appropriate Vitrification Projects Branch personnel. Ongoing training and indoctrination programs are conducted to familiarize personnel with the technical objectives of the activity being monitored, the requirements the activity must meet, the practices and procedures to be executed in verifying conformance to requirements, and the documentation of results.

2.5 INTERFACE COORDINATION

2.5.1 Controls are established by the Vitrification Projects Branch to cover interfaces between individuals or groups performing other activities as well as quality assurance activities. In general, interface control consists of three elements:

- (1) The control of documents through the implementation of document control procedures
- (2) The control of communications using communication control procedures
- (3) The performance of, and participation in, technical and peer reviews

2.6 PROGRAM MANAGEMENT

2.6.1 Quality assurance program activities, which include those major elements listed below, are performed as described in other sections of this program description.

- Program
- Organization
- Document Control
- Audits and Reviews
- Nonconformance Control
- Corrective Action
- Reporting
- Records

2.6.2 The Vitrification Projects Branch has approved a system in which designated plans and actions are documented, including those affecting quality. This system provides a mechanism where the policies and objectives of the D&Q Quality Assurance Program are defined and documented. Within this system, detailed procedures for the mandatory actions have been prepared, approved, and issued for use as described in Section 5.1 of this document. These procedures define both the action to be performed and the responsible person or group for performing the action.

To provide positive identification and control of required procedures for D&Q quality assurance activities, manuals containing these procedures have been assembled and issued, and are closely controlled. These manuals each contain copies of the quality assurance program implementing documents listed in Figure 2.3.2-1. A brief description of those procedures is contained in Attachment II.

- 2.6.3 The procedures manual is controlled by using a document control log that shows the distribution of each copy by copy number, including the distribution of revisions. The Quality Assurance Program Manager, assisted as needed by the Quality Assurance Specialists, is responsible for this activity, as well as for revising and incorporating changes to the manual. The contents of the procedures manual are reviewed and concurrence documented annually as a minimum, and the manual is updated as required to keep it current.
- 2.6.4 In the execution of the program, if a disagreement arises from a difference of opinion, the principals themselves are encouraged to resolve differences. If they fail to resolve the differences, the problem is presented to successively higher levels of management for resolution. Disagreements are discussed in Section 1.5.1.

2.7 WASTE ACCEPTANCE PROCESS ACTIVITIES

2.7.1 Waste Operations Implementation

Additional quality assurance program activities for waste acceptance process activities of high-level waste form development and qualification leading to production have been established and implemented to satisfy the requirements of DOE/RW-0214. These include the following:

- (1) Establishing and implementing a systematic method by which quality assurance activities are selected and applied to waste acceptance process activities of high-level waste form development and qualification. The selective qualification method implemented will be consistent with the provisions of NUREG-1318, Technical Position on Items and Activities in the High-Level Nuclear Waste Repository Program Subject to Quality Assurance Requirements.
- (2) Establishing and implementing the method of selecting, indoctrinating, and training personnel who perform or verify activities affecting quality in Waste Acceptance Process activities of high-level waste form development and qualification. Before assigning personnel to perform activities affecting quality, the Vitrification Projects Branch ensures the positions are evaluated, and that quality-affecting responsibilities are documented and used as a basis for personnel selection. The persons selected receive appropriate training and indoctrination as defined in

accordance with ANSI/ASME NQA-1, Supplement 2S-4, to ensure they are proficient in the activities they perform. Personnel performing activities affecting quality shall be evaluated annually.

Verification activities that require qualified personnel (e.g., lead auditors, inspectors, testers, nondestructive examiners, auditors) are certified in accordance with the detailed requirements of ANSI/ASME NQA-1 Basic Requirement 2, Supplements 2S-1, 2S-2, 2S-3, and 2S-4, and Appendix 2A-1 and other invoked codes and standards. Supplements 2S-1 and Appendix 2A-1 shall only apply to personnel who conduct inspections and test activities to verify conformance of items to specific requirements for the purposes of acceptance, and to demonstrate that items will perform satisfactorily in service. Personnel who verify activities affecting quality are qualified in the principles, techniques, and requirements of the activity being performed.

Other activities performed by personnel that require qualification have their qualification requirements defined and their qualifications determined and documented as follows:

- Types of positions or tasks requiring qualified personnel are identified and procedures are established for the following areas:
 - Selection of Personnel
 - Training and Indoctrination of Personnel
 - Proficiency Evaluation
 - Recording of Qualifications
- Position descriptions are prepared which define the minimum education and experience requirements for each type of position requiring qualification.
- Personnel selected to fill positions requiring qualification are evaluated to determine if they are qualified. The evaluation includes verification of education and experience. Such determinations are documented by managers or supervisors responsible for the activities to be performed.
- For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and date of attendance.
- Appropriate management monitors the performance of individuals involved in activities affecting quality and determines the need for retraining and/or replacement. A system of annual appraisal and evaluation is used to satisfy the determination of satisfactory continued performance.

- (3) A systematic overview is established and implemented for quality assurance activities performed by organizations over which the Vitrification Projects Branch has administrative overview responsibilities. The overview practice includes the following activities:
- Review and acceptance of Operations Offices' quality assurance plans and implementing procedures.
 - Surveillance of Operations Offices' activities affecting quality to verify compliance with requirements and quality of work in progress. Surveillance reports identify the item or activity under surveillance; the persons who conducted the surveillance; the persons contacted; the applicable requirements that were reviewed; summaries of deficiencies, nonconformances, and potential quality problems observed; and the immediate corrective action taken. The persons who perform surveillances are knowledgeable in, and not directly responsible for, the activities under surveillance.
 - Performance of quality assurance audits to verify the adequacy and effectiveness of Operations Offices' quality assurance program activities.

The Vitrification Projects Branch plans and performs these activities as follows:

- Procedures for the review of Operations Offices' quality assurance programs are established to verify adequacy, completeness, and relevance. The overview procedures identify the types of documents submitted by the Operations Offices participant for review and approval; assign responsibility for reviews (either to the quality assurance organization or other designated organizations knowledgeable in quality assurance controls); and identify the methods for documenting review and approval actions.
- Procedures are established for planning, scheduling, performing, and documenting surveillance of Operations Offices' activities related to quality. Surveillance activities are performed by personnel who are not directly responsible for performing the work to be monitored or observed during the surveillance activity. Surveillance activities are performed to written checklists or plans whenever practical.

Surveillance reports identify the item or activity under surveillance, the persons who conducted the surveillance, the persons contacted, the applicable requirements that were

reviewed, summaries of deficiencies, nonconformances and potential quality problems observed, and the immediate corrective action taken. All deficiencies, nonconformances, and potential quality problems identified during the surveillance are documented and monitored until verification of disposition or corrective action is accomplished.

- Procedures are established for planning, scheduling, performing, and reporting quality assurance internal audits and audits of Operations Offices' quality assurance programs. Audit schedules are developed annually and updated as changes occur. Audits of organizations common to more than one project are coordinated whenever practicable to conserve resources.

Audit teams include, whenever possible, a representative that is trained and/or qualified in the technology being audited.

- Documentation of overview activities are retained as quality records in accordance with Section 17.

(4) Methods and procedures are established and implemented for evaluating the effectiveness of the D&Q Quality Assurance Program in ensuring compliance with program requirements. The effectiveness evaluation practice includes the following:

- Annual independent management evaluation by persons above and outside the quality assurance organization
- A clear identification of the quality characteristics to be achieved in meeting the requirements of each WAS
- The identification of an appropriate set of performance indicators that reflect actual quality characteristics being achieved
- A performance-measuring process using review, surveillance, inspection, tests, audit, or other techniques to monitor performance indicators
- An analysis process in which performance data is trended and problem areas are identified
- A reporting practice in which program effectiveness information is prepared and fed back to top management

(5) The format and content of the major participants' quality assurance program descriptions are evaluated against the acceptance criteria of DOE/RW-0214.

- (6) Upon original issue, and after issue of each revision, the HLW Quality Assurance Program Description will be submitted to RW for review and acceptance. The submittal will be for review and acceptance in accordance with Section 2.1 of DOE/RW-0214. Comments will be resolved and any changes will be incorporated in the next revision of the Quality Assurance Program Description.

2.7.2 Requirements of Operations Offices

Each Operations Office that is assigned quality assurance program activities is required to implement and maintain a quality assurance program that fulfills the assigned quality assurance requirements. This includes the following activities:

- (1) Readiness reviews are planned, scheduled, and conducted at selected significant transitional events in Waste Acceptance Process activities of development and qualification. This will ensure that work activity prerequisites have been satisfied, procedures have been reviewed for adequacy and appropriateness, and personnel are trained and qualified before subsequent activity initiation is authorized. Readiness reviews are conducted in accordance with DOE Guidelines for Application of Readiness Reviews to Department of Energy Activities, dated January 1987.
- (2) A systematic method is established and implemented to identify quality assurance activities and items. The requirements and controls are selectively applied to waste acceptance process items and development and qualification activities. The selective application is based on importance, complexity, reliability, history, and regulatory significance of the item or activity.

Operations Offices will require Waste Form Producers to implement NUREG-1318, Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements. The listing of Waste Acceptance Process Activities Relating to Qualification of the Product is Attachment I to this QAPD.

- (3) The method of selecting, indoctrinating, and training personnel who perform or verify activities affecting quality is established and implemented by the Operations Office to ensure they are proficient in the activities they perform. Before assigning personnel to perform activities affecting quality, project participants ensure they receive appropriate training and indoctrination, as defined in Section 2.7.1(2).

Verification activities that require qualified personnel (e.g., lead auditors, inspectors, testers, nondestructive examiners,

auditors) are certified in accordance with the detailed requirements of ANSI/ASME NQA-1 Basic Requirement 2, Supplements 2S-1, 2S-2, 2S-3, and 2S-4, and Appendix 2A-1. Supplement 2S-1 and Appendix 2A-1 apply only to personnel who conduct inspections and test activities to verify conformance of items to specific requirements for the purposes of acceptance, and to demonstrate that items will perform satisfactorily in service.

Other activities performed by personnel that require qualification have their qualification requirements defined and their qualifications determined and documented as follows:

- Types of positions or tasks requiring qualified personnel are identified and procedures are established for the following areas:
 - Selection of Personnel
 - Training and Indoctrination of Personnel
 - Proficiency Evaluation
 - Recording of Qualifications
 - Position descriptions are prepared which define the minimum education and experience requirements for each type of position requiring qualification.
 - Personnel selected to fill positions requiring qualification are evaluated to determine if they are qualified. Such determinations are documented by managers or supervisors responsible for the activities to be performed.
- (4) A systematic overview is established and implemented for quality assurance activities performed by organizations over which Operations Offices have contractual or administrative overview responsibilities. Operations Offices' overview practices include the following activities:
- Review and acceptance of contractor quality assurance plans and implementing procedures
 - Surveillance of contractor activities affecting quality to verify compliance with requirements
 - Performance of quality assurance audits to verify the adequacy and effectiveness of contractor quality assurance program activities

Operations Offices plan and perform these activities as follows:

- Procedures are established for the review of contractor quality assurance programs to verify adequacy, completeness, and relevance. The overview procedures identify the types of documents submitted by contractors for review and approval; assign responsibility for reviews; and identify the methods for documenting review and approval actions.
 - Procedures are established for planning, scheduling, performing, and documenting surveillance of contractor activities related to quality. Surveillance activities are performed by personnel who are not directly responsible for performing the work to be monitored or observed in the surveillance activity. Surveillance activities are performed to written checklists or plans whenever practicable. All deficiencies, nonconformances, and potential quality problems identified during the surveillance are documented and monitored until verification of disposition or corrective action is accomplished.
 - Procedures are established for planning, scheduling, performing, and reporting quality assurance audits of contractor quality assurance programs. Audit schedules are developed annually and updated as changes occur. Audits of organizations common to more than one project are coordinated whenever practical to conserve resources and maintain consistency. Audit teams include, whenever possible, a representative that is trained and/or qualified in the technology being audited.
- (5) Methods and procedures are established and implemented for evaluating the effectiveness of Operations Offices' quality assurance programs in ensuring compliance with their WAS. The effectiveness evaluation practice includes the following:
- A clear identification of the quality characteristics to be achieved in meeting the requirements of their WAS
 - The identification of an appropriate set of performance indicators that reflect actual quality characteristics being achieved
 - A performance measuring process using review, surveillance, inspection, tests, audit, or other techniques to monitor performance indicators
 - An analysis process in which performance data is trended and problem areas identified
 - A reporting practice in which program effectiveness information is prepared and fed back to top management

- 2.7.3 Vitrification Projects Branch monitors Operations Offices' quality assurance program activities related to waste acceptance process activities of high-level waste form development and qualification, and periodically audits those activities to ensure proper implementation and adequacy.

3.0 DESIGN CONTROL

3.1 WASTE OPERATIONS IMPLEMENTATION

3.1.1 Except for selected technical and peer reviews, Waste Operations delegates the responsibility for design control activities, including operational readiness reviews, to Operations Offices. The selection of the reviews is the option of the Vitrification Projects Branch Chief. For the selected reviews, procedures are established to ensure that each review is documented. The documentation identifies, as a minimum, the reviewers, the area or features reviewed, the comments of the reviewers, and the resolution of the comments.

3.2 REQUIREMENTS OF OPERATIONS OFFICES

3.2.1 Operations Offices are required to exercise design control practices in accordance with specified requirements to ensure that these activities are planned and controlled in a systematic manner. These practices include the following:

- (1) The scope of design control includes design activities associated with the preparation and review of design documents, including the correct translation of applicable requirements and design bases into design, procurement, and procedural documents.
- (2) Organizational responsibilities are described for preparing, reviewing, approving, and verifying design documents such as system descriptions, design input and criteria, design drawings, design analyses, computer programs, specifications, and procedures.
- (3) Errors and deficiencies in approved design documents, including design methods (such as computer codes), that could adversely affect waste acceptance process activities are documented; action is taken to ensure that all errors and deficiencies are corrected.
- (4) Deviations from specified quality standards are identified and procedures are established to ensure their control.
- (5) Internal and external design interface controls, procedures, and lines of communication among participating design organizations and across technical disciplines are established and described. This will facilitate the review, approval, release, distribution, and revision of documents involving design interfaces, and ensure items are compatible geometrically, functionally, and with processes and environment. Design inputs are specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions,

accomplishing design verification measures, and evaluating design changes.

- (6) Procedures are established and described requiring a documented check to verify the dimensional accuracy and completeness of design drawings and specifications.
- (7) Procedures are established and described requiring that design drawings and specifications be reviewed by the Operations Office quality assurance organization. This is to ensure the documents are prepared, reviewed, and approved in accordance with applicable procedures, and that the documents contain the necessary quality assurance requirements such as inspection and test requirements, acceptance requirements, and the extent of documenting inspection and test results.
- (8) Guidelines or criteria are established and described for determining the method of design verification (design review, peer review, alternate calculations, or test). Procedures are established to ensure a design or technical review is documented. The documentation, as a minimum, identifies the reviewers, the area or features reviewed, the comments of the reviewers, and the resolution of the comments.
- (9) Procedures are established and described for design verification activities which ensure the following:
 - The verifier is qualified and is not directly responsible for the design (i.e., neither the performer or the performer's immediate supervisor). In exceptional circumstances, the designer's immediate supervisor can perform the verification provided the following are true:
 - The supervisor is the only technically qualified individual.
 - The need is individually documented and approved in advance by the supervisor's management.
 - Quality assurance audits cover frequency and effectiveness of use of supervisors as design verifiers to guard against abuse.
 - The need is individually documented and approved by the Quality Assurance Manager prior to performing the review.
 - Design verification, if other than by qualification testing of a prototype or lead production unit, is completed before the design is released for procurement, manufacturing, construction,

or to another organization for use in other design activities. In those cases where this timing cannot be met, the design verification may be deferred, providing that the justification for this action is documented and the unverified portion of the design output document and all design output documents, based on the unverified data, are appropriately identified and controlled.

Development and qualification activities associated with a design or design change should not proceed without verification past the point where the installation or operation would become irreversible (i.e., require extensive rework). In all cases, the design verification should be complete before relying upon the item or activity to perform its function.

- Procedural control is established for design documents that reflect the commitments of the Safety Analysis Report; this control differentiates between documents that receive formal design verification by interdisciplinary or multi-organizational teams and those which can be reviewed by a single individual (a signature and date is acceptable documentation for personnel certification).

Design documents subject to procedural control include, but are not limited to, specifications, calculations, computer programs, system descriptions, Safety Analysis Report when used as a design document, and drawings including flow diagrams, piping and instrument diagrams, control logic diagrams, electrical single line diagrams, important structural systems, site arrangements, material balance sheets, and equipment locations. Specialized reviews should be used when uniqueness or special design considerations warrant.

- Procedures identify the responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation.

(10) The following provisions are included if the verification method is only by test:

- Procedures provide criteria that specify when verification should be by test.
- Prototype, component, or feature testing is performed as early as possible before installing equipment, or before the point at which the installation would become irreversible.
- Verification by test is performed under conditions that simulate the most adverse design conditions as determined by analysis.

- (11) Design and specification changes, including field changes, are subject to the same design controls that were applicable to the original design. Changes are communicated to affected organizations for evaluation of the impact on their responsibilities, their procedures, and the training of personnel.
- (12) Procedures are established to ensure that verified computer codes are certified for use and that their use is specified.
- (13) Practices are established and implemented for the control of software that is essential to meeting the applicable WAS. These practices are developed, implemented, documented, and controlled in accordance with the following:
 - Software to be controlled is identified in the Waste Form Compliance Plan and documented. The documentation appropriately reflects the provisions of the Nuclear Regulatory Commission's NUREG-0856, Final Technical Position on Documentation of Computer Codes for High-Level Waste Management.
 - Computer software controls pertaining to the control of software that is essential to meeting the Waste Acceptance Specification shall be consistent with Section 3.3 of DOE/RW-0214.
- (14) Technical reviews (which includes Readiness Reviews) are identified, planned, conducted, controlled, and documented. Technical reviews are specified in the following instances:
 - When the information or document is within the state of the art and is based on accepted standards, criteria, principles and practices.
 - When the document, activity, material, or data require verification or validation. The individuals performing technical reviews shall have sufficient knowledge of and experience in the area under review to render an opinion. These individuals shall be independent of those who performed the work.
 - When a significant phase of a work is completed, a Readiness Review, as described in 2.7.2.(1), is conducted.
- (15) Peer reviews are identified, planned, conducted, and controlled for items or data significant to waste acceptance process activities which go beyond the existing technology or where conclusions or assumptions have not been clearly validated by conventional means. Peer review methods and procedures shall reflect the

provisions of NUREG-1297, Generic Technical Position on Peer Review for High-Level Waste Repositories.

(16) Experiments, including development activities, are controlled and documented in a manner which ensures the following:

- The data will be suitable for its intended use
- The activities can be independently reconstructed and evaluated

Controls for experiments and developmental activities address the following:

- Responsibility for initiating experiments and developmental activity
- Selection of qualified personnel
- Review and approval of procedures
- Surveillance and auditing of experiments and developmental activities
- Review and evaluation of the results of experiments and developmental activities
- Documentation of experiments and developmental activities and results
- Responsibility for preparation and retention of documentation

Experiments and development activities in progress are documented on a day-to-day basis and are maintained in retrievable form.

Experimental and developmental records contain the following, either directly or by reference:

- Purpose of the experiment or development activity
- The person(s) initiating and performing the experiment or developmental activity
- Identification of equipment, materials, and procedures actually used in sufficient detail to allow an individual skilled in the technology to reproduce the results
- Original records of data or facsimiles of the original records

Summaries, reports, or evaluations of the experiments or developmental activities (including their results) are clearly referenced in the experimental records.

Experimental or developmental records are collected and maintained as quality records (see Section 17).

- (17) Data or data interpretations are normally acquired or produced under a quality assurance program. Data or data interpretations that were generated outside of a quality assurance program (for whatever reason), as defined in this document, are only accepted based upon the results of a peer review or based on qualification through corroborating data, confirmatory testing, or by having been acquired or produced under an equivalent quality assurance program. Such reviews or other qualification activities are conducted as specified in NUREG-1298, Qualification of Existing Data for High-Level Waste Repositories.

Data that are erroneous, rejected, superseded, or otherwise unsuitable are clearly identified as nonconforming. Such data, before being used, are subjected to the same control and review as data generated outside of a quality assurance program as described above.

- (18) Controls are established and implemented to ensure only approved modifications are made. These controls include the following:
- The application of these controls to items and activities that are essential to canistered waste form certification and acceptance as defined in the applicable WAS, including the following as appropriate:
 - The waste form
 - The waste canister
 - The canistered waste form
 - The production process
 - Processing equipment
 - Processing supplies and consumables
 - Processing plans and procedures
 - Maintenance plans and procedures
 - Process control plans and procedures
 - A controlled listing of the documentation that defines items and activities under modification control
 - Procedures defining elements of the modification control process that address the following:

- Change proposals (including deviation requests and waiver request)
 - Change review and approval
 - Change implementation
 - Change incorporation and issue of changed documentation and records
- Provisions for assessing the need for and accomplishing any needed requalification resulting from modifications
- (19) The definitions of design, design information, and design activities used in the design control program refer to specifications, drawings, design criteria, and component performance requirements for the Waste Acceptance Process activities of high-level waste development and qualification. It includes design inputs and outputs at each stage of design development (i.e., from conceptual design to final design).

Design information and design activities refer to data collection and analyses activities and computer codes that are used in supporting design development and verification. This includes general plans and detailed procedures for data collection and analyses, and related information such as test results and analyses. Data analyses includes the initial step of data reduction, as well as broad level systems analyses (such as performance assessment) which integrate many other data and analyses of individual parameters. The above is consistent with the definition and usage of these terms in 10 CFR Part 60 and the Atomic Energy Act of 1954.

- 3.2.2 The Vitrification Project Branch monitors Operations Offices' design control practices related to development and qualification activities and periodically audits those practices to ensure proper implementation and adequacy.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 WASTE OPERATIONS IMPLEMENTATION

4.1.1 Waste Operations conducts two types of procurement activities:

- (1) The assignment of program execution responsibilities to the appropriate Operations Office(s). This is accomplished through Program Execution Guidance documents. Waste Operations controls the Program Execution Guidance documents by complying with the DOE Orders that control the administrative and financial process. Implementing procedures control the review of Program Execution Guidance Documents to ensure that appropriate quality assurance requirements are included.
- (2) The procurement of administrative support contractors through completion bids. Administrative support contracts are the vehicle through which Headquarters obtains technical support in carrying out its management duties. Such contracts specify both the technical and quality assurance requirements as well as administrative and financial considerations. These contracts are controlled by DOE administrative procedures, DOE Orders, as well as the Federal Acquisition Regulations (FARs) and Department of Energy Acquisition Regulation (DEARs).
- (3) In procurement activities, other than those specified in 4.1.1(1) and 4.1.1(2), Waste Operations assigns execution responsibility for procurement document control to Operations Offices.

4.2 REQUIREMENTS OF OPERATIONS OFFICES

4.2.1 Operations Offices are required to implement and maintain a procurement document control practice that fulfills the assigned quality assurance requirements. This practice will provide for grading requirements appropriate to the item and will include the preparation of procurement documents to contain the following:

- (1) Scope of Work
- (2) Technical and Regulatory Requirements
- (3) Quality Assurance Program Requirements
- (4) Right of Access
- (5) Special Quality Assurance Requirements which must be complied with and specified in the Supplier's Quality Assurance Program
- (6) Documentation Requirements
- (7) Nonconformance Control
- (8) Transfer of Requirements to Lower-tier Participants

4.2.2 This practice will also include the following:

(1) Organizational responsibilities, including the involvement of the quality assurance organization, are described for the following:

- Procurement planning
- Preparation, review, approval, and control of procurement documents
- Supplier selection
- Bid evaluation
- Review and acceptance of supplier quality assurance programs
- Document Control (Release, Distribution, and Change)

4.2.3 Vitrification Projects Branch monitors Operations Offices' procurement document control practices related to development and qualification activities, and periodically audits those practices to ensure proper implementation and adequacy.

5.0 INSTRUCTIONS, PROCEDURES AND DRAWINGS

5.1 WASTE OPERATIONS IMPLEMENTATION

- 5.1.1 Waste Operations has established a management procedures system (see Attachment II, Standard Practice Procedure Descriptions). The procedures prescribe methods for performing quality-related activities in support of development and qualification activities, including quantitative or qualitative acceptance criteria for determining if prescribed activities have been satisfactorily accomplished. These procedures also assign specific responsibilities for performing these activities. Through these procedures, input to the following types of documents is provided:
- Procedures
 - Reports
 - Supporting Records
 - Quality Assurance Program Description
- 5.1.2 The procedures used by the Vitrification Projects Branch are prepared in accordance with a procedure (procedures procedure) that prescribes the format to be followed and the identification system to be used. The procedures are organized under a management procedures system. The system is administered by a procedures coordinator who controls the issue of procedures to ensure coordination and consistency in format, content, etc.
- 5.1.3 The Vitrification Projects Branch Chief, assisted as needed by the Quality Assurance Program Manager and the Quality Assurance Specialists, participates in and monitors the execution of these practices related to development and qualification activities. Periodically, the Branch Chief, assisted as needed by Quality Assurance Program Manager, audits or arranges for independent audit of these practices to ensure implementation and adequacy.
- 5.1.4 Procedures, instructions, and drawings prepared by or issued by EM shall be subject to an independent, documented review. The procedures procedure requires that the reviewer be qualified.
- 5.1.5 The practice of documenting in writing the requirements for and the results of activities affecting quality is executed in accordance with document control procedures identified in Section 6.0 of this document.

5.2 REQUIREMENTS OF OPERATIONS OFFICES

- 5.2.1 Operations Offices are required to establish and implement a practice of prescribing in documented form those activities that fulfill the quality assurance requirements. This practice will include the preparation of the following types of documents:

- (1) Policies, procedures, and instructions
- (2) Quality records
- (3) Quality status reports
- (4) Design specifications, to include quantitative acceptance criteria such as dimensions, tolerances, and operating limits
- (5) Design, manufacturing, construction, and installation drawings, to include as-built drawings that accurately reflect the actual process, processing equipment, and canistered waste form configuration applicable to waste acceptance process activities
- (6) System design descriptions
- (7) Manufacturing, construction, installation, inspection, and testing or process and product specifications, procedures, and instructions, to include qualitative acceptance criteria such as workmanship samples
- (8) Test procedures
- (9) Quality assurance program description and input to Safety Analysis Reports

5.2.2 Vitrification Projects Branch monitors Operations Offices' documentation practices related to development and qualification activities, and periodically audits those practices to ensure proper implementation and adequacy.

6.0 DOCUMENT CONTROL

6.1 WASTE OPERATIONS IMPLEMENTATION

- 6.1.1 Waste Operations has established and implemented a document control system, in support of development and qualification activities, that fulfills the quality assurance program requirements and applies to those types of documents prepared by EM and identified in Section 5 of this program description. Quality assurance requirements are properly stated, are adequate, and are included prior to implementation. The Quality Assurance Program Manager and the Quality Assurance Specialists review the document control system and confirm its readiness to function prior to implementation.
- 6.1.2 Vitrification Projects Branch documents that are related to quality or that affect quality assurance activities are controlled by procedures. These procedures address the following:
- (1) Uniformity of format of initial and subsequent issuances.
 - (2) Proper identification of the originator and date of origin of a document, and a mechanism for verifying the authenticity of information.
 - (3) Procedures for the review, approval, issuance, and revision of documents by the originating organization are established. These procedures ensure that the technical and quality requirements are correctly included, before release, through reviews by qualified authorized personnel who did not provide input to the document.
 - (4) Initial issuance of documents for use at locations where the activity will be performed prior to commencing the work.
 - (5) Prompt and accurate issuance and distribution, including a mechanism for receipt control, of both the original document and subsequent document revisions to prevent inadvertent use of superseded material and to replace documents in work areas in a timely manner.
 - (6) 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.
 - (7) Example of controlled documents are this QAPD and the Standard Practice Procedures.
- 6.1.3 Procedures standardize the identification, format, and numbering of controlled documents. These documents are reviewed for adequacy by the Quality Assurance Program Manager, who is assisted as needed by the Quality Assurance Specialists. The draft controlled document is routed

to the appropriate reviewing personnel/organizations. Reviewing personnel and organizations have access to pertinent data and information. Comments of reviewing personnel are resolved before final approval of the document. The review sequence is documented, and the record is retained.

Except for inconsequential editorial changes and correction of obvious errors, changes or revisions are reviewed and accepted by the same organizations that performed the original review and acceptance. When documents which require verification are released prior to verification, they are so identified, and controlled and authorized for release through signature approval; the bases for release are described.

The Branch Chief, assisted by the Quality Assurance Program Manager, establishes an appropriate periodic review schedule for the accepted controlled document. The primary purpose of these reviews is to determine if changes in project or program status have resulted in the need for revisions to the controlled documents.

- 6.1.4 The Vitrification Projects Branch maintains a listing of quality assurance administrative and technical procedures. The procedures in the listing are under receipt control. A receipt page, attached to the transmitted controlled document, requests the person receiving the document to sign and date the page and return it to the procedures coordinator. Upon receipt of the signed page, The procedures coordinator initials the respective distribution listing to reflect accomplishment of transmittal and receipt.

The procedures coordinator also reviews the controlled document distribution listing at least bi-monthly to follow up on any delinquent receipt pages. This distribution listing is a master list which is updated periodically to show current revision, number distributed, location, etc. Revisions to controlled documents are systematically processed with the same procedure as the original. Changes are also reviewed and approved by the same organizations that performed the original review and approvals.

- 6.1.5 The Quality Assurance Program Manager, assisted by Quality Assurance Specialists, participates in and monitors the execution of the document control system related to development and qualification activities. Periodically the Quality Assurance Program Manager, assisted as needed by Quality Assurance Specialists, audits or arranges for independent audit of the document control system to ensure implementation and adequacy.

6.2 REQUIREMENTS OF OPERATIONS OFFICES

- 6.2.1 Operations Offices are required to implement and maintain a document control system in support of development and qualification activities. The systems will control documents relating to quality or affecting

quality assurance activities. The systems will include procedures that control document preparation, identification, review, approval, issue, and distribution. The procedures will address the processing of revisions and will require that revisions be subjected to the same review, approval, issue, and distribution controls that were applied to the original document(s).

- 6.2.2 Vitrification Projects Branch monitors Operations Offices' document control systems related to development and qualification activities, and periodically audits those activities to ensure proper implementation and adequacy.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 WASTE OPERATIONS IMPLEMENTATION

7.1.1 Waste Operations controls two types of procurement activities:

- (1) Waste Operations controls Program Execution by Operations Offices through an overview process which consists of audits, surveillances, and reviews of the assigned execution activities.
- (2) Waste Operations controls Administrative Support Contracts by complying with standard DOE administrative procedures, DOE Orders, and an overview process which consists of audits, surveillances, and reviews of the contracted services. To the extent that the support contractor functions as a direct extension of Headquarters rather than as a subcontractor, the overview will consist of internal audits, surveillances, and reviews.
- (3) For procurement actions other than those specified in 7.1.1(1) and 7.1.1(2), Waste Operations assigns execution responsibility for control of purchased items and services to Operations Offices.

7.2 REQUIREMENTS OF OPERATIONS OFFICES

7.2.1 Operations Offices are required to establish and implement a system for control of procurements, including interfaces between design, procurement, and quality assurance organizations, which will support development and qualification activities. Each system will include the following elements:

- (1) Procurement document preparation, review, and change control
 - Procurement documents identify the documentation (e.g., drawings, specifications, procedures, inspection, and fabrication plans, inspection and test records, personnel and procedure qualifications, and material, chemical, and physical test results) to be prepared, maintained, and submitted as applicable to the purchaser for review and approval.
 - Procurement documents contain or reference the design basis technical requirements, including the applicable regulatory requirements, components, and material identification requirements, drawings, specifications, codes and industrial standards, test and inspection requirements, and special process instructions for such activities as materials testing and analysis, welding, heat treating, nondestructive testing, and cleaning.

- Procurement documents identify the applicable requirements which must be complied with and described in the supplier's quality assurance program.
- Procurement documents identify those records which shall be retained, controlled, maintained, or delivered to the purchaser prior to use of data or installation of hardware or software.
- Procurement documents contain the procuring agency's right of access to supplier's facilities and records for source inspection and audit.
- Procurement documents provide for spare or replacement parts being subject to controls at least equivalent to those used for the original equipment.
- All changes and revisions to procurement documents are subject to the same review and approval requirements as the original documents.
- Procurement documents are retained in records storage for retrievability, as necessary.

(2) Selection of procurement sources

- Qualified personnel evaluate the supplier's capability to provide services and products of acceptable quality.
- Quality assurance, scientific, and engineering personnel participate in the evaluation of those suppliers providing critical items.
- The evaluation of suppliers is based on one or more of the following:
 - The supplier's capability to comply with the elements of ANSI/ASME NQA-1 that are applicable to the type of item or service being procured.
 - A review of previous records and performance of suppliers who have provided similar articles of the type being procured.
 - A survey of the supplier's facilities and quality assurance program practices to determine their capability to supply a product which meets the design, manufacturing, testing, and quality assurance requirements. Results of these surveys are to be documented and filed at the buyer's facility. If the "CASE" Register is used to establish the qualifications of

the supplier, the documentation on file is to identify the audit used.

(3) Bid evaluation award

- Bid evaluation is performed to determine the extent of conformance to the procurement documents. This evaluation is performed by individuals or organizations designated to evaluate the following subjects, as applicable to the type of procurement:
 - Technical consideration
 - Quality assurance requirements
 - Supplier's personnel
 - Supplier's production capability
 - Supplier's past performance
 - Alternates
 - Exceptions
- Prior to the award of the contract, unacceptable quality conditions resulting from the bid evaluation are resolved or commitments are obtained for their resolutions.

(4) Purchaser's control of supplier's performance

- To ensure conformance to purchase order requirements, surveillance of suppliers during fabrication, inspection, testing, and shipment of items is planned and performed, with quality assurance organization participation, in accordance with written procedures. These procedures provide for the following:
 - Specification of the characteristics or processes to be witnessed, inspected or verified, and accepted; the method of surveillance and the extent of documentation required; and those responsible for implementing these procedures.
 - Audits and surveillance which ensure the supplier complies with all quality and quality assurance requirements. Surveillance is performed on those items where verification of conformance to procurement requirements cannot be determined upon receipt.
 - Where specific quality assurance controls appropriate for nuclear applications cannot be imposed by the purchaser in a practical manner, special quality verification activities to provide the necessary assurance of an acceptable item for commercial "off-the-shelf" items.

(5) Acceptance of item or service

- The item is properly identified; and it corresponds to the identification on the purchase document and with the receiving documentation.
- Prior to installation or use, inspection of items and acceptance records is performed and judged acceptable in accordance with predetermined inspection instructions.
- Prior to installation of use, inspection records or certificates of conformance attesting to the acceptance of items are available at development or qualification site.
- Items accepted and released are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for installation or further work.
- Nonconforming items are segregated when practical, controlled, and clearly identified until proper disposition is made.

(6) Corrective action with regard to the procurement process

- The purchaser and supplier establish and document methods for disposition of items and services that do not meet procurement documentation requirements. These methods contain provisions for the following:
 - Evaluation of nonconforming items
 - Submittal of nonconformance disposition request from supplier with suggested disposition (and justification) for approval
 - Purchaser disposition of supplier recommendation
 - Verification of disposition implementation
 - Maintenance of supplier-submitted nonconformance records

(7) Quality assurance records

- Certifications will specifically identify (e.g., by the purchase order number) the purchased item and the specific procurement requirements (code, standards, specifications, etc.) met by the items.
- Certifications will identify any procurement requirements which have not been met, together with a description of those nonconformances dispositioned "accept as is" or "repair."

- 7.2.2 The review and approval of supplier-furnished data by qualified personnel is performed in accordance with established procedures.
- 7.2.3 Operations Offices review supplier-generated documentation, such as certifications, for completeness, acceptability, and conformance to contract requirements and provide appropriate approval before accepting completed items. Operations Offices routinely or periodically evaluate and verify supplier-furnished material certifications by means of audit, independent inspections, or tests. Operations Offices receipt inspection planning defines the necessary inspections and tests and provides for inspection frequency adjustment depending upon source, quality performance history, lot size, and other factors.
- 7.2.4 Vitrification Projects Branch monitors Operations Offices' procurement practices related to development and qualification activities, and periodically audits those practices to ensure proper implementation and adequacy.

8.0 IDENTIFICATION AND CONTROL OF ITEMS

8.1 WASTE OPERATIONS IMPLEMENTATION

Waste Operations assigns execution responsibility for identification and control of items (including materials and samples) in support of development and qualification activities to the Operations Offices.

8.2 REQUIREMENTS OF OPERATIONS OFFICES

8.2.1 Operations Offices are required to establish and implement identification and control practices to support development and qualification activities. The description of the practices should include organizational responsibilities. The requirements for identification are to be determined during the initial planning stages and their practice will ensure the following:

- (1) Identification of the item is maintained, both on or attached to the item and on records traceable to the item as required throughout fabrication, erection, installation, and use of the item or throughout storage, handling, or testing activities.
- (2) The item(s) can be traced to the appropriate documentation such as drawings, specifications, technical reports, test records, purchase orders, manufacturing and inspection documents, deviation reports, and physical and chemical test reports.
- (3) The method and location of identification does not affect the function or quality of the item being identified.
- (4) Prior to the release for fabrication, assembly, shipping, and installation or testing, items are correctly identified and the identification is verified.

8.2.2 These practices are designed to preclude the use of incorrect or defective materials and parts important to the development and qualification of an acceptable canistered waste form product.

8.2.3 Vitrification Projects Branch monitors Operations Offices' identification and control of item practices related to development and qualification activities, and periodically audits those practices to ensure proper implementation and adequacy.

9.0 CONTROL OF PROCESSES

9.1 WASTE OPERATIONS IMPLEMENTATION

Waste Operations assigns execution responsibility for control of processes in support of development and qualification activities to Operations Offices.

9.2 REQUIREMENTS OF OPERATIONS OFFICES

9.2.1 Operations Offices are required to establish and implement practices to ensure adequate performance and control of processes such as melting and cleaning. These practices will include the following elements:

- (1) The criteria are described for determining those processes that are controlled as special processes. A listing of special processes, which are generally those processes where direct inspection is impossible or not advantageous, should be provided.
- (2) The organizational responsibilities are described, including those for the quality assurance program organization, for qualification of special processes, equipment, and personnel, and for prototype testing and technical reviews.
- (3) Procedures, prototype test plans, technical review plans, equipment, and personnel for performance of special processes are qualified in accordance with applicable codes, standards, quality assurance procedures, specifications, or supplementary requirements. The quality assurance organization conducts audits and surveillances of the qualification activities to ensure that they are satisfactorily performed.
- (4) Special processes are performed by qualified personnel using qualified procedures and equipment, with established procedures for recording evidence of acceptable accomplishment.
- (5) Qualification records of procedures, equipment, and personnel associated with special processes are established, filed, and kept current.
- (6) Development and qualification processes that have a significant effect on quality characteristics of the canistered waste form and that produce results that cannot be readily verified by inspection or testing of the final product are to be identified and controlled. The controls which are established and implemented on such processes are performed by qualified personnel using qualified procedures in accordance with specified requirements and include the following provisions:

- Process requirements are specified and maintained in controlled documentation.
 - Process procedures or instructions are prepared and maintained as controlled documents with unique identification and revision status and are readily available in the work area where the process is being performed. These procedures or instructions contain the following as a minimum:
 - Identification of required equipment and instrumentation
 - Identification of control parameters and the operating limits for those parameters
 - Environmental conditions and requirements
 - Instrument calibration frequency
 - Reference to applicable codes, standards, and specifications
- (7) These procedures or instructions are included in controlled documents such as drawings, checklists, travelers, work orders, or specifications. Copies of process requirements, procedures or instructions, and documentation of personnel qualifications are collected and maintained as quality records (see Section 17).

9.2.2 Vitrification Projects Branch monitors Operations Offices' process control practices related to development and qualification activities, and periodically audits those practices to ensure proper implementation and adequacy.

10.0 INSPECTION

10.1 WASTE OPERATIONS IMPLEMENTATION

Waste Operations assigns to Operations Offices the execution responsibility for direct inspection of items and work practices in support of development and qualification activities.

10.2 REQUIREMENTS OF OPERATIONS OFFICES

- 10.2.1 Operations Offices are required to establish and implement an inspection and monitoring practice of sufficient scope to be fully effective. The practice will identify and verify conformance of items and services to the documented specifications, instructions, procedures, and drawings for accomplishing the required activities.

Both inspection and process monitoring will be used when control is inadequate without both. The program will ensure the following:

- (1) Organizational responsibilities for inspection are described and documented. Inspection personnel are independent from the individual or group performing the activity being inspected. If the individuals performing inspections are not part of the quality assurance organization, the inspection procedures, personnel qualification criteria, and independence from undue pressure such as cost and schedule are reviewed for acceptability by the quality assurance organization prior to initiation of the activity.
- (2) Program procedures are developed, with quality assurance organization participation, to provide criteria for determining the accuracy requirements of inspection equipment and the timing of required inspection or definition of how and when inspections are performed.
- (3) Inspection procedures, instructions, and checklists contain the following:
 - Identification of characteristics to be inspected
 - Identification of the individuals or groups responsible for performing the inspection operations
 - Acceptance and rejection criteria
 - A description of the method of inspection
 - Specification of the necessary measuring and test equipment, including accuracy requirements

- Identification of required procedures, drawings, and specifications, including the applicable edition or revision
- (4) Inspection procedures or instructions are available with necessary drawings and specifications for use prior to performing inspection operations.
 - (5) Inspectors [including non-destructive test (NDT) personnel] are qualified in accordance with appropriate codes, standards, and company training programs, and their qualifications and qualification records (certifications) are kept current.
 - (6) Modifications, repairs, and replacements are inspected in accordance with the original design and inspection requirements or acceptable alternatives.
 - (7) Provisions are established that identify mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector.
 - (8) The individuals or groups who perform receiving and process verification inspections are identified.
 - (9) Provisions are established for indirect control by monitoring processing methods, equipment, and personnel if direct inspection is not possible.
 - (10) Inspection results are documented, evaluated, and their acceptability determined by a responsible individual or group.
 - (11) The inspection records shall, as a minimum, identify the following:
 - (a) Item inspected
 - (b) Date of inspection
 - (c) Inspector
 - (d) Inspection procedure
 - (e) Type of observation and characteristics inspected
 - (f) Results or acceptability and identification of inspection criteria or reference documents used to determine acceptance
 - (g) Specific equipment used during the inspection
 - (h) Any special expertise used
 - (i) Information on action taken in connection with nonconformances
 - (12) Provisions are established to ensure inspection support data meets the requirement of Section 3.0.

10.2.2 Vitrification Projects Branch monitors Operations Offices' inspection practices associated with development and qualification activities, and periodically audits those practices to ensure proper implementation and adequacy.

11.0 TEST CONTROL

11.1 WASTE OPERATIONS IMPLEMENTATION

Waste Operations assigns execution responsibility for testing and test control practices in support of development and qualification activities to Operations Offices.

11.2 REQUIREMENTS OF OPERATIONS OFFICES

11.2.1 Operations Offices are required to establish required tests, including proof tests prior to installation, preoperational tests, and product certification tests. Operations Offices also are required to establish a test control practice that includes the following elements:

- (1) Identification of required testing to demonstrate that the item will perform satisfactorily in service; and that testing activities are identified, documented, and accomplished in accordance with written controlled procedures. The test program is conducted by trained and appropriately qualified personnel.
- (2) Written test procedures that incorporate or reference the requirements and acceptance limits contained in applicable design and procurement documents.
- (3) Written test procedures that include the following:
 - Instructions for testing method and test equipment and instrumentation
 - Provisions for the following as appropriate:
 - Calibrated instrumentation
 - Adequate and appropriate equipment, properly maintained
 - Trained, qualified, and licensed or certified personnel
 - Preparation, condition, and completeness of item to be tested
 - Precision and accuracy considerations
 - Suitable and controlled environmental conditions
 - Mandatory inspection hold points for witness by DOE, contractor, or authorized inspector
 - Provisions for data collection and storage
 - Acceptance and rejection criteria
 - Methods of documenting and recording test data and results
 - A listing of test prerequisites and provisions for ensuring test prerequisites have been met
 - Identification of potential sources of uncertainty and error and the affected parameters
- (4) Test results are documented and evaluated, and the acceptance status identified by a qualified, responsible individual or group.

- (5) Modifications, repairs, and replacements are tested in accordance with the original design and testing requirements or acceptable alternates.
- (6) Provisions are established to ensure test control support data meet the requirements of Section 3.0.
- (7) Additionally, test control activities involving archival samples used for waste form qualification or for certification of canistered waste forms are prepared and controlled as follows:
 - Sample preparation and use are planned and documented. The planning identifies the following:
 - What samples are used for (number, size, origin, or other characteristics)
 - Where and when they are taken or prepared
 - Where and how they are kept
 - Where and how they are analyzed
 - When and how the results are used
 - Methods and procedures for sample preparation, maintenance, and use are prepared and used. These cover the following areas as a minimum:
 - Sample taking or preparation
 - Logging and labeling or otherwise identifying
 - Packing, storage, and monitoring
 - Locating, storage, and monitoring
 - Retrieval
 - Analysis
 - Treatment of data and results
 - Sample ultimate disposal
 - Documentation and other forms of evidence necessary to demonstrate the performance of activities essential to the integrity of sample use are collected and maintained as quality records (see Section 17).

11.2.2 Vitrification Projects Branch monitors Operations Offices' test control practices related to development and qualification activities, and periodically audits those practices to ensure proper implementation and adequacy.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 WASTE OPERATIONS IMPLEMENTATION

Waste Operations assigns execution responsibility for control of measuring and test equipment which supports development and qualification activities to Operations Offices.

12.2 REQUIREMENTS OF OPERATIONS OFFICES

12.2.1 Operations Offices are required to establish and implement a system for calibration and control of measuring and test equipment. This system will include the following elements:

- (1) Procedures that describe the calibration technique and frequency; maintenance, storage, and control of all measuring and test instruments, tools, gages, fixtures; reference and transfer standards; and NDT equipment that is used in the measurement, inspection, and monitoring of quality-related items. The review and documented concurrence of these procedures are described, and the organizations responsible for these functions are identified.
- (2) Measuring and test equipment is identified and the calibration test data are identified according to the equipment to which they apply.
- (3) Measuring and test equipment is labeled, tagged, or "otherwise controlled" to indicate the due date of the next calibration and/or servicing. The method of "otherwise controlled" shall be described.
- (4) Measuring and test instruments are serviced and calibrated at specified intervals based on the required accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement.
- (5) Calibrating standards have greater accuracy than the equipment being calibrated unless limited by the state-of-the-art. Calibrating standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by responsible management. The management authorized to perform this function is identified.
- (6) Measures are taken and documented to determine the validity of previous inspections performed and the acceptability of items inspected or tested since the last calibration when measuring and test equipment was found to be out of calibration. Inspections or tests are repeated on items determined to be suspect.

- (7) Reference and transfer standards are traceable to nationally recognized standards; or where national standards do not exist, provisions are established to document the basis for calibration.
- (8) Provisions are established to ensure that measuring and test equipment support data meet the requirements of Section 3.0.
- (9) Additionally, measuring and test equipment control involving computer software that is essential to meeting the WAS is also treated in accordance with Section 3.0.
- (10) Documentation describing the complete status of all items under the calibration system must be maintained.

12.2.2 Vitrification Projects Branch monitors Operations Offices' measuring and test equipment control practices related to development and qualification activities, and periodically audits those practices to ensure proper implementation and adequacy.

13.0 HANDLING, STORAGE, AND SHIPPING

13.1 WASTE OPERATIONS IMPLEMENTATION

Waste Operations assigns execution responsibility for handling, storage, and shipping practices which support development and qualification activities to the Operations Offices.

13.2 REQUIREMENTS OF OPERATIONS OFFICES

- 13.2.1 Operations Offices are required to establish and implement practices for handling, storage, and shipping of items in support of development and qualification activities. These practices will include the following:
- (1) Special handling, preservation, storage, cleaning, packaging, and shipping requirements are specified and accomplished by suitably qualified individuals in accordance with predetermined work and inspection instructions.
 - (2) Procedures are prepared in accordance with design and procurement specification requirements to establish and describe controls for cleaning, handling, storage, packaging, shipping, and preserving items to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity.
 - (3) The methods of handling, storage, and packaging of items and samples take into consideration controls as appropriate for limited life expectancy and special cleanliness.
 - (4) Procedures are prepared to control planning, preparation, collection, and storage of archival samples used for waste form qualification. The procedures will address location, size, and number; preparation; labeling; analysis; storage; retention; and documentation.
- 13.2.2 Vitrification Projects Branch monitors Operations Offices' handling, storage, and shipping practices related to development and qualification activities, and periodically audits those practices to ensure implementation and adequacy.

14.0 INSPECTION, TEST, AND OPERATING STATUS

14.1 WASTE OPERATIONS IMPLEMENTATION

Waste Operations assigns to the Operations Offices the execution responsibility for inspection, test, and operating status measures which support development and qualification activities.

14.2 REQUIREMENTS OF OPERATIONS OFFICES

14.2.1 Operations Offices 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 will include provisions for the following:

- (1) Maintaining the identification of the inspection, test, and operating status of items throughout development and qualification activities
- (2) Controlling the application and removal of inspection and welding stamps and status indicators such as tags, markings, labels, and stamps
- (3) Altering the sequence of or bypassing the required inspections, tests, and other essential operations through controlled, documented measures under the cognizance of the quality assurance organization and subject to the same controls as the original review and approval
- (4) Documenting, identifying, and controlling nonconforming, inoperative, or malfunctioning items to prevent inadvertent use; and identifying the organizations responsible for this function

14.2.2 Vitrification Projects Branch monitors Operations Offices' practices related to development and qualification activities for indicating inspection, test, and operating status, and periodically audits those practices to ensure implementation and adequacy.

15.0 CONTROL OF NONCONFORMING ITEMS

15.1 WASTE OPERATIONS IMPLEMENTATION

15.1.1 Waste Operations, through Vitrification Projects Branch, has established and implemented practices for control, review, and disposition of nonconforming items or activities which support development and qualification activities. These practices are designed to ensure that measures are established to control items or activities which do not conform to defined requirements in order to prevent their inadvertent use. The nonconformance control practice includes the following elements:

- Identification
- Documentation and Reporting
- Segregation and Control
- Review, Evaluation, and Disposition

15.1.2 All reports of deviations that are proposed for disposition in such a way that the finished item or completed service will not conform to the approved requirements, are processed for approval in accordance with procedures that provide a level of approval equivalent to the approval of the original requirements. The Vitrification Projects Branch Chief dispositions reports of deviations. The Quality Assurance Program Manager, assisted by the Quality Assurance Specialists, tracks the status and closes out nonconformances [Deviation and Corrective Action Reports (DCAR)] upon completion of the required corrective action. These reports are quality records and are administered in accordance with Section 17.

15.1.3 Errors or deficiencies reported or discovered, which could adversely affect the development and qualification of an acceptable canistered waste form product or production process and which represent a breakdown in the quality assurance program or deviation from performance specifications, are evaluated by the Vitrification Projects Branch Chief, assisted by the Quality Assurance Program Manager, for consideration as an unusual occurrence under DOE Order 5000.3. Defects or noncompliance in items or activities that are reported to, or discovered by, Vitrification Projects Branch personnel are also evaluated by the Vitrification Projects Branch Chief, assisted by the Quality Assurance Program Manager, for consideration as an unusual occurrence under DOE Order 5000.3. The deficiency, whether an unusual occurrence or not, is further evaluated against the procedural requirements that should have prevented the occurrence. When the procedural system is deficient, the affected organization is required to take whatever steps are necessary to achieve appropriate corrective action to the system to preclude recurrence of the deficiency.

15.1.4 The Vitrification Projects Branch Chief, assisted by the Quality Assurance Program Manager, resolves allegations of inadequate quality,

whether they originate internally or externally. This practice includes the following elements:

- Documentation and Reporting
- Segregation and Control
- Review, Evaluation, and Disposition

15.1.5 The Vitrification Project Branch Chief, assisted by the Quality Assurance Program Manager, also participates in and monitors the execution of the nonconformance control practices related to development and qualification activities, and periodically audits or arranges for an independent audit of the control practices to ensure proper implementation and adequacy.

15.1.6 DCARs are periodically analyzed by the Quality Assurance Program Manager and the Quality Assurance Specialists to show quality trends and to help identify root causes of nonconformances. The significant results are reported to the Vitrification Projects Branch Chief, the Associate Director of Waste Operations, the EM-30 Quality Assurance Manager, and the Manager of the Office of Environmental Quality Assurance/Quality Control for review and assessment.

15.2 REQUIREMENTS OF OPERATIONS OFFICES

15.2.1 Operations Offices are required to establish and implement a practice for the control of nonconforming items or activities in support of development and qualification activities. These nonconformance control practices will include the following elements:

- (1) Nonconforming items or activities are identified, documented, segregated (where practical), reviewed, and dispositioned. Affected organizations are notified of the nonconforming items or activities (including design consideration and computer codes), if the disposition is other than to scrap or rework.
- (2) Documentation identifies the nonconforming item or activities; describes the nonconformance, the disposition of the nonconformance, and the inspection requirements; and includes signature approval of the disposition. Nonconformances are corrected or resolved before initiating the preoperational test program on the item.
- (3) Provisions are established for identifying those individuals or groups, including the quality assurance organization, who are assigned the responsibility and authority to approve the dispositioning and closeout of nonconforming items.
- (4) Nonconforming items are segregated, where practical, from acceptable items and identified as nonconforming until they are properly dispositioned.

- (5) Acceptability of rework or repair is verified by reinspecting the items as originally inspected, or by a method that is at least equal to the original inspection method. Inspection, rework, and repair procedures are documented.
 - (6) Nonconformance reports dispositioned "use as is," "use as repaired," or "use as modified" are made part of the inspection record and forwarded to Operations Office management.
 - (7) Nonconformance reports are periodically analyzed to show quality trends. The significant results are forwarded to management for review and assessment.
- 15.2.2 These practices will ensure that nonconforming items and activities are reviewed and dispositioned in accordance with documented procedures. They will include measures which control further processing, delivery, or installation pending proper disposition of the deficiency.
- 15.2.3 Provisions are established for resolving allegations of inadequate quality. These allegations may originate within the responsible organization(s) or from outside the responsible organization(s).
- 15.2.4 Vitrification Projects Branch monitors Operations Offices' nonconformance control practices related to development and qualification activities and periodically audits nonconformance practices to ensure implementation and adequacy.

16.0 CORRECTIVE ACTION

16.1 WASTE OPERATIONS IMPLEMENTATION

16.1.1 Waste Operations, through the Vitrification Projects Branch, has established and implemented a system for corrective action for conditions which affect the development and qualification of an acceptable canistered waste form product and/or production process. This corrective action system requires conditions adverse to quality such as failures, nonconformances, malfunctions, deficiencies and defective material and equipment be reported through nonconformance and unusual occurrence reporting procedures. Quality assurance activities found deficient in reviews and audits of Operations Offices are also reported. The corrective action system includes the following elements:

- (1) Evaluation of nonconformances to determine the need for corrective action and significant conditions adverse to quality. Evaluation is in accordance with established procedures and criteria. Corrective action is required for nonconformances that are significant conditions adverse to quality, repetitive, or concern inadequate disposition of deviations.
- (2) Corrective action includes identification of root cause(s) and action to prevent recurrence.
- (3) Documented review, by a quality assurance specialist, to determine adequacy of the corrective action.
- (4) Follow up reviews by quality assurance specialists to verify the proper implementation of the corrective action.
- (5) Identification of significant conditions adverse to quality, identification of the root cause(s), resolution of generic implications, trending [reference Section 1.3.1(3)], and review by an appropriate level of Waste Operations management. This documented review includes the definition of corrective action and the action to prevent recurrence.

16.1.2 The Vitrification Projects Branch Chief, assisted by the Quality Assurance Program Manager and the Quality Assurance Specialists, executes the corrective action system relating to development and qualification activities, and arranges for periodic independent audit of the system to ensure implementation and adequacy.

16.2 REQUIREMENTS OF OPERATIONS OFFICES

16.2.1 Operations Offices are required to establish and implement a corrective action system which supports development and qualification activities. Each system will include the following elements:

- (1) Evaluation of nonconformances to determine the need for corrective action. Evaluation is in accordance with established procedures. Corrective action is required for nonconformances that are significant conditions adverse to quality, repetitive, or concern inadequate disposition of deviations.
- (2) Corrective action includes identification of root cause(s) and action to prevent recurrence.
- (3) Documented review, by the Operations Office quality assurance organization to determine adequacy of the corrective action.
- (4) Follow up reviews by the Operations Office quality assurance organization to verify the proper implementation of the corrective action.
- (5) Identification of significant conditions adverse to quality, identification of root cause(s), trending, resolution of generic implications, and review by appropriate levels of management. This documented review includes the definition of corrective action and the action to prevent recurrence.

16.2.2 Vitrification Projects Branch monitors Operations Offices' corrective action systems related to development and qualification activities, and periodically audits those activities to ensure implementation and adequacy.

17.0 QUALITY ASSURANCE RECORDS

17.1 WASTE OPERATIONS IMPLEMENTATION

17.1.1 Waste Operations, through the Vitrifications Project Branch, has established a quality assurance records system for collecting, storing, and maintaining Vitrification Projects Branch-prepared records in support of development and qualification activities.

b Waste Operations will identify in the WCP and/or the WQR those quality records required to be a permanent part of the overall canistered waste form product certification package. These quality records will be identified, packaged, and transferred to RW in accordance with the following:

1. The records package will be identified as either QRP x.x.x. (Quality Records Package), ARP x.x.x (Administrative Record Package), or RTP x.x.x (Record Turnover Package), with the "x.x.x" being the DOE-designated project identifier.
2. The Waste Form Producers do not assign Quality Levels to Waste Acceptance Process activities. However, all activities relating to the quality of the canistered waste form and its PR will be accomplished under a quality assurance program that is equivalent to a Quality Level I (QL-I) program within RW. As a result, QL-I will be the Quality Level identifier for all quality records sent to RW by the Waste Form Producers.
3. A Table of Contents will accompany the package, with the above package identifier and Quality Level in the upper right corner of the first page.
4. The records package will be sent to RW using a transmittal form.

c The Vitrification Project Branch's record management system includes the following elements:

- The scope of the records program is described which ensures that sufficient records affecting quality are identified, maintained and able to be retrieved. Quality assurance records include reports of audits, surveillances and monitoring of work performance; qualification of personnel; procedures; technical reports; records of management assessments; and deviation, corrective action, and trend reports.
- Responsibilities are described for the definition and implementation of record activities, particularly in the retention and safe storage of records.

- Records are legible, accurate, authenticated, identified, and retrievable.
 - Responsibilities and requirements are detailed for record creation, transmittal, retention, and maintenance consistent with applicable codes, and standards.
 - Suitable facilities for the storage of records are described and utilized.
 - Work not directly associated with the records program is prohibited within the records storage facility.
 - Smoking, eating, or drinking is prohibited throughout the records storage facility.
 - Criteria are established and described for determining when a document becomes a quality assurance record subject to the controls of this section and the retention periods for such records.
 - Controls are established and described for controlling, protecting, and maintaining those records before they are entered and stored in the quality record control storage area.
 - Methods of documenting/recording, reviewing, and confirming accuracy of records are described. Those records include laboratory and field notebooks and log books, data sheets, data reduction documents, and software.
- 17.1.2 Vitrification Projects Branch has assigned execution responsibility for other records preparation and collection, storage, and maintenance related to development and qualification activities to the Operations Offices.
- 17.1.3 The Quality Assurance Program Manager, assisted as needed by Quality Assurance Specialists, participates in and monitors the implementation of the records system related to development and qualification activities. Periodically the Quality Assurance Program Manager audits or arranges for independent audit of the records system to ensure implementation and adequacy.
- 17.2 REQUIREMENTS OF OPERATIONS OFFICES**
- 17.2.1 Operations Offices are required to maintain a quality assurance records system which supports development and qualification activities. Each records system will contain provisions that ensure the following:
- (1) Quality assurance records are identified and maintained to provide documentary evidence of the quality of items and the activities affecting quality.

- (2) Quality assurance records include, but are not limited to operating logs; results of reviews, inspections, tests, audits, and material analyses; monitoring of work performance; qualification of personnel, procedures, and equipment; and other documentation such as design documents, drawings, specifications, procurement documents, maintenance and servicing reports, calibration procedures and reports, and nonconformance and corrective action reports.
- (3) Records are legible, accurate, authenticated, identified, and retrievable.
- (4) Requirements and organizational responsibilities for record transmittals, retention, and maintenance subsequent to completion of work are consistent with applicable codes, standards, and procurement documents.
- (5) Inspection and test records contain the following:
 - Identification of the procedure
 - A description of the type of observation
 - Evidence of completing and verifying a manufacturing, inspection, or test operation
 - The date and results of the inspection or test
 - Information related to nonconformances and other conditions adverse to quality
 - Inspector or data recorder identification
 - A statement as to the acceptability of the results
 - Action taken to resolve any discrepancies noted
- (6) Operations Offices' documentation sufficient to demonstrate canistered waste form compliance with their WAS is prepared and maintained as quality records. The quality assurance records transferred to RW shall be legible, accurate, and complete; and properly identified for RW records processing in accordance with the records identification criteria of RW-0194, Section A.3.1.

Operations Offices' documentation that is sufficient to demonstrate satisfactory implementation of their WCPs and completion of WQRs is collected and maintained as lifetime quality records by the major participant that generated or caused the

generation of the documentation. 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 documentation generated during preparation and implementation of the WCP and WQR is collected and maintained as nonpermanent quality records.

- (7) Record storage facilities are constructed, located and secured to prevent destruction of the records by fire, flooding, theft, and deterioration by environmental conditions such as temperature or humidity; or provisions are made for duplicate storage of records.
- (8) Smoking, eating, or drinking is prohibited throughout the records storage facility. Work not directly associated with the records program is prohibited in the records storage facility.

17.2.2 Vitrification Projects Branch monitors Operations Offices' quality assurance records systems related to development and qualification activities through periodic audits to ensure implementation and adequacy.

18.0 AUDITS

18.1 WASTE OPERATIONS IMPLEMENTATION

18.1.1 Waste Operations, through Vitrification Projects Branch, has established and implemented a quality assurance audit practice ^{that} which supports development and qualification activities to provide a comprehensive, independent verification and evaluation, both internally and externally, of the status and adequacy of the overall D&Q Quality Assurance Program, including methods, quality-related procedures and activities. This practice involves all levels of management and includes the EM program as well as the programs of the Operations Offices and their contractors and suppliers. This practice is also designed to ensure that procedures and activities are meaningful and comply with the overall D&Q Quality Assurance Program requirements. The practice includes the following elements:

- (1) Planning
- (2) Conduct
- (3) Reporting
- (4) Follow-Up and Closeout

18.1.2 ^a The quality assurance audit practice was established by EM with the scope and frequency of the audits planned and scheduled to support the development and qualification of an acceptable canistered high-level waste form product. Audits are planned in a general way on an annual basis, with a more detailed plan and schedule prepared and issued on a quarterly basis. Audits are planned to cover not only the evaluation of internal practices of EMs program but also to cover the practices of each of the Operations Offices. The need for an external audit of new contractors will be evaluated after the award of the contract.

^b Each audit plan for each Operations Office 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 Operations Offices' program, identified elements of interface control are evaluated with respect to each Operations Offices' internal activities, as well as interfacing activities with contractors.

✓ The audit plan is supplemented by unscheduled audits where the need becomes evident.

18.1.3 ^a Each audit is conducted to pre-established written procedures and a plan. The detailed plan for the audit addresses the quality of

products and technical work, as appropriate, as well as programmatic compliance. Development of audit plans will include an evaluation of previous internal and external audits and the impact of changes in personnel, organization, or the quality assurance program. The plan will include a written checklist of items to be investigated, a meeting with responsible management personnel 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.

The audit report includes an evaluation of quality assurance program effectiveness. The results are reported to management for review, assessment, and appropriate action. The management review is documented. Each audit will be conducted by a trained audit team.

The audit team leader and audit team members will be certified in accordance with Section 2.7. The audit team members will not have direct responsibility for the areas being audited. The audit team will include persons with the technical expertise or experience in the work being audited to assess the quality of the products and technical work. Status of audit findings are tracked to help ensure all audit findings are properly prioritized and addressed.

- 18.1.4 The audited organization is required to address the audit findings and to provide formal responses to the auditing organization. The formal responses describe the proposed and completed action(s) and the cause of each finding. Provisions are established to ensure the cause of each finding is identified. The corrective action for it is identified, and deficient areas are monitored and promptly reaudited, when necessary, until corrections have been accomplished.
- 18.1.5 Audit summaries are provided in both internal and external monthly progress and status reports. The audit reports and data are analyzed by the quality assurance organization for quality trends indicating any quality problems and the effectiveness of the quality assurance program, including the need for re-audit of deficient areas. These reports are provided to management for review and assessment.
- 18.1.6 Vitrification Projects Branch audit practice is performed as a minimum in those areas of the D&Q quality assurance program where the requirements of DOE/RW-0214 are being implemented. Each Operations Office is responsible for preparing a matrix showing which procedures are used for implementing each of the principle quality assurance activities in the requirements of DOE/RW-0214. The activities and practices which carry out these procedures are audited upon implementation and at least annually thereafter.

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b These activities include the following:

- (1) The preparation, review, approval, and control of the quality assurance program description, designs, specifications, procurement documents, instructions, procedures, and drawings
- (2) The determination of those site operations that affect the integrity of development and qualification activities
- (3) Requests for proposal and evaluations of bids
- (4) Indoctrination and training programs
- (5) Interface control among DOE offices and major project participants
- (6) Calibration and nonconformance control systems
- (7) Quality assurance program commitments
- (8) Activities associated with computer codes

18.2 REQUIREMENTS OF OPERATIONS OFFICES

18.2.1 Operations Offices are required to establish and implement an audit practice which supports development and qualification activities and satisfies the quality assurance requirements. Each office's audit practice will include the following elements:

- (1) Planning
- (2) Conduct
- (3) Reporting
- (4) Follow-up and Closeout

18.2.2 Operations Offices responsible for overview of quality assurance activities performed by organizations over which they have administrative overview responsibilities are required to establish the following additional audit practices for waste acceptance process activities of high-level waste form development and qualification:

- (1) Procedures are established for planning, scheduling, performing, and reporting quality assurance audits of project office quality assurance programs. Audit schedules are developed annually and updated as changes occur.
- (2) Audit teams include, whenever possible, a representative that is trained and/or qualified in the technology being audited.
- (3) Documentation of overview activities is retained as quality records.

(4) Operations shall audit the prime contractors at least annually. These audits will verify that subcontractors and suppliers are being evaluated annually and audited at least on a triennial basis.

18.2.3 A periodic summary of the actions and accomplishments of each Operations Office overview audit practices related to development and qualification activities is made to Vitrification Projects Branch for review and evaluation. The Branch monitors Operations Offices' audit practices related to development and qualification activities, and periodically audits the Operations Offices' practices to ensure implementation and adequacy.

19.0 REFERENCES

- ANSI/ASME NQA-1, 1989 Quality Assurance Program Requirements for Nuclear Facilities (Sections I, II, III and 2A-1 of IV)
- DOE Order 5700.6B, Quality Assurance (9/23/86)
- Office of Civilian Radioactive Waste Management Quality Assurance Requirements Document (DOE/RW-0214)

20.0 ACRONYMS

ANL	- Argonne National Laboratory
ANSI	- American National Standards Institute
ASME	- American Society of Mechanical Engineers
CH	- DOE - Chicago Operations
CWFD	- Canister and Waste Form Description
DHLW	- Defense High-Level Waste
DOE	- Department of Energy
D&Q	- Development and Qualification
DuPont	- E. I. duPont de Nemours and Company
DWPF	- Defense Waste Processing Facility
EH	- DOE-Environment, Safety, and Health
EM	- DOE Office of Environmental Restoration and Waste Management
ESAAB	- Energy System Acquisition Advisory Board
HLW	- High-Level Waste
HLCWF	- High-Level Canistered Waste Form
HLNWR	- High-Level Nuclear Waste Repositories
HWVP	- Hanford Waste Vitrification Plant
ID	- DOE - Idaho Operations
MCC	- Materials Characterization Center
MIO	- Materials Integration Office
MRB	- Materials Review Board
MSC	- Materials Steering Committee
NEPA	- National Environmental Policy Act

NRC - Nuclear Regulatory Commission
NWPA - Nuclear Waste Policy Act of 1982
OCRWM - DOE - Office of Civilian Radioactive Waste Management
OGR - DOE - Office of Geologic Repositories
ORR - Operational Readiness Review
PNL - Pacific Northwest Laboratories
PR - Production Records
QAPD - Quality Assurance Program Description
RL - DOE - Richland Operations
RW - DOE - Office of Civilian Radioactive Waste Management
SR - DOE - Savannah River Operations
WAC - Waste Acceptance Committee
WAP - Waste Acceptance Process
WAPS - Waste Acceptance Preliminary Specification
WAS - Waste Acceptance Specification
WCP - Waste Compliance Plan
WHC - Westinghouse Hanford Company
WINCO - Westinghouse Idaho Nuclear Company, Inc.
WSRC - Westinghouse Savannah River Company
WQR - Waste Qualification Report
WVDP - West Valley Demonstration Project
WVNS - West Valley Nuclear Services

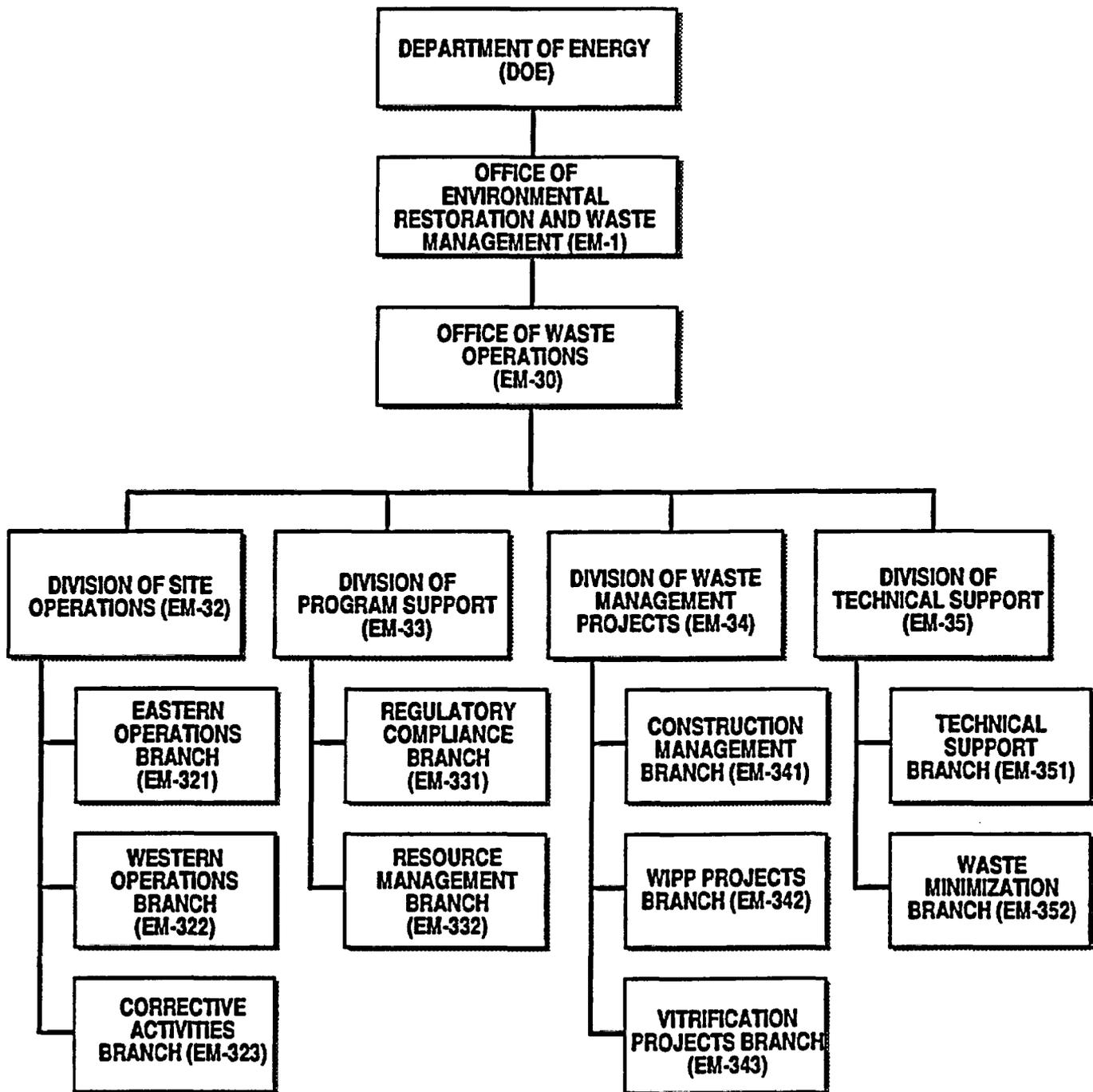


FIGURE 1.0-1
DOE HEADQUARTERS ORGANIZATION

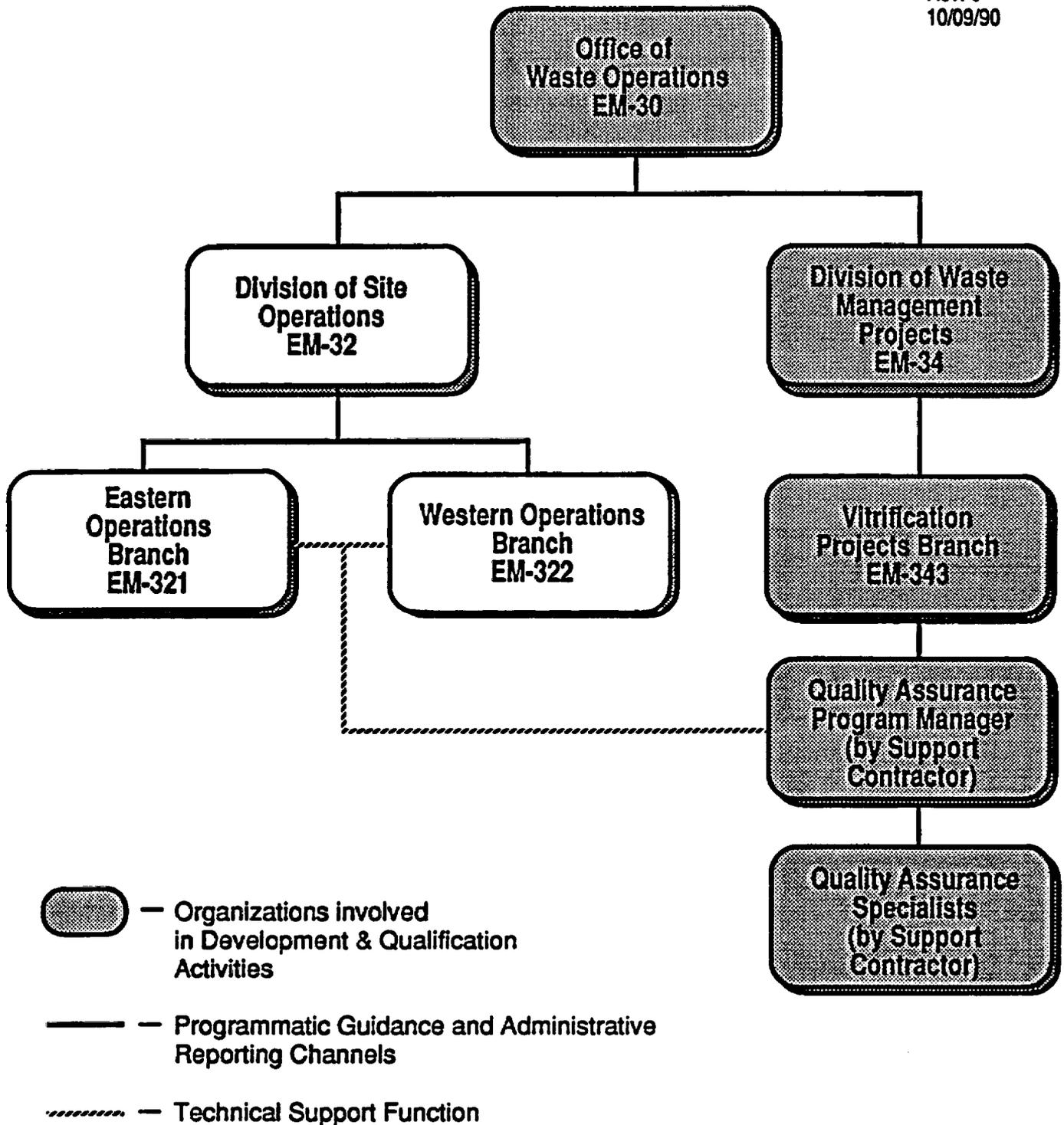


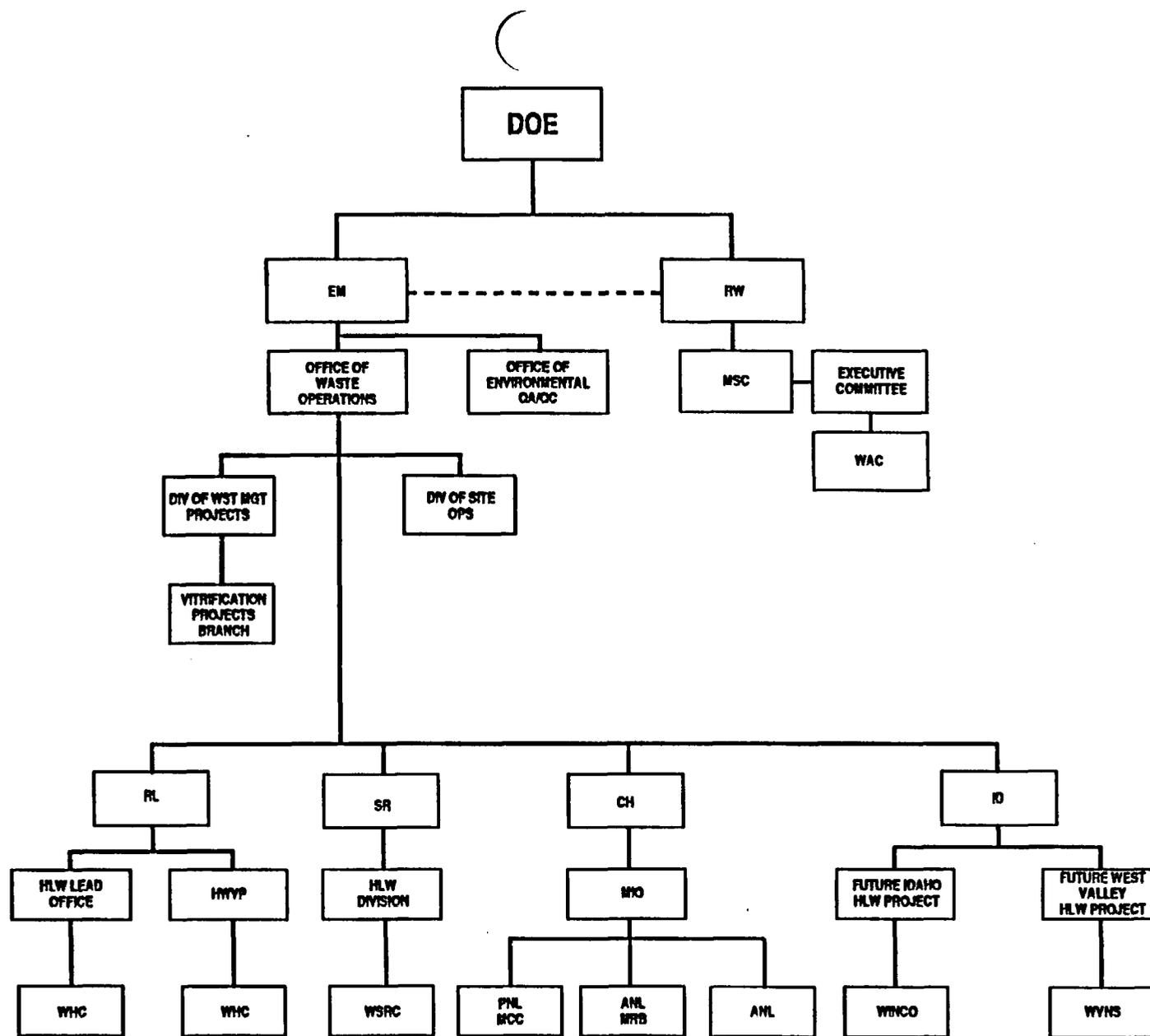
FIGURE 1.0-2
DOE WASTE OPERATIONS ORGANIZATION

DOE HEADQUARTERS ORGANIZATIONS (off site)

DOE OPERATIONS OFFICES (off site)

DOE PROJECT OFFICES (off site and on site)

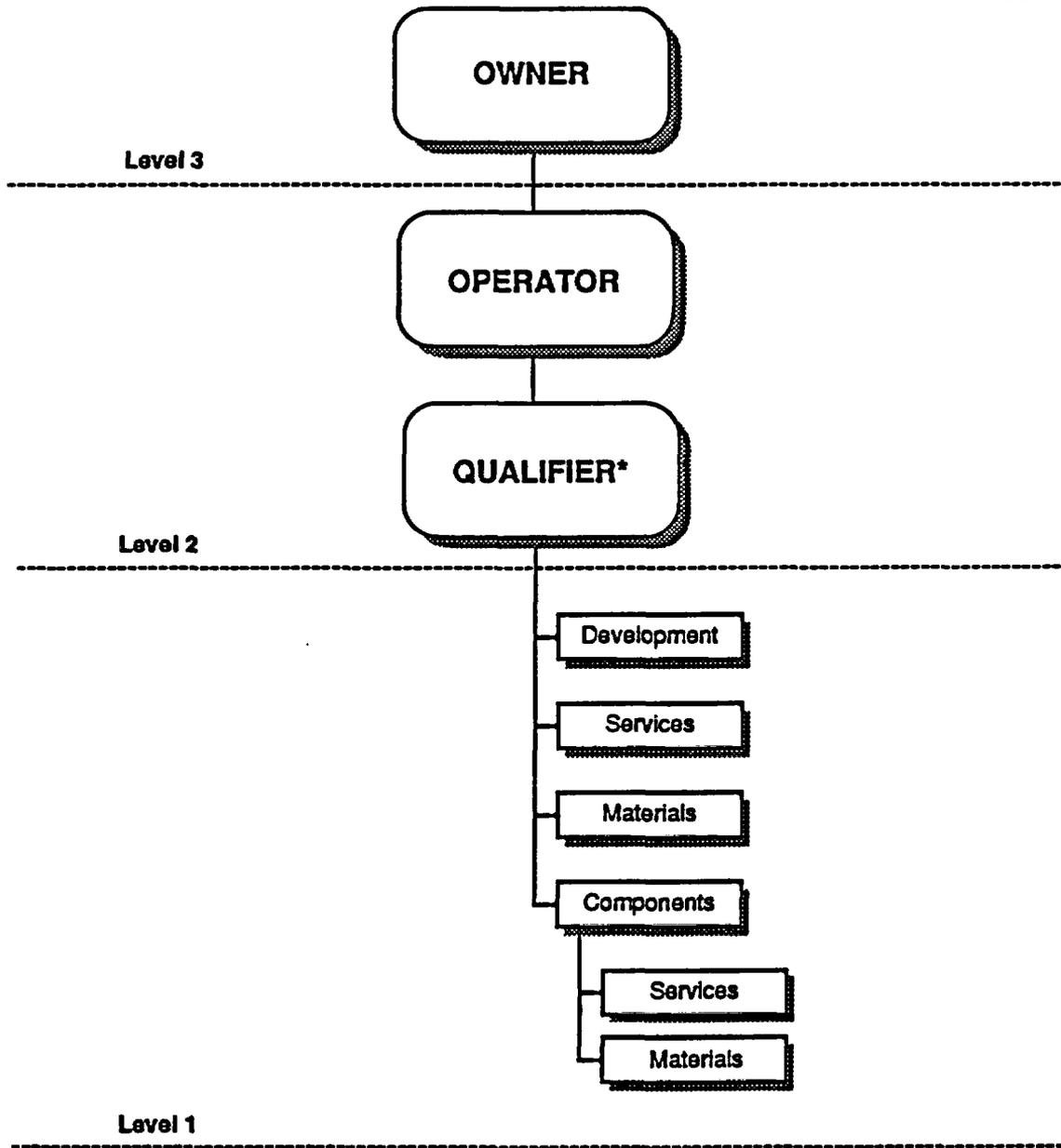
OPERATING CONTRACTORS (off site and on site)



———— = Program Guidance And Funding

- - - - - = Major Program Interfaces

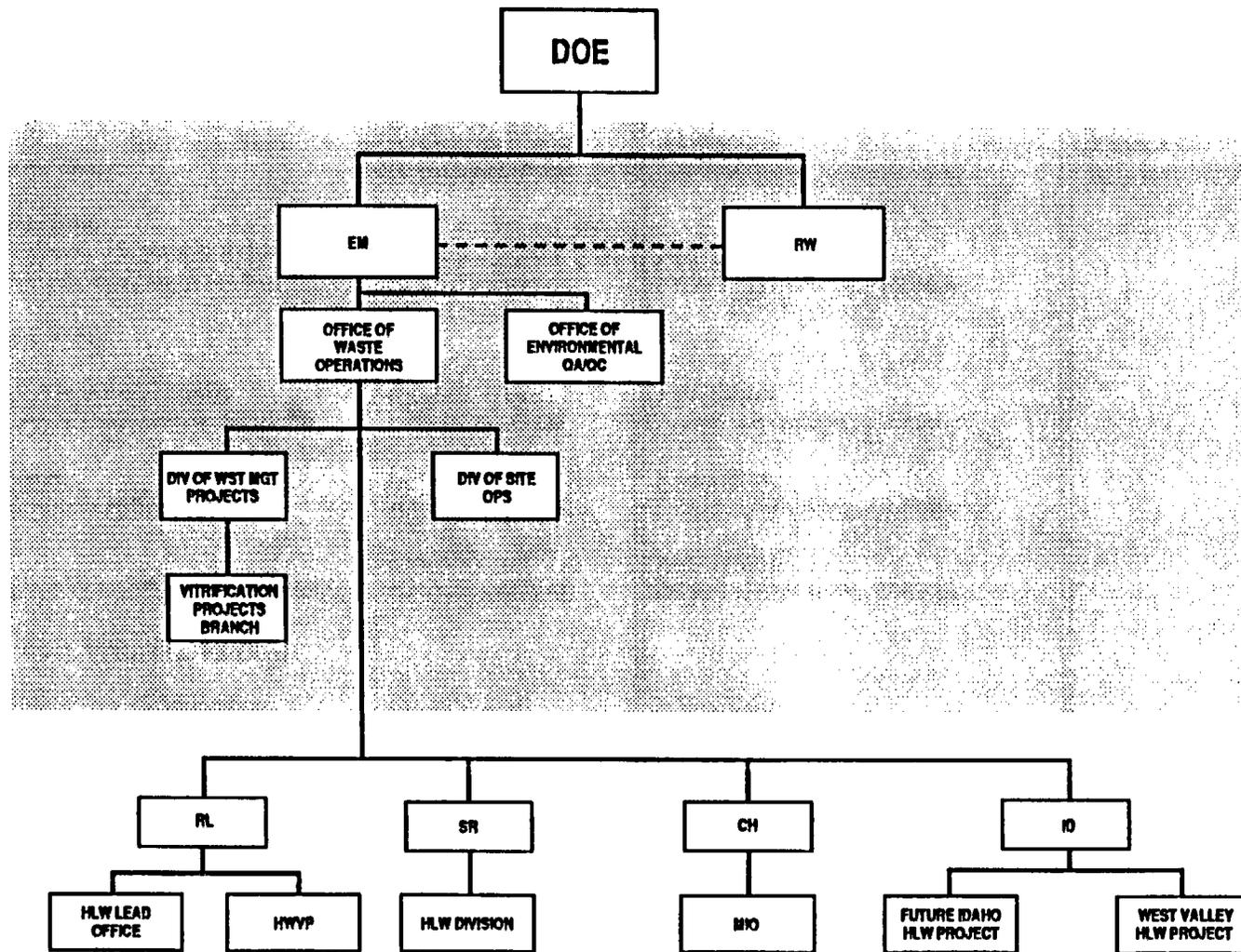
FIGURE 1.2.1-1
WASTE ACCEPTANCE PARTICIPANTS



* Includes program responsibility for development and qualification activities

**FIGURE 2.2.1-1
DEVELOPMENT AND QUALIFICATION QUALITY
ASSURANCE FUNCTIONAL ORGANIZATION OF PROGRAM RESPONSIBILITY**

DOE
HEADQUARTERS
ORGANIZATIONS



DOE
OPERATIONS
OFFICES

DOE PROJECT
OFFICES

———— = Program Guidance And Funding

- - - - - = Major Program Interfaces

FIGURE 2.2.1-2
PARTICIPANTS IN HIGH-LEVEL WASTE PROCESSING

**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
1	ORGANIZATION			
1.0	General			
	• NQA-1-BR-1 Organization	DOE/EM/WO/02 (Section 1.0)	Quality Assurance Program Description	
	• NQA-1-1S-1 Supplementary Requirements for Organization	DOE/EM/WO/02 (Section 1.0)	Quality Assurance Program Description	
1.1	GENERAL 0214 AMPLIFICATIONS:			
	Quality Assurance Program Management	DOE/EM/WO/02 (Section 1.0)	Quality Assurance Program Description	
	Quality Assurance Organization Responsibilities	DOE/EM/WO/02 (Para. 1.2.2)	Quality Assurance Program Description	
	• Identify Quality Assurance Manager and Listing of Qualifications	DOE/EM/WO/02 (Section 1.2.2)	Quality Assurance Program Description	
1.2	Delegation of Work			
	• Person designated within organization responsible for the quality of the delegated work.	DOE/EM/WO/02 (Section 1.0 and 2.4)	Quality Assurance Program Description	
1.3	Dispute Resolution			
	- Provisions for resolution of disputes involving quality.	DOE/EM/WO/02 (Para. 1.5.1) and SPP 10.03	Differing Staff Opinions and Allegations	SPP Manual for Quality Assurance

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT*		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
1.4	Allegation and Quality Concern Resolution - Provisions for individuals to express allegations and quality concerns.	DOE/EM/WO/02 (Para. 1.5.1) and SPP 10.03	Quality Assurance Program Description Differing Staff Opinions and Allegations	SPP Manual for Quality Assurance
1.5	Stop Work Provisions - Criteria for stopping work - Authorities and responsibilities - Methodology for lifting stop work	DOE/EM/WO/02 (Para. 1.2.3(6) and SPP 5.03	Quality Assurance Program Description Control of Unsatisfactory Conditions (Stop Work Orders)	SPP Manual for Quality Assurance
2	QUALITY ASSURANCE PROGRAM			
2.0	General • NQA-1-BR-2 Quality Assurance Program • NQA-1-2S-1 Supplementary Requirements for the Qualification of Inspection and Test Personnel	DOE/EM/WO/02 (Section 2.0) DOE/EM/WO/02 (Para. 2.7.2(3))	Quality Assurance Program Description Quality Assurance Program Description	Waste Operations Quality Assurance Program elements assigned to Operations Offices are also described in Section 2.0 of the QAPD. Assigned to Operations Office

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
2.0 (continued)	• NQA-1-2S-2 Supplementary Requirements for the Qualification of NDE Personnel	DOE/EM/WO/02 (Para. 2.7.2(3))	Quality Assurance Program Description	Assigned to Operations Office
	• NQA-1-2S-3 Supplementary Requirements for the Qualification of Quality Assurance Program Audit Personnel	DOE/EM/WO/02 (Para. 2.7.2(3)) and SPP 3.03	Quality Assurance Program Description	Assigned to Operations Office
			Certification of Quality Assurance Audit Personnel	SPP Manual for Quality Assurance
	• NQA-12S-4 Supplementary Requirements for Personnel Indoctrination and Training	DOE/EM/WO/02 (Para. 2.7.2(3)), SPP 3.01, SPP 3.02, and SPP 3.04	Quality Assurance Program Description	Assigned to the Operations Office
			Preparation and Maintenance of Plans for Personnel Training, Indoctrination and Orientation	SPP Manual for Quality Assurance
Preparation and Conduct of Personnel Training, Indoctrination, and Orientation			SPP Manual for Quality Assurance	
• NQA-1-2A-1 Nonmandatory Guidance on Qualification of Inspection and Test Personnel	DOE/EM/WO/02 (Para. 2.7.2(3))	Certification of Quality Assurance Audit Personnel	SPP Manual for Quality Assurance	
		DOE/EM/WO/02 (Para. 2.7.2(3))	Quality Assurance Program Description	Assigned to the Operations Offices

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
2.1	GENERAL (0214) AMPLIFICATIONS			
	Quality Assurance Program			
	• Quality Assurance Program Description	SPP 2.03	Quality Assurance Program Description Preparation, Maintenance, and Control	SPP Manual for Quality Assurance
		and SPP 4.10	Review of Operations Quality Assurance Program Descriptions and Procedures	SPP Manual for Quality Assurance
	• Technical Procedures	SPP 4.11	Review of Waste Acceptance Process Technical Documents	SPP Manual for Quality Assurance
	• Quality Assurance Administrative Procedures	SPP 2.01	Standard Practice Procedures	SPP Manual for Quality Assurance
		and SPP 2.04	Control of SPP Manual	SPP Manual for Quality Assurance
2.2	Reporting Independence of Personnel	DOE/EM/WO/02 (Para. 1.2.2, 1.2.3, and 1.3.1)	Quality Assurance Program Description	Responsibility assigned to support services personnel to provide Quality Assurance Manager and appropriate Quality Assurance Specialist for verifying quality assurance effectiveness

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
2.2 (continued)	<p>Verification personnel not part of a formal quality assurance organization have sufficient authority, access to work areas, and organizational freedom to:</p> <ul style="list-style-type: none"> - identify quality problems - initiate, recommend, or provide solutions - verify implementation - ensure that further use is controlled until proper dispositioning is made of nonconformances. 	DOE/EM/WO/02 (Para. 1.3.1)	Quality Assurance Program Description	
2.3	<p>Planning</p> <ul style="list-style-type: none"> - Definition of Activities - Applicability of quality assurance program to items and activities - Selective application of requirements - Assignment of responsibilities - Identification of specific information to be collected, analyzed or used 	SPP 4.12	Review of Program Execution Guidance Documents	SPP Manual for Quality Assurance

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
2.3 (continued)	- Identification of management control and verification activities			
	- Identification of procedures for sampling, testing, and analysis activities			
	- Provisions for identification of records			
2.4	Readiness Review - Work activities prerequisites satisfied - Procedures reviewed - Personnel trained and qualified	DOE/EM/WO/02 (Para. 2.7.2(1))	Quality Assurance Program Description	Responsibility assigned to each Operations Office
2.5	Graded Quality Assurance Program	DOE/EM/WO/02 (Para. 2.7.1(1))	Quality Assurance Program Description	
	- Methodology to identify items and activities - Application of requirements and controls	SPP 2.05	Selective Application of Quality Assurance Activities	SPP Manual for Quality Assurance
2.6	Personnel Selection, Indoctrination, Training, and Qualification	DOE/EM/WO/02 (Para. 2.7.1(2)) and	Quality Assurance Program Description	Assigned to Operations Offices
	- 2S-1 and 2A-1 apply to inspection and test personnel - Monitor and assess performance of individuals - Documentation of formal training	SPP 3.05	Administration of Personnel Certification and Qualification Records	SPP Manual for Quality Assurance

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
2.7	Surveillance - Planning, performing, documenting, and reporting surveillances - Objectives of surveillances - Qualifications of surveillance personnel - Reporting surveillances	SPP 4.04	Administration & Conduct of Surveillance	SPP Manual for Quality Assurance
2.8	Management Assessment - Annual independent management assessment - Assessments evaluate Effectiveness of program Adequacy of controls Effectiveness of corrective actions Adequacy of organization structure and staffing Adequacy of indoctrination, orientation, and training Adequacy of information tracking, evaluation, and reporting	DOE/EM/WO/02 (Para. 2.2.3(4), 2.7.1 (4))	Quality Assurance Program Description	
		SPP 8.02, and	Quality Assurance Program Evaluation and Assessment of Adequacy and Effectiveness	SPP Manual for Quality Assurance
		SPP 8.03	Review and Reporting of Quality Assurance Program Progress and Status	SPP Manual for Quality Assurance

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
2.9	Quality Assurance Program Management- Information Reporting and Tracking - Report, disseminate and track quality related management information - Periodic reports	SPP 8.03,	Review & Reporting of Quality Assurance Program Progress and Status	SPP Manual for Quality Assurance
		SPP 9.0,	Preparation & Maintenance of the Program Schedules	SPP Manual for Quality Assurance
		SPP 9.02,	HLW Monthly Progress Reporting	SPP Manual for Quality Assurance
		SPP 9.03,	Preparation & Maintenance of the Work Breakdown Structure	SPP Manual for Quality Assurance
		and SPP 10.01	Identification & Analysis of Adverse Quality Trends and Problems	SPP Manual for Quality Assurance
APP. B	AMPLIFICATIONS OF QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR WASTE ACCEPTANCE PROCESS ACTIVITIES OF HIGH-LEVEL WASTE FORM PRODUCTION:			
2.0 (B)	AMPLIFICATION OF QARD SECTION 2.0-QUALITY ASSURANCE PROGRAM DESCRIPTION FOR THE WASTE ACCEPTANCE PROCESS			
2.1 (B)	Method Description - QAPD identify items and activities that are part of waste acceptance process	DOE/EM/WO/02 (Para. 3.2.1(18), and 2.7.2(2))	Quality Assurance Program Description	Assigned to Operations Offices

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
2.2 (B)	Readiness Reviews	DOE/EM/WO/02 (Para. 2.7.2(1))	Quality Assurance Program Description	Assigned to Operations Offices
	<ul style="list-style-type: none"> - Planned, scheduled, and conducted at significant transitional events - Completed before authorizing initiation of subsequent activity 			
2.3 (B)	Graded Quality Assurance Program	DOE/EM/WO/02 (Para. 2.7.2(2))	Quality Assurance Program Description	Assigned to Operations Offices
	<ul style="list-style-type: none"> • Methodology to identify items to which quality assurance applies 	DOE/EM/WO/02 (Para. 2.7.2(2))	Quality Assurance Program Description	
	<ul style="list-style-type: none"> • Selectively applies 	Para. 2.7.2(2)	Quality Assurance Program Description	Addressed in WCP
	<ul style="list-style-type: none"> • Describe in Waste Form Compliance Plan 	Not Applicable to D & Q		
2.4 (B)	Personnel Selection, Indoctrination, Training, and Qualification	DOE/EM/WO/02 (Para. 2.7.2(3))	Quality Assurance Program Description	Assigned to Operations Offices
	<ul style="list-style-type: none"> • Qualification of inspection and test personnel will meet Section 2.6 of QARD 	DOE/EM/WO/02 (Para. 2.7.1(2))	Quality Assurance Program Description	
	<ul style="list-style-type: none"> • Requirements for others requiring qualification will meet 2S-1 except Para. 2.7 & 2.8 	DOE/EM/WO/02 (Para. 2.7.1(2))	Quality Assurance Program Description	
2.5 (B)	Management Assessments	DOE/EM/WO/02 (Para. 2.7.2(4))	Quality Assurance Program Description	Assigned to Operations Offices
	<ul style="list-style-type: none"> - Evaluate conformance to Waste Acceptance Specification 			

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
3	DESIGN CONTROL			
3.0	General <ul style="list-style-type: none"> • NQA-1-BR-3, Design Control • NQA-1-3S-1, Supplementary Requirements for Design Control 	DOE/EM/WO/02 Section 3.0	Quality Assurance Program Description	Design Control Responsibilities are assigned to Operations Offices
		DOE/EM/WO/02 Section 3.0	Quality Assurance Program Description	
		DOE/EM/WO/02 Section 3.0	Quality Assurance Program Description	
	GENERAL (0214) AMPLIFICATIONS:			
3.1	Design Error and Deficiency Control <ul style="list-style-type: none"> - Documentation and Corrective Action for design errors and deficiencies 	DOE/EM/WO/02 (Para. 3.2.1(3) and Para. 3.2.1 (4))	Quality Assurance Program Description	Assigned to Operations Offices
3.2	Design Changes <ul style="list-style-type: none"> - Evaluation of impact of design changes on procedures and training 	DOE/EM/WO/02 (Para. 3.2.1(11))	Quality Assurance Program Description	Assigned to Operations Offices

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
3.3	Computer Software Design and Control <ul style="list-style-type: none"> - Application of Requirements - Software Quality Assurance Plans - Planning, prooftesting - Verification - Validation - Configuration management - Documentation - Reviews - Discrepancy Reporting and Corrective Action - Physical media control and security - Acquired software - Application 	DOE/EM/WO/02 (Para. 3.2.1(13))	Quality Assurance Program Description	Assigned to the Operations Offices
3.4	Technical Reviews <ul style="list-style-type: none"> - Reviews for technical verification and validation - Competence and Independence of reviewers - Documentation of technical reviews 	DOE/EM/WO/02 (Para. 3.2.1(14)), SPP 4.06, and SPP 4.11	Quality Assurance Program Description Control of Technical Reviews Review of Waste Acceptance Process Technical Documents	Except for Selected Reviews Assigned to Operations Offices SPP Quality Assurance Manual SPP Quality Assurance Manual

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
3.0	APPENDIX B AMPLIFICATION OF QARD SECTION 3-DESIGN CONTROL			
3.1 (B)	Peer Review - Applicability of peer reviews - Qualification of peers and of the team - Peer review process - Peer review report	DOE/EM/WO/02 (Para. 3.2.1(15))	Quality Assurance Program Description	Assigned to Operations Offices
3.2 (B)	Control of Experiments and Development Activities			
3.2.1 (B)	Experimental and Development Activities - Data suitable for intended use - Ability to independently reconstruct and achieve same result	DOE/EM/WO/02 (Para. 3.2.1(16))	Quality Assurance Program Description	Assigned to Operations Offices

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/ REMARKS
3.2.2 (B)	Minimum Controls for Developmental Activities <ul style="list-style-type: none"> - Identification of responsibility - Selection of personnel - Review and approval of procedures - Surveillance and audits - Review and evaluation of results - Documentation of experiments and development activities and results - Preparation and retention of documentation 	DOE/EM/WO/02 (Para. 3.2.1(16))	Quality Assurance Program Description	Assigned to Operations Offices
3.2.3 (B)	Documentation <ul style="list-style-type: none"> - Document activities on day to day basis 	DOE/EM/WO/02 (Para. 3.2.1(16) 3rd Para.)	Quality Assurance Program Description	Assigned to Operations Offices
3.2.4 (B)	Experimental and Developmental Records Control <ul style="list-style-type: none"> - Detail in records - Identify equipment, materials, and procedures used - Records include originals or facsimiles - Records shall be signed - Summaries, reports, and evaluations shall clearly reference the experimental records - Experimental or developmental records of waste acceptance process activities are quality assurance records 	DOE/EM/WO/02 (Para. 3.2.1(16) 4th Para.)	Quality Assurance Program Description	Assigned to Operations Offices

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
3.2.5 (B)	Qualification of Data - Acceptance of data generated outside a quality assurance program	DOE/EM/WO/02 (Para. 3.2.1(17))	Quality Assurance Program Description	Assigned to Operations Offices
3.2.6 (B)	Modification Control - Control of modifications are established - Applied to items and activities essential to certification of canistered waste form - Controlled listing of items and activities under modification control - Procedures define elements of modification control <ul style="list-style-type: none"> • Change proposals • Change review and approval • Change implementation • Issue of documentation of change - Requalification resulting from modifications	DOE/EM/WO/02 (Para. 3.2.1(18))	Quality Assurance Program Description	Assigned to Operations Offices
3.3 (B)	Computer Software Design Control - Essential to Waste Acceptance Specification controlled same as Section 3.3	DOE/EM/WO/02 (Para. 3.2.1(13))	Quality Assurance Program Description	Assigned to Operations Offices

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
4	PROCUREMENT DOCUMENT CONTROL			
4.0	General <ul style="list-style-type: none"> • NQA-1-BR-4, Procurement Document Control • NQA-1-4S-1, Supplementary Requirements for Procurement Document Control 	DOE/EM/WO/02 (Section 4.0)	Quality Assurance Program Description	
	GENERAL (0214) AMPLIFICATIONS			
4.1	Review <ul style="list-style-type: none"> - Procurement Review by Quality Assurance Organization 	DOE/EM/WO/02 (Para. 4.2.2(1))	Quality Assurance Program Description	Assigned to Operations Offices
4.2	Applicability of Purchaser's Quality Assurance Program <ul style="list-style-type: none"> - Applying purchasers quality assurance program to supplier activities 	DOE/EM/WO/02 (Para. 4.2.2(1))	Quality Assurance Program Description	Assigned to Operations Offices

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**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
5	INSTRUCTIONS, PROCEDURES, AND DRAWINGS			
5.0	General	DOE/EM/WO/02 (Section 5.0),	Quality Assurance Program Description	
	• NQA-1-BR-5, Instructions, Procedures, and Drawings	SPP 2.01,	Standard Practice Procedures	SPP Manual for Quality Assurance
		SPP 2.03,	Quality Assurance Program Description Preparation, Maintenance and Control	SPP Manual for Quality Assurance
		and SPP 2.04	Control of Standard Practices Procedures Manual	SPP Manual for Quality Assurance (Assigned to Operations Offices)
	GENERAL (0214) REQUIREMENTS			
5.1	Reviews	SPP 4.10	Review of Operations Offices Quality Assurance Program Descriptions and Procedures	SPP Manual for Quality Assurance
	- Independent review by originating organization			
5.2	Procedures List	SPP 1.01	Index of HLW SPP for Quality Assurance	SPP Manual for Quality Assurance
	- Controlled list of technical procedures			

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**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
6	DOCUMENT CONTROL	DOE/EM/WO/02 (Section 6.0)	Quality Assurance Program Description	Document Control Responsibilities are retained by Waste Operations and also assigned to the Operations Offices
6.0	General	SPP 6.01,	Official HLW Files	SPP Manual for Quality Assurance
	• NQA-1-BR-6, Document Control	SPP 6.02,	Correspondence	SPP Manual for Quality Assurance
	• NQA-1-6S-1, Supplementary Requirements for Document Control	SPP 6.03, and	Incoming Mail	SPP Manual for Quality Assurance
		SPP 6.04	Commitment Control	SPP Manual for Quality Assurance
	GENERAL (0214) REQUIREMENTS			
6.1	Control	SPP 6.05	Controlled Documents	SPP Manual for Quality Assurance
	- Correct and applicable documents available at the work place			
6.2	Control System	DOE/EM/WO/02 (Section 6.0)	Quality Assurance Program Description	Responsibilities are retained by Waste Operations and also assigned to Operations Offices
	- Review access to background data			
	- Resolution of mandatory comments			
	- Documentation of review comments and resolution			
	- Control of preapproval releases			

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**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
6.3	Controlled Documents - Evaluation of changes - Controlled documents list - Receipt acknowledgement system - Control of obsolete or superseded documents	SPP 6.05	Controlled Documents	SPP Manual for Quality Assurance
7	CONTROL OF PURCHASED ITEMS AND SERVICES			
7.0	General - NQA-1-BR-7, Control of Purchased Items and Services - NQA-1-7S-1, Supplementary Requirements for Control of Purchased Items and Services GENERAL (0214) REQUIREMENTS	DOE/EM/WO/02 (Section 7.0)	Quality Assurance Program Description	Assigned to Operations Offices
7.1	Suppliers' Quality Assurance Program - Review and acceptance prior to initiation of work	DOE/EM/WO/02 (Para. 7.2.1)	Quality Assurance Program Description	Assigned to Operations Offices

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**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
8	IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS	DOE/EM/WO/02 (Section 8.0)	Quality Assurance Program Description	Assigned to Operations Offices
8.1	General - NQA-1-BR-8, Identification and Control of Items - NQA-1-8S-1, Supplementary Requirements for Identification and Control of Items	DOE/EM/WO/02 (Para. 8.2)	Quality Assurance Program Description	Assigned to Operations Offices
9	CONTROL OF PROCESS	DOE/EM/WO/02 (Section 9.0)	Quality Assurance Program Description	Assigned to Operations Offices
9.0	General - NQA-1-BR-9, Control of Processes - NQA-1-9S-1, Supplementary Requirements for Control of Processes	DOE/EM/WO/02 (Para. 9.2)	Quality Assurance Program Description	
	GENERAL (0214) AMPLIFICATIONS			
9.1	List of Special Processes - Provide list of special processes	DOE/EM/WO/02 (Para 9.2.1(1))	Quality Assurance Program Description	Assigned to Operations Offices

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**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
9.2	Quality Assurance Organization Involvement in Qualification Activities - Involvement in qualification activities to assure satisfactory performance	DOE/EM/WO/02 (Para. 9.2.1(2))	Quality Assurance Program Description	Assigned to Operations Offices
9.3	Evidence of Accomplishment - Provide for recording evidence that special processes are accomplished.	DOE/EM/WO/02 (Para. 9.2.1(4))	Quality Assurance Program Description	Assigned to Operations Offices
9.0 (B)	APPENDIX B AMPLIFICATION OF QARD SECTION 9.0-CONTROL OF PROCESSES			
9.1 (B)	Process Control - Includes production processes for WAS	Not Applicable to D & Q		
1 0	INSPECTION	DOE/EM/WO/02 (Section 10.0)	Quality Assurance Program Description	Assigned to Operations Offices
10.0	General - NQA-1-BR-10, Inspection - NQA-1-10S-1, Supplementary Requirements for Inspection	DOE/EM/WO/02 (Para. 10.2)	Quality Assurance Program Description	Assigned to Operations Offices

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/ REMARKS
10.1	GENERAL (0214) AMPLIFICATIONS Inspection Records include: <ul style="list-style-type: none"> - Inspection procedures - Characteristics inspected - Inspection criteria - Identification of specific equipment - Identification of special expertise 	DOE/EM/WO/02 (Para. 10.2.(11))	Quality Assurance Program Description	Assigned to Operations Offices
11 11.0	TEST CONTROL General <ul style="list-style-type: none"> - NQA-1-BR-11, Test Control - NQA-1-11S-1, Supplementary Requirements for Test Control 	DOE/EM/WO/02 (Section 11.0)	Quality Assurance Program Description	Assigned to Operations Offices
11.1	GENERAL (0214) AMPLIFICATIONS Uncertainty and Error <ul style="list-style-type: none"> - Identification of uncertainty and error and affected parameters identified and controlled 	DOE/EM/WO/02 (Para. 11.2.1(3))	Quality Assurance Program Description	Assigned to Operations Offices
11.2	Precision and Accuracy <ul style="list-style-type: none"> - Procedures include identification of precision and accuracy considerations in test procedures 	DOE/EM/WO/02 (Para. 11.2.1(3))	Quality Assurance Program Description	

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**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
12	CONTROL OF MEASURING AND TEST EQUIPMENT			
12.0	General - NQA-1-BR-12, Control of Measuring and Test Equipment - NQA-1-12S-1, Supplementary Requirements for Control of Measuring and Test Equipment GENERAL (0214) AMPLIFICATIONS	DOE/EM/WO/02 (Section 12.0)	Quality Assurance Program Description	Assigned to Operations Offices
12.1	Accuracy of Calibration Standards - Calibration standards shall have greater accuracy than items being calibrated	DOE/EM/WO/02 (Para. 12.2.1(5))	Quality Assurance Program Description	Assigned to Operations Offices
13	HANDLING, STORAGE, AND SHIPPING			
13.0	General - NQA-1-BR-13, Handling, Storage, and Shipping - NQA-1-13S-1, Supplementary Requirements for Handling, Storage, and Shipping	DOE/EM/WO/02 (Para. 13.2)	Quality Assurance Program Description	Assigned to Operations Offices

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**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
13.0 (B)	APPENDIX B			
	AMPLIFICATIONS OF QARD SECTION 13-HANDLING, STORAGE, AND SHIPPING			
13.1 (B)	Archival of Samples	Not Applicable to D & Q		
	<ul style="list-style-type: none"> - Sample preparation planned and documented - Procedures for sample preparation, maintenance and use - Documentation of samples are quality assurance records 			
14	INSPECTION, TEST, AND OPERATING STATUS			
14.0	General	DOE/EM/WO/02 (Section 14.0)	Quality Assurance Program Description	Assigned to Operations Offices
	<ul style="list-style-type: none"> - NQA-1-BR-14, Inspection, Test and Operating Status 			

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**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
1 5 15.0	CONTROL OF NONCONFORMING ITEMS General - NQA-1-BR-15, Control of Nonconforming Items - NQA-1-15S-1, Supplementary Requirements for Control of Nonconforming Items	DOE/EM/WO/02 (Section 15.0), SPP 5.01, SPP 5.02, SPP 5.03, SPP 5.04, SPP 5.05, and SPP 5.06	Quality Assurance Program Description Deviation Reporting and Disposition Management Action Request Control of Unsatisfactory Conditions (Stop Work Orders) Disposition of Deviations Identified by Outside Organizations Review of Unusual Occurrences Control and Disposition of Deviations and Recommendations for Improvement by Outside Organizations	Responsibilities retained by Waste Operations and also assigned to Operations Offices SPP Manual for Quality Assurance SPP Manual for Quality Assurance
1 6 16.0	CORRECTIVE ACTION General - NQA-1-BR-16, Corrective Action	DOE/EM/WO/02 (Section 16)	Quality Assurance Program Description	Responsibilities are retained by Waste Operations & Implementation assigned to Operations Offices

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**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
	GENERAL (0214) AMPLIFICATIONS			
16.1	Trend Analysis - Analyze and report trends - Identify adverse trends	SPP 10.01	Identification & Analysis of Adverse Quality Trends and Problems	SPP Manual for Quality Assurance
16.2	Significant Conditions Adverse to Quality - Criteria for significant conditions adverse to quality (SCAQ) - Identify, document, and correct SCAQs - Flag to senior management - Corrective Action documentation to management and OCRWM Office of Quality Assurance	DOE/EM/WO/02 (Para. 16.1.1) SPP 5.01	Quality Assurance Program Description Deviation Reporting and Disposition	 SPP Manual for Quality Assurance
17	QUALITY ASSURANCE RECORDS			
17.0	General - NQA-1-BR-17, Quality Assurance Records - NQA-1-17S-1, Supplementary Requirements for Quality Assurance Records	DOE/EM/WO/02 (Section 17.0), SPP 7.01, and SPP 7.02	Quality Assurance Program Description Preparation, Transfer and Receipt of Quality Records Quality Records Management	Responsibilities are retained by Waste Operations and Implementation assigned to Operations Offices SPP Manual for Quality Assurance SPP Manual for Quality Assurance

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
17.1	GENERAL (0214) AMPLIFICATIONS Compliance with OCRWM Records - Management Program <ul style="list-style-type: none"> - 0194 Section 4, Definitions - 0194 Subsection 5.5, Requirements for Participants - 0194 Appendix A, Program Criteria for Records Management and System Implementation - 0194 Appendix E, Requirements for Packaging and Turnover of Program Records - 0194 Appendix F, Local Records Center Requirements - 0194 Appendix G, Storage Requirements for Machine Readable Records 	DOE/EM/WO/02 (Section 17.0)	Quality Assurance Program Description	Assigned to Operations Offices
17.0	APPENDIX B AMPLIFICATION OF QARD SECTION 17- QUALITY ASSURANCE RECORDS			
17.1 (B)	Product Certification <ul style="list-style-type: none"> - Identify types of records to be developed during waste form production. 	Not Applicable to D & Q		Addressed in WCP

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**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
17.2 (B)	Determination of Quality Assurance Records - Lifetime quality assurance records for waste form production	DOE/EM/WO/02 (Para. 17.1.1)		
17.3 (B)	Production Documentation - Traceable to canister and is lifetime record	Not Applicable to D & Q		
18	AUDITS			
18.0	General • NQA-1-BR-18, Audits • NQA-1-18S-1, Supplementary Requirements for Audits	DOE/EM/WO/02 (Section 18.0)	Quality Assurance Program Description	Audit responsibilities are retained by Waste Operations and also assigned to Operations Offices (Para. 18.2)
	GENERAL (0214) AMPLIFICATIONS			
18.1	Technical Considerations - Audit quality of products and technical work - Audit team members technically qualified	SPP 3.03	Certification of Quality Assurance Audit Personnel	SPP Quality Assurance Manual

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
18.2	Program Participants Audits - Annually audit next lower tier program	SPP 4.01	Planning & Scheduling of Evaluation Activities	SPP Quality Assurance Manual
18.3	Analysis of Audit - Results analyzed by audit team members - Analysis results reported to management			
18.4	Internal Audit Scheduling - Audit annually and at least once in life of activity - Consider previous internal and extensive audits - Impact of changes	SPP 4.02, and SPP 4.03	Administration of Quality Assurance Audits Conduct of Quality Assurance Audits	SPP Quality Assurance Manual SPP Quality Assurance Manual
18.5	External Audit Scheduling - Need evaluation - At least triennial basis - Audits by others - Evaluate suppliers annually	SPP 4.02, and SPP 4.03	Administration of Quality Assurance Audits Conduct of Quality Assurance Audits	SPP Quality Assurance Manual SPP Quality Assurance Manual

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

**TABLE 2.3.2-1, DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	SOURCE OF PROCEDURE/REMARKS
18.0	APPENDIX B AMPLIFICATION OF QARD SECTION 18.4 - QUALITY ASSURANCE AUDITS			
18.1 (B)	Planning and Certification - Establish procedures for planning, scheduling, performing, and reporting audits of participants - Audit schedules developed annually and updated as changes occur	SPP 4.02 and 4.03	Administration of Quality Assurance Audits Conduct of Quality Assurance Audits	SPP Quality Assurance Manual SPP Quality Assurance Manual
18.2 (B)	Audit Team Selection - Audit Teams include a member who is qualified in the technology being audited	SPP 4.02	Administration of Quality Assurance Audits	SPP Quality Assurance Manual

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

ATTACHMENT I

WASTE ACCEPTANCE PROCESS ACTIVITIES
RELATING TO QUALIFICATION OF THE CANISTERED WASTE FORM PRODUCT

This Table contains a listing of ". . . items and activities associated with research and development that (are) essential to qualification of the waste form . . ."1 to which the Quality Assurance Program will be applied.

1. RW-0214

SAVANNAH RIVER DEFENSE WASTE PROCESSING FACILITY

WASTE ACCEPTANCE PROCESS ACTIVITIES
RELATING TO QUALIFICATION OF THE DWPF PRODUCT

<u>SPECIFICATION</u>	<u>ACTIVITY</u>
1.1.1 Chemical Composition Projections	<ul style="list-style-type: none"> • Determine the composition and the amount of waste currently stored in tanks. • Determine glass frit composition.
1.2.1 Radionuclide Inventory Projections	<ul style="list-style-type: none"> • Determine radionuclide inventory of waste currently stored in tanks.
1.3.2 Verification of Radionuclide Release	<ul style="list-style-type: none"> • Develop sampler for DWPF glass • Develop correlation between measurable quantities and repository tests. • Develop Product Consistency Test (PCT). • Demonstrate method of verification in Integrated Cold Runs.
1.4 Chemical and Phase Stability	<ul style="list-style-type: none"> • Develop SRL leach test (PCT). Relate PCT to repository test.
2.2 Canister Fabrication and Closure	<ul style="list-style-type: none"> • Specify fabrication methods in canister procurement documents • Perform parametric study to determine acceptable weld conditions. • Verify weld leaktightness in DWPF Integrated Cold Runs.
2.3 Canister Identification and Labeling	<ul style="list-style-type: none"> • Specify labeling requirements in canister procurement documents.
3.1 Free Liquids	<ul style="list-style-type: none"> • Develop technique to measure leaktightness of temporary seal in DWPF.
3.2 Free Gases	<ul style="list-style-type: none"> • Demonstrate canistered waste form does not contain free gas.
3.3 Explosives, Pyrophorics and Combustibles	<ul style="list-style-type: none"> • Document that borosilicate glass does not contain explosives, pyrophorics, or combustibles.

**SAVANNAH RIVER DEFENSE WASTE PROCESSING FACILITY
 (Cont'd)**

**WASTE ACCEPTANCE PROCESS ACTIVITIES
RELATING TO QUALIFICATION OF THE DWPF PRODUCT**

<u>SPECIFICATION</u>	<u>ACTIVITY</u>
3.4 Organic Materials	<ul style="list-style-type: none"> • Develop controls to keep out organics after filling.
3.5 Free Volume	<ul style="list-style-type: none"> • Demonstrate methods of canister level detection during DWPF operation.
3.7.1 Heat Generation Projections	<ul style="list-style-type: none"> • Estimate thermal output based on radionuclide inventory projections
3.7.2 Heat Generation During Production	<ul style="list-style-type: none"> • Describe calculation and accuracy for determination of heat generation.
3.8.1 Dose Rate Projections	<ul style="list-style-type: none"> • Project dose rates from radionuclide projections.
3.8.2 Does Rate During Production	<ul style="list-style-type: none"> • Develop methods to determine does rates.
3.9 Chemical Compatibility	<ul style="list-style-type: none"> • Experimentally evaluate chemical compatibility.
3.10 Subcriticality	<ul style="list-style-type: none"> • Determine nuclear characteristics of DWPF canistered waste form.
	<ul style="list-style-type: none"> • Perform bounding calculations to show $k_{eff} \ll 1$.
3.11 Weight, Length, Diameter, and Overall Dimensions	<ul style="list-style-type: none"> • Specify length, diameter, and wall thickness requirements in canister procurement documents.
3.12 Drop Test	<ul style="list-style-type: none"> • Perform drop test on prototypic canisters.
3.13 Handling Features	<ul style="list-style-type: none"> • Design grapple for lifting canisters. • Test grapple for lifting canisters.

**SAVANNAH RIVER DEFENSE WASTE PROCESSING FACILITY
(Cont'd)**

SIMULATED SLUDGE RUN ACTIVITIES
RELATING TO QUALIFICATION OF THE DWPF PRODUCT

To Be Added Later

HANFORD WASTE VITRIFICATION PROCESSING FACILITY

WASTE ACCEPTANCE PROCESS ACTIVITIES RELATING TO QUALIFICATION OF THE HWVP PRODUCT

To Be Added Later

WEST VALLEY DEMONSTRATION PROJECT

WASTE ACCEPTANCE PROCESS ACTIVITIES RELATING TO QUALIFICATION OF THE WVDP PRODUCT

To Be Added Later

Future IDAHO WASTE VITRIFICATION PROCESSING FACILITY

WASTE ACCEPTANCE PROCESS ACTIVITIES
RELATING TO QUALIFICATION OF THE ICPP PRODUCT

To Be Added Later

ATTACHMENT II

STANDARD PRACTICE PROCEDURES DESCRIPTIONS

<u>SPP NUMBER</u>	<u>TITLE</u>
1.01	<u>Index of High-Level Waste Standard Practice Procedures for Quality Assurance</u>

This procedure contains a listing of all the Standard Practice Procedures along with their current revision status.

2.01 Standard Practice Procedures

This procedure defines the responsibilities and actions for the preparation, review, approval, distribution, and revision of the Standard Practice Procedures. This procedure establishes the framework for the dissemination of basic policies, information, and procedural practices.

2.03 Quality Assurance Program Description Preparation, Maintenance, and Control

This procedure defines the responsibilities and actions required to prepare and maintain the EM HLW Quality Assurance Program Description.

2.04 Control of the Standard Practice Procedures Manual

This procedure defines the actions and responsibilities for the preparation, maintenance, and control of the Standard Practice Procedures Manual which contains copies of all Waste Operations Procedures, including those for quality assurance activities.

2.05 Selective Application of Quality Assurance Activities

This procedure defines the responsibilities and actions required to delineate the quality-affecting activities to be performed by Waste Operations at Headquarters and the method by which quality assurance requirements are selectively applied to those activities.

3.01 Preparation and Maintenance of Plans for Personnel Training, Indoctrination, and Orientation

This procedure defines the responsibilities and actions for planning the indoctrination, training, and orientation of personnel who carry out duties affecting the integrity of defense high-level waste processing activities.

3.02 Preparation and Conduct of Personnel Training, Indoctrination, and Orientation

This procedure defines the responsibilities and actions required to prepare and conduct personnel training, indoctrination, and orientation of personnel who carry out duties affecting the integrity of defense high-level waste activities.

3.03 Certification of Quality Assurance Audit

This procedure defines the responsibilities and actions required to certify quality assurance audit personnel to audit program activities.

3.04 Documentation of Surveillance and Review Personnel Qualifications

This procedure defines the responsibilities and actions required to document the qualifications of quality assurance surveillance and review personnel.

3.05 Administration of Personnel Certification and Qualification Records

This procedure defines the responsibilities for administering the certification for personnel directly involved in quality verification, testing, evaluation, or audit activities. The procedure also details the action associated with collection and maintenance of records pertaining to personnel qualifications.

4.01 Planning and Scheduling of Evaluation Activities

This procedure covers the planning and scheduling of evaluation activities to determine that management control and work activities which affect quality are performed in a controlled environment, and to assess the adequacy and effectiveness of those controls.

4.02 Administration of Quality Assurance Audits

This procedure defines the responsibilities for initiating, planning, follow-up, and close out of quality assurance audits. This procedure also details the actions in documenting the audit activity.

4.03 Conduct of Quality Assurance Audits

This procedure defines the responsibilities and actions required to plan, prepare, conduct, and report on quality assurance audits.

4.04 Administration and Conduct of Surveillance

This procedure defines the responsibilities for the planning, conduct, and reporting of surveillance activities.

4.05 Administration of Technical Reviews

This procedure defines the responsibilities for initiating, planning, and follow-up of Technical Reviews.

4.06 Conduct of Technical Reviews

This procedure defines the responsibilities and actions required to prepare, conduct and report on technical review activities.

4.08 Administration of Peer Reviews

This procedure defines the responsibilities for initiating, planning, and follow-up of Peer Reviews.

4.09 Conduct of Peer Reviews

This procedure defines the responsibilities and actions required to prepare, conduct, and report on peer review activities.

4.10 Review of Operations Offices Quality Assurance Program Descriptions and Procedures

This procedure defines the responsibilities for review of Operations Offices or contractors quality assurance plans and procedures to determine their adequacy. The acceptance process is also described.

4.11 Review of Waste Acceptance Process Technical Documents

This procedure defines the responsibilities and actions required to review and evaluate selected Operations Office or contractor technical documents.

4.12 Review of Program Execution Guidance Documents

This procedure defines the responsibilities and actions required to review program requirement specifications (Program Execution Guidance) for adequacy as related to quality assurance requirements. The procedure also details the process of documenting the review findings.

4.13 Participation in Evaluation Activities Led by External Organizations

This procedure defines the responsibilities and actions required for participating in evaluation activities led by external organizations and using those evaluations in lieu of internal duplicate evaluations.

5.01 Deviation Reporting and Disposition

This procedure defines the responsibilities and actions required to initiate and process deviation reports. It also includes the responsibilities and actions to follow-up on and to ensure disposition of deviations and actions to prevent recurrence.

5.02 Management Action Request

This procedure defines the responsibilities and actions required to escalate management attention to deviations identified during quality assuring activities. This includes the responsibilities and actions required to initiate, process, and follow-up on Management Action Requests.

5.03 Control of Unsatisfactory Conditions (Stop Work Orders)

This procedure defines the responsibilities and actions required for issuing and processing Stop Work Orders which stop further fabrication, installation, or use of nonconforming items or processes which would result in a condition adverse to quality.

5.04 Disposition of Deviations Identified by Outside Organizations

This procedure defines the responsibilities and actions required to evaluate proposed dispositions, from deviations identified by organizations external to EM.

5.05 Review of Unusual Occurrences

This procedure defines the responsibilities and actions required to review Unusual Occurrences reported by organizations external to EM.

5.06 Control and Disposition of Deviations and Recommendations for Improvement by Outside Organizations

This procedure defines the responsibilities and actions required to control and disposition deviations and recommendations for improvements by organizations external to EM.

6.01 Official HLW Office Files

This procedure defines the actions and responsibilities for establishing a file identification, collection, maintenance and retrieval system. The procedure details the particulars for handling and filing all official HLW documents.

6.02 Preparation of Correspondence

This procedure describes the approved format for the preparation and handling of EM correspondence.

6.03 Incoming Mail

This procedure defines the actions and responsibilities for receipt and control of incoming mail.

6.04 Commitment Control

This procedure covers the establishment of action correspondence identification and control and the access of action correspondence status information.

6.05 Controlled Documents

This procedure defines the responsibilities and actions of EM for controlling documents generated by program participants external to EM.

7.01 Preparation, Transfer, and Receipt of Quality Records

This procedure defines the responsibilities and actions for preparation, transfer, and receipt of Quality Records.

7.02 Quality Records Management

This procedure defines the actions and responsibilities for managing, storing, and dispositioning HLW records, including quality records.

8.01 Coordination of Reviews and Evaluations by Outside Organizations

This procedure defines the responsibilities and actions required to coordinate reviews and evaluations by organizations external to EM.

8.02 Quality Assurance Program Evaluation and Assessment of Adequacy and Effectiveness

This procedure defines the responsibilities and actions required to evaluate and assess the High-Level Waste Processing Quality Assurance Program for adequacy and effectiveness.

8.03 Review and Reporting of Quality Assurance Program Progress and Status

This procedure defines the responsibilities and actions for the review of the HLW Quality Assurance Program on a monthly basis, as well as the preparation of comprehensive program status reports for the Director, Division of Waste Management Projects.

9.01 Preparation and Maintenance of the Program Schedules

This procedure defines the actions and responsibilities for preparations, review, approval, and maintenance of the program schedules.

9.02 HLW Monthly Progress Reporting

This procedure defines the actions and responsibilities for the preparation, review, approval, and distribution of the HLW Monthly Progress Report.

9.03 Preparation and Maintenance of the Work Breakdown Structures (WBS)

This procedure defines the actions and responsibilities for preparation and maintenance of a program Work Breakdown Structure (WBS), as well as the WBS Dictionary.

10.01 Identification and Analysis of Adverse Quality Trends and Problems

This procedure defines the responsibilities and actions required to analyze causes and contributors to quality problems.

10.02 Planning and Conduct of Quality Improvement

This procedure defines responsibilities and actions required to plan and conduct quality improvement activities which cannot be adequately addressed within the deviation control and corrective action systems.

10.03 Differing Staff Opinions and Allegations

This procedure provides guidelines, assigns responsibilities and actions which will document, evaluate, and respond to differing staff opinions or allegations that relate to issues of inadequate quality or safety.

7/1/91

At the present time, the procedure system utilized by EM-343 is undergoing a transition. Specific actions are:

1. The SPPs were issued in 2/90. In October 1990, the EM-343 Quality Assurance Program was declared operational and orientation for the SPPs was presented to all affected persons.

After the first four months of use, an effort was initiated to update and streamline the SPPs, primarily based on lessons learned from the users. This revision resulted in major changes to some SPPs, minor changes to some SPPs, cancellation of some SPPs, and combination of certain SPP.

To date, these revised SPPs have completed their review cycle by QARG and comments have been resolved on all procedures except:

- SPP 4.14 - "Preparation of a Review Team Charter." This is a new procedure and QARG is now finalizing their review comments.
- SPP 4.15 - "Administration and Performance of Technical Reviews." This is a new procedure that will replace SPP 4.05, 4.06, 4.10, 4.11, and 4.12. This procedure is being updated to incorporate internal EM-343 comments in preparation for review by the QARG.

We are expediting the finalization of these two SPPs and plan to issue the entire revised manual in the next few weeks. This revision will also incorporate any changes resulting from the informal review by RW of the HLW QAPD (submitted to Rw 5/26/91).

2. EM-30 is developing a Standard Operating Practice Procedure (SOPP) Manual. It is anticipated that some of these procedures will replace certain SPPs and will be directly implemented by EM-343 via the "gold sheet" method or by identification on a responsibility matrix.
3. EM-1 is developing a QAPD and implementing procedures. Seventeen procedures have been identified and ten have been drafted. Again, it is anticipated that certain of these procedures will be directly implemented by EM-30 and 343 via this "gold sheet" method or by identification on a responsibility matrix. These procedures include subjects such as auditor qualification, peer review, technical review, etc.
4. The SPP revision effort is continuing in order to define the entire EM-343 program. They will be used in the development of the "gold sheets" for the EM-30 or EM-1 procedures and may continue to be used by contractors supporting the EM-343 effort.

The attached matrix projects only step 1 above. It is designed to assist in the understanding of who performs specific tasks, where they are located, and where the appropriate records are maintained. For example, the QAPD (SPP 2.04) preparation and coordination has been assigned to PTSO/PDC in Oak Ridge and the required records (previous issues, review comments, comment resolutions, controlled distribution, etc.) are maintained by PDC in Oak Ridge.

**EM-343
STANDARD PRACTICE PROCEDURES**

SPP	SPP Title	Proposed Disposition	Contractor Support
1.01	Index of High-Level Waste Standard Practice Procedures for Quality Assurance	Index	
2.01	Standard Practice Procedures	Minor	PDC/OR
2.03	Quality Assurance Program Description Preparation, Maintenance, and Control	Minor	PDC/OR
2.04	Control of the Standard Practice Procedures Manual	Combine with SPP 6.05	PDC/OR
3.01	Preparation and Maintenance of Plans for Personnel Training, Indoctrination, and Orientation	Minor	
3.02	Preparation and Conduct of Personnel Training, Indoctrination, and Orientation	Minor	
3.03	Certification of Quality Assurance Audit Personnel	Major	PDC/OR

**EM-343
STANDARD PRACTICE PROCEDURES**

SPP	SPP Title	Proposed Disposition	Contractor Support
3.04	Documentation of Surveillance and Review Personnel Qualifications	Minor	PDC/OR
3.05	Administration of Personnel Certification and Qualification Records	Minor	PDC/OR, HQ training records maintained by EM-343
4.01	Planning and Scheduling of Evaluation Activities	Minor	Past - PDC/OR Present - HQ
4.02	Administration of Quality Assurance Audits	Minor	PTSO/RL, PDC/OR
4.03	Conduct of Quality Assurance Audits	Minor	PTSO/RL, PDC/OR
4.04	Administration and Conduct of Surveillance	Minor	PTSO/RL, PDC/OR
4.05	Administration of Technical Reviews	Replace by SPP 4.15	PTSO/RL, ANL

**EM-343
STANDARD PRACTICE PROCEDURES**

SPP	SPP Title	Proposed Disposition	Contractor Support
4.06	Conduct of Technical Reviews	Replace by SPP 4.15	PTSO/RL, ANL
4.08	Administration of Peer Reviews	Minor	None to date
4.09	Conduct of Peer Reviews	Minor	None to date
4.10	Review of Operations Offices Quality Assurance Program Descriptions and Procedures	Replace by SPP 4.15	PTSO/RL, PDC/GTN (QARG)
4.11	Review of Waste Acceptance Process Technical Documents	Replace by SPP 4.15	PTSO/RL, ANL (TRG)
4.12	Review of Program Execution Guidance Documents	May be replaced by SPP 4.15	

**EM-343
STANDARD PRACTICE PROCEDURES**

SPP	SPP Title	Proposed Disposition	Contractor Support
4.13	Participation in Evaluation Activities Led by External Organizations	Minor	None to date
5.01	Deviation Reporting and Disposition	Major	PDC/OR
5.02	Management Action Request	Minor	PDC/OR
5.03	Control of Unsatisfactory Conditions (Stop Work Orders)	Minor	None to date
5.04	Disposition of Deviations Identified By Outside Organizations	Minor	None to date
5.05	Review of Unusual Occurrences	Minor	None to date

**EM-343
STANDARD PRACTICE PROCEDURES**

SPP	SPP Title	Proposed Disposition	Contractor Support
5.06	Control and Disposition of Deviations and Recommendations for Improvement by Outside Organizations	Void	None to date
6.01	Official HLW Office Files	Minor	
6.02	Preparation of Correspondence	Minor	
6.03	Incoming Mail	Void	
6.04	Commitment Control	Minor	
6.05	Controlled Documents	Major	

**EM-343
STANDARD PRACTICE PROCEDURES**

SPP	SPP Title	Proposed Disposition	Contractor Support
7.01	Preparation, Transfer, and Receipt of Quality Records	Minor	
7.02	Quality Records Management	Minor	
8.01	Coordination of Reviews and Evaluations by Outside Organizations	Minor	None to date
8.02	Quality Assurance Program Evaluation and Assessment of Adequacy and Effectiveness	Major	None to date
8.03	Review and Reporting of Quality Assurance Program Progress and Status	Major	PDC/OR
9.01	Preparation and Maintenance of the Program Schedules	Major	PDC/OR (partial)

**EM-343
STANDARD PRACTICE PROCEDURES**

SPP	SPP Title	Proposed Disposition	Contractor Support
9.02	HLW Monthly Progress Reporting	Major	
9.03	Preparation and Maintenance of the Work Breakdown Structures (WBS)	Minor	Not yet implemented
10.01	Identification and Analysis of Adverse Quality Trends and Problems	Minor	Insufficient data to trend
10.02	Planning and Conduct of Quality Improvement	Minor	Not yet implemented
10.03	Differing Staff Opinions and Allegations	Minor	None to date

High-Level Waste

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Standard Practice
PROCEDURES

Manual Assignment Page

Copy Number 78 is Issued

To: C. D. Morell

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STANDARD PRACTICE PROCEDURE

SPP 1.01
Page 1 of 5
Rev. 0
Effective
Date 02/02/90

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INDEX OF HIGH-LEVEL WASTE STANDARD PRACTICE PROCEDURES FOR QUALITY ASSURANCE

Section 1.0 - QUALITY ASSURANCE PROGRAM OVERVIEW

<u>SPP Number</u>	<u>Title</u>	<u>Revision</u>
1.01	Index of High-Level Waste Standard Practice Procedures for Quality Assurance	0

Section 2.0 - CONTROL OF PROGRAM DEFINING DOCUMENTS

<u>SPP Number</u>	<u>Title</u>	<u>Revision</u>
2.01	Standard Practice Procedures	0
2.03	Quality Assurance Program Description Preparation, Maintenance, and Control	0
2.04	Control of the Standard Practice Procedures Manual	0

Section 3.0 - TRAINING AND CERTIFICATION

<u>SPP Number</u>	<u>Title</u>	<u>Revision</u>
3.01	Preparation and Maintenance of Plans for Personnel Training, Indoctrination, and Orientation	0
3.02	Preparation and Conduct of Personnel Training, Indoctrination, and Orientation	0
3.03	Certification of Quality Assurance Audit Personnel	0
3.04	Documentation of Surveillance and Review Personnel Qualifications	0

3.05 Administration of Personnel Certification and Qualification Records 0

Section 4.0 - PROGRAM CONTROL AND VERIFICATION

<u>SPP Number</u>	<u>Title</u>	<u>Revision</u>
4.01	Planning and Scheduling of Evaluation Activities	0
4.02	Administration of Quality Assurance Audits	0
4.03	Conduct of Quality Assurance Audits	0
4.04	Administration and Conduct of Surveillance	0
4.05	Administration of Technical Reviews	0
4.06	Conduct of Technical Reviews	0
4.08	Administration of Peer Reviews	0
4.09	Conduct of Peer Reviews	0
4.10	Review of Operations Offices Quality Assurance Program Descriptions and Procedures	0
4.11	Review of Waste Acceptance Process Technical Documents	0
4.12	Review of Program Execution Guidance Documents	0
4.13	Participation in Evaluation Activities Led by External Organizations	0

Section 5.0 - NONCONFORMANCE, DEVIATION, AND CORRECTIVE ACTION CONTROL

<u>SPP Number</u>	<u>Title</u>	<u>Revision</u>
5.01	Deviation Reporting and Disposition	0
5.02	Management Action Request	0
5.03	Control of Unsatisfactory Conditions (Stop Work Orders)	0
5.04	Disposition of Deviations Identified By Outside Organizations	0
5.05	Review of Unusual Occurrences	0
5.06	Control and Disposition of Deviations and Recommendations for Improvement by Outside Organizations	0

Section 6.0 - DOCUMENTATION CONTROL

<u>SPP Number</u>	<u>Title</u>	<u>Revision</u>
6.01	Official HLW Office Files	0
6.02	Preparation of Correspondence	0
6.03	Incoming Mail	0
6.04	Commitment Control	0
6.05	Controlled Documents	0

Section 7.0 - QUALITY RECORDS MANAGEMENT

<u>SPP Number</u>	<u>Title</u>	<u>Revision</u>
7.01	Preparation, Transfer, and Receipt of Quality Records	0
7.02	Quality Records Management	0

Section 8.0 - PROGRAM COORDINATION, EVALUATION, AND REPORTING

<u>SPP Number</u>	<u>Title</u>	<u>Revision</u>
8.01	Coordination of Reviews and Evaluations by Outside Organizations	0
8.02	Quality Assurance Program Evaluation and Assessment of Adequacy and Effectiveness	0
8.03	Review and Reporting of Quality Assurance Program Progress and Status	0

Section 9.0 - PROJECT MANAGEMENT

<u>SPP Number</u>	<u>Title</u>	<u>Revision</u>
9.01	Preparation and Maintenance of the Program Schedules	0
9.02	HLW Monthly Progress Reporting	0
9.03	Preparation and Maintenance of the Work Breakdown Structures (WBS)	0

Section 10.0 - PROGRAM IMPROVEMENT

<u>SPP Number</u>	<u>Title</u>	<u>Revision</u>
10.01	Identification and Analysis of Adverse Quality Trends and Problems	0
10.02	Planning and Conduct of Quality Improvement	0
10.03	Differing Staff Opinions and Allegations	0

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STANDARD PRACTICE PROCEDURES

1. PURPOSE:

To provide guidelines for the preparation, review, approval, and revision of Standard Practice Procedures.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 1.01, Standard Practice Procedure Index
- b. SPP 2.04, Control of the Standard Practice Procedure Manual
- c. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records

4. GENERAL:

None

5. PROCEDURE:

All actions except those performed by the Reviewers may be performed by the Manager when necessary.

a. Procedure Preparation, Review and Approval

<u>Performer</u>	<u>Action</u>
Manager	(1) Receives notification of, or identifies the need for the generation of a new, or revision to an existing SPP.
	(2) Assigns responsibility for its preparation and informs the SPP Coordinator accordingly.
SPP Coordinator	(3) Assigns titles and identification numbers for each SPP as directed by the Manager.

<u>Performer</u>	<u>Action</u>
SPP Coordinator	(4) Prepares the SPP Coordination Log (Attachment A) by appointing a reviewer/type of review to be performed, i.e. technical, quality assurance, or administrative adequacy.
Preparer	(5) Prepares a draft SPP in the format described in Attachment B. (6) Includes in the SPP (as appropriate) the following: (a) Provisions for the generation of documented evidence that activities affecting quality are being, or have been accomplished as required. (b) Acceptance criteria for determining that important activities have been satisfactorily accomplished. These may be quantitative or qualitative. (7) Forwards the SPP and review/comment form (Attachment C) to the designated reviewers for a technical, quality assurance, or administrative review.
Designated Reviewers	(8) Review the SPP for technical content, ensure governing documents are identified and requirements are met, ensure all principal organizations and performers with responsibilities are identified, and all organizational interfaces are correctly identified. (9) Forward written comments to the SPP preparer.
Preparer	(10) Resolves comments with all involved parties and secures concurrence. (11) Updates the SPP draft, and forwards it to the Manager.

<u>Performer</u>	<u>Action</u>
Manager	(12) Reviews the SPP and provides written comments (see Attachment C) to the SPP Preparer.
Preparer	(13) Resolves all comments and prepares the SPP in final form. <u>Note:</u> If changes from the original draft are extensive, prepares a new draft SPP and repeats the appropriate previous steps.
	(14) Forwards the SPP Coordination Log (Attachment A) and copies of original comments to the designated reviewers.
Reviewers	(15) Sign and date the appropriate blank on the SPP Coordination Log denoting agreement. <u>Note:</u> If reviewers cannot agree with the SPP, they shall immediately contact the SPP Preparer and identify problem(s).
	(16) Forward the package (SPP and Coordination Log) to the SPP Preparer.
Preparer	(17) Obtains the Quality Assurance Specialist's (QAS's) signature (with date) denoting agreement on the coordination log and forwards the package (SPP and coordination log) to the manager. ✓
Manager	(18) Approves the SPP by signing the appropriate blank on coordination log. ✓ (19) Forwards the approved SPP and SPP Coordination Log to the SPP Coordinator.

b. Index Preparation and Approval

<u>Performer</u>	<u>Action</u>
SPP Coordinator	(1) Prepares a new index (see Attachment D) for each distribution of SPP, which contains as a minimum: (a) SPP number and title. (b) SPP revision. (c) Index revision number and date of index issue or revision. (2) Forwards the index to the Manager for review and approval by the Manager along with the approved SPP(s) for distribution.
Manager	(3) Reviews the index for accuracy, approves, and forwards it to the SPP Coordinator.
SPP Coordinator	(4) Distributes the SPP and revised index in accordance with Reference 3.a.

c. Revisions

<u>Performer</u>	<u>Action</u>
Preparer	(1) Revises SPPs following the same steps used to develop the originals after being notified of, or discovering the need for, a change. (2) Designates revised portions of the SPP with a vertical line in the right margin, except when the revision is a major rewrite. If revision is a major rewrite, such notation must be made in revision Coordination Log.

d. Records

<u>Performer</u>	<u>Action</u>
SPP Coordinator	<ul style="list-style-type: none"> (1) Prepares the following as quality records in accordance with Reference 3.b: <ul style="list-style-type: none"> (a) Each implementing SPP and revision as issued. (b) SPP Coordination Log for each SPP revision. (c) Each revision of the SPP Index. (d) Review/Comment Form from each reviewer of each SPP review. (2) Maintains the following records for working and historical purposes: <ul style="list-style-type: none"> (a) Copies of all previously issued revisions and reviewers comments (obtains from the SPP Preparer). (b) Current SPP original. (c) A copy of the SPP Coordination Log for each revision.

e. Annual SPP Review

<u>Performer</u>	<u>Action</u>
SPP Coordinator	(1) Conducts an annual review of those SPPs not revised during the past twelve months and lists those which need updating with the reason on a memorandum to the Manager.
Manager	<ul style="list-style-type: none"> (2) Authorizes revisions to SPP as necessary based on the SPP Coordinator's recommendations. (3) Appoints preparer to revise procedures in accordance with Section e.

6. ATTACHMENTS:

- a. Attachment A - SPP Coordination Log (Example)**
- b. Attachment B - SPP Format**
- c. Attachment C - SPP Review/Comment Form**
- d. Attachment D - SPP Manual Index (Example)**

Attachment A

Standard Practice Procedure Coordination Log (Example)

**STANDARD PRACTICE PROCEDURE (SPP)
 COORDINATION LOG**

SPP No. _____ Revision _____

SPP Title _____

	Signature	Date
Prepared/Revised By:		
Reviewed By:		
<input type="checkbox"/>		
Quality Assurance Specialist		

Reason(s) for Revision:

Approval of SPP for issuance _____
Manager Date

Attachment B

Standard Practice Procedure Format

1. Subheadings

The subheadings for each section in each SPP are as indicated below and are underlined. All subheadings except for "CANCELLATION" are included even if there is no information given. The word "none" is placed directly under the subheading title in this case.

- a. **PURPOSE:** - Section 1 contains a concise statement of the SPP intent.
- b. **CANCELLATION:** - Section 2 contains a list of all SPPs cancelled by the issue of the current SPP by SPP number and title. When appropriate this section may be omitted with the rest of the sections renumbered accordingly.
- c. **SCOPE:** - Section 3 specifies the extent of application of the SPP or the areas to which requirements of the SPP apply. Since the contents of the SPPs have limited application the following Standard Scope Statement applies: The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.
- d. **REFERENCES:** - Section 4 contains instructions and documents referred to in the body of the procedure in the order they are used in the procedure. References include procedure or document number (if applicable) and title.
- e. **GENERAL:** - Section 5 may be used as a lead-in to the procedure itself, for background or policy information, and/or for general information as appropriate.

Attachment B (Cont'd)

- f. **PROCEDURE:** - Section 6 contains definitive step-by-step sequence of instructions [in the playscript format (Attachment C)] which are required for the implementation and execution of the procedure. Procedures are of sufficient detail to allow implementation without additional procedures.

Note: A paragraph format may be used (as in this attachment) instead of playscript when a statement of policy or function is needed instead of a written SPP.

- g. **ATTACHMENTS:** - Section 6 lists documents such as flowcharts, forms, graphs, charts, checklists, tables as necessary to supplement the SPP.

2. Paragraph Identification

- a. Each paragraph within a section uses the following number/letter sequence:

- (1) 1.
- (2) a.
- (3) (1)
- (4) (a)
- (5) 1
- (6) a

3. Paragraph Notes

- a. Notes may be added to clarify or provide detailed interpretations to various portions of the SPP. All notes are headed by the word "Note:"

Attachment B (Cont'd)

4. SPP Pages

- a. The top of each SPP page contains a SPP number, revision level, page number, total pages, and effective date as shown in this SPP.

Note: Revision levels are indicated by an Arabic number with "0" representing the original issue. Prior to original issue, a draft number and date are used to indicate that the SPP is still in draft status.

- b. The first page of each SPP also contains the SPP title block as shown in this SPP.
- c. Attachment pages contain an attachment identifier and title (e.g., "Attachment A - Standard Procedure Format") and are numbered as a portion of the entire SPP. The attachment identifier is repeated on continuation pages; the attachment title is not repeated on continuation pages.

Attachment B (Cont'd)
Example of Playscript Format

SPP 2.01
 Page 4 of 13
 Effective
 Date

A conditional action may be shown like this

Performer

Action

Preparer

(13) Resolves all comments and prepares the SPP in final form.

Note: If changes from the original draft are extensive, prepares a new draft SPP and repeats the appropriate previous steps.

The "performer" in playscript is a person, group, or organization

Reviewers

(14) Forwards the SPP Coordination Log (Attachment B) and copies of original comments to the designated reviewers .

(15) Sign and date the appropriate blank on the SPP Coordination Log denoting agreement.

Note: If reviewers cannot agree with the SPP, they shall immediately contact the SPP Preparer and identify problem(s).

Preparer

(16) Forward the package (SPP and coordination log) to the SPP Preparer.

Initial action verbs should be used for clear presentation of the action sequence

Manager

(17) Obtains the Quality Assurance Specialist's (QAS's) signature (with date) denoting agreement on the coordination log and forwards the package (SPP and coordination log) to the manager.

(18) Approves the SPP by signing the appropriate blank on coordination log.

(19) Forwards the approved SPP and SPP Coordination Log to the SPP Coordinator.

Attachment C

Standard Practice Procedure Review/Comment Form

STANDARD PRACTICE PROCEDURE REVIEW/COMMENT FORM			
Reviewer:		Organization:	Date:
Page/Section	Comments	Resolutions	Reviewer Concurrence

Attachment D

Standard Practice Procedure Manual Index (Example)

SUBJECT: STANDARD PRACTICE PROCEDURE INDEX

Section 1.0 - QUALITY ASSURANCE PROGRAM OVERVIEW

<u>SPP Number</u>	<u>Title</u>	<u>Revision</u>
1.01	Standard Procedures Index	0
1.02	Policy Statement	.
1.03	Quality Assurance Program Requirements Matrix	.
1.04	Description of the Overview Process	.

Section 2.0 - CONTROL OF PROGRAM DEFINING DOCUMENTS

<u>Instruction Number</u>	<u>Title</u>	<u>Revision</u>
2.01	Standard Practice Procedures	0
2.03	Quality Assurance Program Description Preparation, Maintenance, and Control	.
2.04	Control of the Standard Practice Procedure Manual	.

Section 3.0 - TRAINING AND CERTIFICATION

<u>Instruction Number</u>	<u>Title</u>	<u>Revision</u>
3.01	Preparation and Maintenance of Plans for Personnel Training, Indoctrination, and Orientation	0
3.02	Preparation and Conduct of Personnel Training, Indoctrination, and Orientation	0
3.03	Certification of Quality Assurance Audit Personnel	.
3.04	Documentation of Surveillance and Review Personnel Qualifications	.
3.05	Administration of Personnel Certification and Qualification Records	.

STANDARD PRACTICE PROCEDURE

SPP 2.03
Page 1 of 19
Rev. 0
Effective
Date 02/02/90

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QUALITY ASSURANCE PROGRAM DESCRIPTION PREPARATION, MAINTENANCE, AND CONTROL

1. PURPOSE:

To provide instructions for the preparation, review, approval, and maintenance of the Quality Assurance Program Descriptions (QAPD) of program participants in the U. S. DOE's Civilian Radioactive Waste Management Program.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. OCRWM Quality Assurance Program Requirements for the Civilian Radioactive Waste Management Program (QAPR DOE/RW-0214).
- b. DOE Order 5700.6, Quality Assurance
- c. SPP 2.01, Standard Practice Procedures
- d. SPP 2.04, Control of the SPP Manual
- e. SPP 7.02, Quality Records Management

4. GENERAL:

- a. Waste Acceptance Process Activities of High-Level Waste Form Production is unique in that the canistered waste form product of the Waste Processing Facilities must meet specified requirements in order to be found acceptable for the federal repository. The Office of Civilian Radioactive Waste Management (OCRWM or RW) is responsible for construction and operation of the federal repository which is subject to Nuclear Regulatory Commission (NRC) licensing requirements. RW developed DOE/RW-0214 for meeting NRC licensing requirements. It identifies the quality assurance requirements that waste form producers must meet to ensure the acceptability of the canistered waste form.

- b. A requirement of DOE/RW-0214 is for each waste form producer to prepare a written description of its quality assurance program. To satisfy this requirement the QAPD will consist of three stand-alone parts. The first part of the QAPD is an introductory part which gives background information and summarizes Parts 2 and 3 activities to satisfy DOE Order 5700.6 on Quality Assurance and the requirements of DOE/RW-0214. The word "QAPD" as used in the rest of this SPP refers to all three parts although each part is capable of standing alone.

5. PROCEDURE:

All actions may be performed by the QAPD Manager (hereafter "Manager") when necessary, except those action steps performed by the Reviewers.

a. QAPD Preparation and Review

<u>Performer</u>	<u>Action</u>
Manager	<ul style="list-style-type: none"> (1) Prepares or directs the preparation of a draft QAPD in the following three parts in accordance with the instructions in Attachment A: <ul style="list-style-type: none"> (a) High-Level Waste Processing. (b) High-Level Waste Form Development and Qualification. (c) High-Level Waste Form Production.
QAPD Preparer	<ul style="list-style-type: none"> (2) Prepares an index for each part of the QAPD which contain the following as a minimum: <ul style="list-style-type: none"> (a) QAPD identifying number and date of approval. (b) A page by page index with the page number and the revision level of each page. (3) Assembles the three parts of the QAPD including the three indices in a package and forwards the package to selected managers for review.

<u>Performer</u>	<u>Action</u>
Reviewers	(4) Review the QAPD using review criteria approved by the Manager and provide any comments in writing to the Manager using the review/comment form of reference 3.c or by annotating a hard copy of the QAPD.
Manager	(5) Coordinates and resolves all comments on the review/comment form or on the annotated QAPD and prepares the QAPD and indices in final form.
	Note: If changes from the original draft are extensive, prepares a new draft QAPD and repeats Steps 1 through 4.

b. Approval Cycle

<u>Performer</u>	<u>Action</u>
Manager	(1) Initiates a QAPD Coordination Log (Attachment B) by: <ul style="list-style-type: none"> (a) Checking the QAPD parts being originated/revised. (b) Entering the revision number and date of the index for each applicable part. (c) Signing the appropriate "Prepared/Revised By" signature line. (2) Forwards the finalized QAPD, dispositioned review/comment form, if required, and Coordination Log to each manager for review.
Reviewer	(3) Signs and dates the appropriate blank of the review/comment form to denote agreement with each part of the QAPD under question.

<u>Performer</u>	<u>Action</u>
Reviewer	(4) Forwards the package (i.e., the QAPD, the review/comment form, and the Coordination Log) to the Manager for provisional approval.
Manager	(5) Receives comments on the QAPD for disposition action and resolves comments. (6) Assures incorporation of the agreed upon dispositions into the QAPD. (7) Approves by signing. (8) Forwards the QAPD to the SPP Coordinator for distribution in accordance with Section 5.e.

c. Revisions

<u>Performer</u>	<u>Action</u>
Manager	(1) Revises and issues individual pages or parts of the QAPD following the same steps used to develop the originals. Note: Indices with multiple pages should be revised and indexed as a complete document to avoid confusion. (2) Designates revised portions of each page with a vertical line in the right margin.

d. Annual QAPD Review

<u>Performer</u>	<u>Action</u>
Quality Assurance Specialist (QAS)	(1) Conducts an annual review of the QAPD and prepares a memorandum to the Manager documenting the review and listing those portions which need updating with the reason(s).

<u>Performer</u>	<u>Action</u>
QAS	(2) Obtains the Manager's concurrence of the memorandum and initiates any necessary revisions to the QAPD in accordance with Section 5.c.

e. Control and Distribution of the QAPD Manual

<u>Performer</u>	<u>Action</u>
SPP Coordinator	<p>(1) Develops and maintains a distribution list of persons or positions who should receive controlled copies of the QAPD Manual or any of the stand alone parts.</p> <p>(2) Obtains approval for the distribution list and any revisions from the Manager.</p> <p>(3) Assigns copies of the QAPD Manual(s) to those on the distribution list.</p> <p>(4) Provides a Manual Assignment Page (Attachment C) with a unique control number for placement in the front of each controlled manual.</p> <p>(5) When the QAPD or any part is prepared/revised and approved, obtains the required number of copies or the applicable revised pages or parts including the indices.</p> <p>(6) Distributes the manual(s) and indices or distributes the manual revision packages by transmittal memorandum similar to Attachment D and requests an acknowledgement of receipt within 10 working days (Attachment E).</p>

Note: Uncontrolled copies may be distributed to interested personnel as long as they are readily distinguishable from controlled copies.

<u>Performer</u>	<u>Action</u>
Manual Holders	(7) Comply with instructions on the transmittal memorandum.

f. Records

<u>Performer</u>	<u>Action</u>
SPP Coordinator	(1) Prepares the following as quality records in accordance with Reference 3.e: <ul style="list-style-type: none">(a) A record of each revision of the QAPD.(b) Coordination Logs for each QAPD revision.(c) Indices for each revision of the QAPD.(d) Memorandum(s) documenting the annual review.(e) Review/Comment forms from each reviewer of each instruction review.
	(2) Maintains the following records for working and historical purposes: <ul style="list-style-type: none">(a) Copies of all previously issued (approved) revisions, requests for comments, and reviewers comments and dispositions.(b) Current QAPD master copy.(c) Each QAPD revision Coordination Log.(d) Records of Receipt or Log(s) recording receipt status for QAPD Manual distributions.

6. ATTACHMENTS:

- a. Attachment A - Instructions for QAPD Preparation**
- b. Attachment B - QAPD Coordination Log (Example)**
- c. Attachment C - QAPD Manual Assignment Page (Example)**
- d. Attachment D - QAPD Transmittal Memorandum (Example)**
- e. Attachment E - QAPD Manual Record of Receipt (Example)**
- f. Attachment F - QAPD Cover Sheets (Example)**

Attachment A

Instructions for QAPD Preparation

1. SCOPE

a. Part 1 - High-Level Waste Processing

Part 1 should describe the quality assurance program for all high-level waste processing activities. To accomplish this, Part 1 should reference the basic requirements sections of Parts 2 and 3 to apply them to the broader scope of high-level waste processing activities.

b. Part 2 - High-Level Waste Form Development and Qualification

Part 2 should describe the quality assurance program for waste acceptance process activities of high-level waste development and qualification only. Part 2 should cover the requirements of DOE/RW-0214 in a way that distinguishes the basic requirements of DOE/RW-0214 from the supplemental requirements of DOE/RW-0214 to maintain the two requirements' identity.

c. Part 3 - High-Level Waste Form Production

Part 3 should describe the quality assurance program for waste acceptance process activities of high-level waste production only. Part 3 should cover the requirements of DOE/RW-0214 in a way that distinguishes the basic requirements from the supplemental requirements of DOE/RW-0214 to maintain the two requirements' identity.

Attachment A (Cont'd)

2. FORMAT AND CONTENT

a. General

- (1) Each page of the QAPD including index pages and figures shall include a header in the upper right-hand corner which contains the following:
 - (a) The document identifiers are as follows:
 - DOE/EM-0061 (for Part 1 although this identifier is also used when referring to the complete manual)
 - DOE/EM-0062 (for Part 2)
 - DOE/EM-0063 (for Part 3)
 - (b) Page number
 - (c) Revision number
 - (d) Date approved (also the effective date)
- (2) Each part of the QAPD should have a cover page with the document number and appropriate descriptive titles (see Attachment F).
- (3) The second page of each QAPD part shall be an approval page with the appropriate DOE Office or Division, approval signature line at the bottom of the page.

Attachment A (Cont'd)

b. Part 1 - High-Level Waste Processing

- (1) This part should be organized as follows:
 - (a) 1.0 Introduction
 - (b) 2.0 Program Objectives
 - (c) 3.0 Program Application
 - Describes the project background, scope, strategy, responsibilities, and schedule.
 - (d) 4.0 Program Content
 - Describes the program requirements, transfer of requirements to participants, program participation, program elements, program breakdown, and program overview.
 - (e) 5.0 References
 - (f) 6.0 Acronyms
 - (g) Figures

Attachment A (Cont'd)

c. Part 2 - High-Level Waste Form Development, Qualification, and Part 3 Production

- (1) Parts 2 and 3 shall conform to the requirements in Section 5.3 with the following clarifications:
 - (a) Chapter "17" numbering system (as described in NRC Regulatory Guide 1.70) will be implemented by RW when Part 3 of the QAPD is ready to be packaged with the DOE Project Office QAPD and the operating contractor's QAPD in preparation for RW's licensing process (only Part 3 "Production" numbering need change at that point).

Note: RW will do the renumbering prior to inclusion in their safety analysis report.

- (b) Part 2 of the QAPD is to be included in the Waste Form Compliance Plan and part 3 of the QAPD is to be included by reference only.

Attachment B

QAPD Coordination Log (Example)

QAPD COORDINATION LOG

<input type="checkbox"/> Part 1 - High-Level Waste Processing Index Revision No. ____ Dated	Signature	Date
Prepared/Revised By:		
Reviewed By:		

<input type="checkbox"/> Part 2 - HLW Form Dev. & Qual. Index Revision No. ____ Dated	Signature	Date
Prepared/Revised By:		
Reviewed By:		

<input type="checkbox"/> Part 3 - HLW Form Production Index Revision No. ____ Dated	Signature	Date
Prepared/Revised By:		
Reviewed By:		

Attachment C

QAPD Manual Assignment Page (Example)

<p>U. S. DEPARTMENT OF ENERGY OFFICE OF ENVIRONMENTAL RESTORATION & WASTE MANAGEMENT OFFICE OF WASTE OPERATIONS WASHINGTON, DC 20545</p>	<p>DOE/EM-0061 DOE/EM-0062 DOE/EM-0063</p>
<p>QUALITY ASSURANCE PROGRAM DESCRIPTIONS</p>	
<p>HIGH-LEVEL WASTE</p>	
<p>Manual Assignment Page</p>	
<p>Copy Number _____ is Issued</p>	
<p>To: _____</p>	
<p>This controlled manual is the property of the U. S. DOE/EM 34. Please return the manual to the U. S. DOE/EM 34 HLW-Instructions Coordinator when requested or no longer needed.</p>	
<p>DATE</p>	
<p>SEAL</p>	

Attachment D

QAPD Transmittal Memorandum (Example)

HLW Quality Assurance Program Description (QAPD) Manual Holders

**DISTRIBUTION OF MATERIAL FOR THE HLW QAPD
MANUAL - TRANSMITTAL MEMORANDUM NO. _____**

**The following material is attached for filling in your HLW QAPD Manual in
accordance with the attached Index:**

Revision.

DOE/EM-0061 Page(s)

DOE/EM-0062 Page(s)

DOE/EM-0063 Page(s)

**Please insert the attached material into your manual, discard the superseded
material, check the contents of your manual with the Index, and return the
acknowledgment receipt.**

HLW Program Manager

Attachments

Attachment E

QAPD Manual Record of Receipt (Example)

Note to Recipient:

1. For any changes or missing pages contact the HLW Instructions Coordinator. Changes to distribution should be requested in writing to the HLW-Program Manager.
2. Upon receipt of Transmittal Memorandum No. _____, please comply with the instructions and sign, date, and return this form within ten working days from time of receipt.

Manual Holder

Manual Number

Date

RETURN TO: HLW-INSTRUCTIONS COORDINATOR
HLW Program Manager
U. S. Department of Energy
EM34
Washington, DC 20545

Attachment F

QAPD Manual Cover Sheet (Example)

DOE/EM-0061
DOE/EM-0062
DOE/EM-0063

U. S. DEPARTMENT OF ENERGY
OFFICE OF ENVIRONMENTAL RESTORATION & WASTE MANAGEMENT
OFFICE OF WASTE OPERATIONS
WASHINGTON, DC 20545

QUALITY ASSURANCE
PROGRAM DESCRIPTIONS

HIGH-LEVEL WASTE

DATE

SEAL

Attachment F (Cont'd)

QAPD Part 1 Cover Sheet (Example)

U. S. DEPARTMENT OF ENERGY
OFFICE OF ENVIRONMENTAL RESTORATION & WASTE MANAGEMENT
OFFICE OF WASTE OPERATIONS

QUALITY ASSURANCE
PROGRAM DESCRIPTION

DOE/EM-0061

DOE-EM
HIGH-LEVEL WASTE PROCESSING

Date
Rev. _____

Attachment F (Cont'd)

QAPD Part 2 Cover Sheet (Example)

<p>U. S. DEPARTMENT OF ENERGY OFFICE OF ENVIRONMENTAL RESTORATION AND WASTE MANAGEMENT OFFICE OF WASTE OPERATIONS</p>
<p>QUALITY ASSURANCE PROGRAM DESCRIPTION</p>
<p>DOE/EM-0062</p>
<p>DOE-EM HIGH-LEVEL WASTE FORM DEVELOPMENT AND QUALIFICATION</p>
<p>Date Rev.</p>

Attachment F (Cont'd)

QAPD Part 3 Cover Sheet (Example)

**U. S. DEPARTMENT OF ENERGY
OFFICE OF ENVIRONMENTAL RESTORATION AND WASTE MANAGEMENT
OFFICE OF WASTE OPERATIONS**

**QUALITY ASSURANCE
PROGRAM DESCRIPTION**

DOE/EM-0063

**DOE-EM
HIGH-LEVEL WASTE FORM PRODUCTION**

Date
Rev. ____

STANDARD PRACTICE PROCEDURE

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SPP 2.04
Page 1 of 6
Rev. 0
Effective
Date 02/02/90

CONTROL OF THE STANDARD PRACTICE PROCEDURES MANUAL

1. PURPOSE:

To establish guidelines and responsibilities for the control and distribution of the Standard Practice Procedures (SPP) Manual; and control and distribution of the revision packages for the SPP Manual.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

a. None

4. GENERAL:

The Standard Practice Procedures Manual is intended to contain all standard practice procedures in support of the OCRWM HLW Waste Management Program. The initial transmittal of the SPP Manual to a person on the controlled distribution list will consist of the binder containing the title page, control page, index, and available instructions. Subsequent transmittals will include instructions or revised SPPs. After all SPPs are developed, the SPP Manual, complete with all inserts, will be issued to persons whose names are added to the controlled distribution list after the initial distribution.

5. PROCEDURE:

a. Control and Distribution of the SPP Manual

<u>Performer</u>	<u>Action</u>
SPP Coordinator	(1) Develops and maintains a distribution list of persons or positions who are to receive controlled copies of the SPP Manual.

<u>Performer</u>	<u>Action</u>
SPP Coordinator	<p>Note: Controlled copies of Standard Practice Procedures should be available at the location where activities, described by the SPPs, are to be performed before that work commences.</p> <p>(2) Seeks approval for the SPP Manual distribution list and any revisions from the person who approves the SPP Manual distribution list (hereafter "Approver").</p>
Approver	<p>(3) Signs the SPP Manual distribution list signifying its approval and returns it to the SPP Coordinator.</p>
SPP Coordinator	<p>(4) Assigns and distributes controlled copies of the SPP Manual to those on the approved distribution list.</p> <p>(5) When SPPs are prepared/revised, prepares a new SPP Manual index, which contains as a minimum:</p> <ul style="list-style-type: none">(a) SPP numbers and titles.(b) SPP revisions.(c) Index revision number and date of index issue or revision. <p>(6) Obtains the required number of copies of the SPP(s) including the index.</p> <p>(7) When assigning SPP Manuals, provides a Manual Assignment Page (Attachment A) with a unique control number for placement in the front of each controlled manual.</p>

<u>Performer</u>	<u>Action</u>
SPP Coordinator	<p>(8) Distributes the SPP Manual(s) or distributes the manual revision packages by a transmittal memorandum (Attachment B) and requests an acknowledgement of receipt of the document within ten working days.</p> <p><u>Note:</u> Provides uncontrolled copies as requested. Uncontrolled copies may be distributed to personnel as long as they are identified as an "uncontrolled" copy and are readily distinguishable from controlled copies.</p>
SPP Manual Holder	<p>(9) Complies with instructions on Part A of the transmittal memorandum (Attachment B) in inserting the new index and with updating the SPP Manual, completes Part B of the transmittal memorandum and returns it as indicated.</p>
SPP Coordinator	<p>(10) Files or logs the completed transmittal memorandum when received from the manual holders.</p> <p>(11) Ensures all manual holders have completed Part B of the transmittal memorandum and have returned the memorandum as indicated.</p> <p><u>Note:</u> (1) If the transmittal memorandum has not been signed and returned to the SPP Coordinator by the required acknowledgement date identified on the transmittal memorandum, the SPP Coordinator will issue a formal inquiry to the SPP Manual holder with a copy to his/her immediate supervisor requesting an immediate response to and return of the signed transmittal memorandum.</p>

<u>Performer</u>	<u>Action</u>
SPP Coordinator	(2) If the inquiry to the manual holder is not responded to as requested, the SPP Manual holder shall be formally notified to return or destroy all contents of his/her assigned SPP Manual. The manual holder shall be further informed that his/her name has been removed from the SPP Manual controlled distribution list.

b. Records

<u>Performer</u>	<u>Action</u>
SPP Coordinator	(1) Maintains the following as non-quality assurance records for working and historical purposes: (a) Receipts or Log(s) recording receipt status for SPP Manuals or manual revisions.

6. ATTACHMENTS:

- a. Attachment A - Standard Practice Procedures Manual Assignment Page (Example)
- b. Attachment B - Standard Practice Procedures Transmittal Memorandum (Example)

Attachment A

Standard Practice Procedure
Manual Assignment Page (Example)

High-Level Waste

Standard Practice
PROCEDURES

Manual Assignment Page

Copy Number ____ is Issued

To: _____

This Controlled Manual is the property of Performance Development Corporation, 109
Jefferson Avenue, Oak Ridge, Tennessee 37830. Please return the Manual to this
address when no longer needed or requested.

Attachment B

**Standard Practice Procedure
 Transmittal Memorandum (Example)**

PART A	<p>TO: Standard Practice Procedures (SPP) Manual Holders</p> <p>FROM: Standard Practice Procedures (SPP) Coordinator</p> <p>DATE:</p> <p>SUBJECT: DISTRIBUTION OF MATERIAL FOR THE SPP MANUAL - TRANSMITTAL MEMORANDUM NO.</p> <p>The following material is attached for filing in your SPP Manual in accordance with the attached Index:</p> <table style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th style="text-align: center;"><u>Description</u></th> <th style="text-align: center;"><u>Revision</u></th> </tr> </thead> <tbody> <tr> <td style="height: 100px;"> </td> <td> </td> </tr> </tbody> </table> <p>Please insert the attached material into your manual, discard the superseded material, check the contents of your manual with the Index, and return the completed receipt acknowledgement as indicated below within 10 working days.</p> <p>For any changes or missing pages contact the SPP Coordinator. Changes to distributions should be requested in writing to the above.</p> <p style="text-align: center;">Attachments</p>	<u>Description</u>	<u>Revision</u>		
<u>Description</u>	<u>Revision</u>				
PART B	<p style="text-align: center;"><u>ACKNOWLEDGEMENT RECEIPT</u></p> <p>TO: Standard Practice Procedures Coordinator: _____</p> <p>FROM _____</p> <p>I have received subject material for the SPP Manual and have complied with the above instructions for updating my assigned manual number _____.</p> <p>_____</p> <p style="display: flex; justify-content: space-between;"> DATE SIGNATURE </p>				

STANDARD PRACTICE PROCEDURE

SPP 3.01
Page 1 of 9
Rev. 0
Effective
Date 02/02/90

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PREPARATION AND MAINTENANCE OF PLANS FOR PERSONNEL TRAINING, INDOCTRINATION, AND ORIENTATION

1. PURPOSE:

To provide guidelines and assign responsibility and actions to develop and maintain a training, indoctrination, and orientation (TI&O) plan and schedule. This will ensure that training needed to perform effectively is systematically identified, planned, conducted, and recorded.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 3.02, Preparation and Conduct of Personnel Training, Indoctrination, and Orientation
- b. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records

4. GENERAL:

Managers shall, in cooperation with the assigned Quality Assurance Specialist, assess the training needs (including quality assurance) of personnel and establish a TI&O plan and schedule. These TI&O plans and schedules will be used to develop training courses as detailed in SPP 3.02.

a. Definitions

- (1) Manager - Any individual having supervision over or responsibility for the performance of others.
- (2) Orientation - The act or process of acquainting individuals with the existing situation, environment, or condition.
- (3) Indoctrination - To instruct in fundamentals so as to provide understanding of principles involved.

- (4) 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.

5. PROCEDURE:

All actions described in this SPP may be performed by a designated Manager as necessary.

a. Development of the TI&O Plan and Schedule

<u>Performer</u>	<u>Action</u>
Training Coordinator	(1) Prepares a plan and schedule for the annual training needs assessment of all individuals who perform quality related work and informs their management accordingly.
Manager(s)	(2) Annually assesses the TI&O needs of personnel performing quality related activities under their cognizance. This assessment should include commitments from requirements documents, including the Quality Assurance Program Description, QARD DOE/RW-0214, etc.
	<u>Note:</u> A TI&O Needs Assessment Worksheet (Attachment A) should be used to perform and document the assessment. (The instructions for completing a TI&O Needs Assessment Worksheet are also included as a part of Attachment A.)
	(3) Forwards completed assessment to the designated Quality Assurance Specialist.
Training Coordinator	(4) Annually assesses the overall TI&O needs of personnel performing both quality achieving and quality assuring functions by reviewing and analyzing the assessments made by their individual managers.

<u>Performer</u>	<u>Action</u>
Training Coordinator	<p>(5) Discusses the results of the overall needs assessment with the managers. Receives input from them on TI&O priorities and ways to meet these priorities, including courses to be developed.</p> <p>(6) Uses the results of the needs assessment plus input received from the personnel to be trained to formulate the annual TI&O Plan and Schedule (see Attachment B).</p> <p><u>Note:</u> The TI&O Plan and Schedule should take advantage of courses and development activities that are offered outside the organization.</p> <p>(7) Develops the draft TI&O plan and schedule. Includes all courses/activities planned for personnel for the year.</p> <p>(8) Forwards draft TI&O Plan and Schedule to the managers for review.</p>
Managers	<p>(9) Provide comments on the TI&O Plan to the Training Coordinator.</p>
Training Coordinator	<p>(10) Incorporates their review comments, prepares final plan for review and approval by the responsible manager.</p>

b. Distribution and Implementation of the TI&O Plan and Schedule

<u>Performer</u>	<u>Action</u>
Training Coordinator	<p>(1) Distributes the approved TI&O Plan and Schedule to the managers by January of each year.</p>

<u>Performer</u>	<u>Action</u>
Training Coordinator	(2) Coordinates and oversees the implementation of the TI&O Plan and Schedule and assists the managers in implementing the plan and schedule. (3) Coordinates and monitors participation in outside training courses. (4) Assists the managers in meeting newly identified training needs not included in the approved TI&O Plan and Schedule. (5) Keeps the managers apprised of implementation progress.

c. Maintenance of the TI&O Plan and Schedule

<u>Performer</u>	<u>Action</u>
Training Coordinator	(1) Evaluates any training needs identified by personnel; and includes appropriate training and development activities to meet the training needs of personnel in the next revision of the TI&O Plan and Schedule. (2) Maintains the TI&O Plan and Schedule and, as a minimum, updates and distributes the TI&O Plan by January of each year to correspond with the annual needs assessment. (3) Ensures each revision of the TI&O is reviewed and approved in the same manner as the original.

d. Records

<u>Performer</u>	<u>Action</u>
Training Coordinator	(1) Maintains a copy of each approved TI&O Plan and Schedule as a quality record in accordance with SPP 7.01.

<u>Performer</u>	<u>Action</u>
Training Coordinator	(2) Maintains a working file which contains the current TI&O Plan and Schedule and past needs assessments.

6. **ATTACHMENTS:**

- a. Attachment A - Needs Assessment Worksheet (Example)
- b. Attachment B - TI&O Plan and Schedule Format

Attachment A (Cont'd)

Instructions to Management for Completing the Quality Assurance Training Needs Assessment Worksheet

1. ITEM NO.:

This column is provided so that individual needs shown on the Worksheet can be easily identified. The first item on the sheet should be numbered "1," the second "2," and so on.

2. TOPIC:

In this column enter a brief description of the topic, subject, or application in which training is needed. Be as specific as possible. For example, list as separate items specific quality assurance (QA) instructions, or specific groups of instructions in which training is needed rather than just saying "QA Instructions." Remember that the QAS must be able to compare training needs across different Programs; this will be done much more effectively if the manager lists the needs of personnel in specific terms.

3. REQUIRED KNOWLEDGE/SKILL LEVEL:

This is a key to helping ensure that personnel receive the depth of training required for the identified topics. Enter, in the columns provided, the employee needs to receive either a basic indoctrination, orientation, or in-depth skills training for each topic listed. Note: In-depth skills training will normally require testing to demonstrate comprehension of the course material. Testing is optional for the other types of training.

4. NEEDED BY:

List the day, month, and year by which training is required. If the day is not listed, the QAS will assume that training can be provided at any time during the month.

Attachment A (Cont'd)

5. COMMENTS:

Enter information that cannot be entered in the other columns. For example, if personnel are only available for a specific training activity during a specific time period (such as the month of June), an entry such as "must be done in June" could be appropriate.

Attachment B

TI&O Plan and Schedule Format

The TI&O Plan and Schedule should, at minimum, include the following elements:

1. A cover page, clearly identifying the document.
2. An introductory section explaining the purpose, scope, and use of the TI&O Plan and Schedule.
3. A summary schedule that provides an overview of the TI&O activities scheduled for the year, and the basic time frames in which they are scheduled to occur.

STANDARD PRACTICE PROCEDURE

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SPP 3.02
Page 1 of 12
Rev. 0
Effective
Date 02/02/90

PREPARATION AND CONDUCT OF PERSONNEL TRAINING, INDOCTRINATION, AND ORIENTATION

1. PURPOSE:

To provide guidelines for preparing and conducting training, indoctrination, and orientation (TI&O) courses/activities for personnel who are assigned responsibilities for, or who participate in quality achieving or quality assuring activities.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 3.01, Preparation and Maintenance of Plans for Personnel Training, Indoctrination, and Orientation
- b. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records

4. GENERAL:

Managers, in cooperation with the Quality Assurance Specialist, shall ensure that persons performing activities affecting quality or activities assuring quality shall be indoctrinated, trained, and oriented prior to performing the activity. Training, indoctrination, and orientation (TI&O) shall be in accordance with the TI&O Plan developed in SPP 3.01.

5. PROCEDURE:

All actions described in this SPP may be performed by a designated Manager as necessary.

a. Development and Preparation of Training, Indoctrination, and Orientation Course Material

<u>Performer</u>	<u>Action</u>
Manager	<ol style="list-style-type: none">(1) Identifies the need for developing a project-specific TI&O course material/training materials based on the approved TI&O Plan produced in SPP 3.01. Ensures that the need is valid and its scope adequately addressed.(2) Reviews the identified need with the Quality Assurance Specialist (QAS) and incorporates QAS identified needs.(3) Appoints a Course Developer for each TI&O course/activity whether classroom or On the Job Training (OJT).
Course Developer	<ol style="list-style-type: none">(4) Identifies the need for and thereafter obtains assignment of Subject Matter Experts (SMEs) to assist in the development and preparation of TI&O course materials.(5) Uses the stated objectives and course descriptions presented in the current TI&O Plan to prepare a lesson plan for each identified course, in a format similar to Attachment A, for submission to the SME for review and comment.(6) Incorporates appropriate SME comments and finalizes the lesson plan.(7) Coordinates the lesson plan with the QAS and the manager and obtains his/her signature on the lesson plan, signifying approval of the lesson plan.

b. Scheduling and Conduct of Indoctrination Classes

<u>Performer</u>	<u>Action</u>
Manager	(1) Ensures that personnel receive Quality Assurance Indoctrination as specified in the TI&O Plan and Schedule developed in SPP 3.01.
Instructor/Trainer	(2) Conducts project-specific indoctrination classes for personnel performing quality-related activities.
	(3) Conducts reindoctrination of personnel within a period of three years from initial indoctrination.
	(4) Ensures that each indoctrination session is documented (Attachment B), and documentation is maintained as a quality record in accordance with SPP 7.01.

c. Scheduling and Conduct of Orientation and Training Classes

<u>Performer</u>	<u>Action</u>
Manager	(1) Submits to other interested Managers/Staff Members a notification of the new course(s) schedule and proposed attendance list.
	(2) Appoints an instructor or trainer for each TI&O course.
	(3) Notifies staff members of training course schedule and need for attendance.
Instructor/Trainer	(4) Administers any required TI&O pretesting and analyzes the test scores.
	(5) Conducts training whether classroom or OJT.

<u>Performer</u>	<u>Action</u>
Instructor/Trainer	(6) Evaluates each participant and ensures satisfactory completion of the training (see Attachment B). (7) Documents training class with attendance forms and forwards all resulting records to the QAS and interested manager.
Personnel	(8) Attend TI&O class sessions as scheduled or notify the responsible manager or training coordinator for rescheduling.
Manager	(9) Ensures affected personnel under their supervision receive orientation or training as to the contents of revised quality assurance instructions or new instructions prior to performing their quality related activities.

Note: Formal classroom training is not always required. Management must take whatever steps are necessary to ensure affected personnel receive adequate orientation or training.

- (10) Ensures that documentation of each orientation, training course, or training activity for each participant includes the following:
- (a) The subject, date, and duration of training.
 - (b) Signature of the participant.
 - (c) Signature of the instructor or trainer.

d. Evaluation and Revision of Training, Indoctrination, and Orientation Courses and Classes

<u>Performer</u>	<u>Action</u>
Instructors/Trainers	(1) Administer the training, indoctrination, and orientation class posttest (where applicable), analyze the results, and compare with any pretest results.
Manager	(2) Forwards test results to the QAS as quality records. (3) Determines the need for targeted retraining. (4) Administers the TI&O class evaluation and analyze the results. (5) Provides evaluations to Instructors/Trainers and Course Developers on course and class conduct, based on sessions attended.
Course Developer	(6) Reviews course evaluations received from management and personnel who attended the class sessions and takes actions to improve the training program. (7) Revises TI&O course materials based on class evaluations and evaluations from management. (8) Coordinates to obtain approval for the revision using the same process as for the original.

e. Records

<u>Performer</u>	<u>Action</u>
Training Coordinator	(1) Maintains completed Indoctrination/Orientation/Training Records as quality assurance records in accordance with SPP 7.01.

<u>Performer</u>	<u>Action</u>
Manager	(2) Establishes and maintains an indoctrination/ orientation/training file for each person performing quality-related activities and updates with copies of their completed Indoctrination/Orientation/Training Record(s).

6. ATTACHMENTS:

- a. Attachment A - Lesson Plan Development Guidelines
- b. Attachment B - Administration of Course Documentation

Attachment A

Lesson Plan Development Guidelines

The main functions of the lesson plan are to provide an objective basis for review and approval of course content before the course is taught, to provide for consistent instruction across different course sessions and instructors, and to provide an accurate record of the material that was covered in the course. Ensuring that all lesson plans meet the criteria described below will help ensure that all lesson plans meet these goals.

COVER

1. Be sure that the course title, the course number and revision level are prominently displayed on the cover of the lesson plan.

TITLE PAGE

1. Course Title: The title of the course as it appears on the cover. If the overall course is composed of two or more separate lessons, enter the lesson title.
2. Lesson Number: The course number as it appears on the title page, and the lesson number if the course is composed of two or more separate lessons.
3. Learning Objectives: These describe the desired outcome of the course or lesson. They are stated in terms of what the student is expected to know or be able to do at the end of the course or lesson. They should not be stated in terms of material to be covered.

This section of the lesson plan should contain a terminal objective (the main, overall learning objective that the course or lesson is aimed at helping the students meet) and a series of enabling objectives (the intermediate objectives the student will have to meet in order to meet the terminal objective.)

Attachment A (Cont'd)

Simply stated, your terminal objective is a statement of where you want the student to end up; your enabling objectives are the steps along the way.

4. Teaching Time: The length of time of a single session.
5. Teaching Method: Lecture, discussion, demonstration, etc.
6. Training Materials: Training aids that will be needed. This includes instructor aids (lesson plan, overhead projector, etc.), student aids (handouts, exercises), and course administration materials (tests, critique sheets, attendance sheets, etc.).
7. Instructor Guidance: This provides basic guidance to the instructor regarding specific steps to be taken before, during, and after class that are not included in the main body of the lesson plan.
8. Signatures: This should consist of spaces for the signatures of the Course Developer and the Training Coordinator and the dates signed.

BODY

Lesson plan pages can be in a variety of formats. As long as the format chosen provides clear, consistent direction to the instructor, contains specific directions for activities such as exercises, tests, and other activities, and provides adequate documentation of the content of the course, the specific format chosen is largely a matter of taste. No matter the format being used, each page of the body should be numbered. The range of format choices available is illustrated by Exhibits 1 and 2.

1. Exhibit 1, the standard two-column format, is the most common format for lesson plan pages.

Attachment A (Cont'd)

2. **Presentation**: The left-hand column, "PRESENTATION" contains the basic remarks the instructor is to make during the presentation. It should be complete enough to provide adequate guidance to the instructor to avoid omitting important material but should be flexible enough to allow for the use of personal or impromptu examples. Most course developers find that the use of a series of short, direct phrases separated by adequate white space to allow the instructor to write personal notes into the lesson plan is the best approach.
3. **Remarks**: The right-hand column, "REMARKS" contains guidance to the instructor to change visuals, conduct exercises, etc.
4. Exhibit 2 is an effective alternative to the standard columnar format. Many people find it easier to use this format since it clearly indexes any remarks and exercises to the appropriate visual aid, and requires little mental "processing" time on the instructor's part. It is especially useful the first few times a new instructor conducts a course, since it is considerably easier to "walk through" the presentation using this format.
5. The box in the top-left corner of the page contains either a reduced-size copy of the visual to be used, or the number of the visual (either is effective). The remainder of the space on the page contains anything the instructor is to say or do during the class.

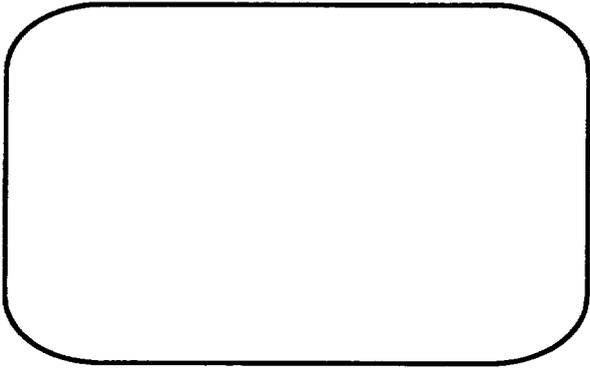
Attachment A (Cont'd)

Exhibit 1

Presentation	Visual/Notes
Lesson Plan	<i>Course/Lesson Title</i> <i>Course/Lesson Number</i>

Attachment A (Cont'd)

Exhibit 2

		
<i>Lesson Plan</i>	<i>Course/Lesson Title</i> <i>Course/Lesson Number</i>	<i>Page #</i>

Attachment B

Administration of Course Documentation

At the completion of each training course, the instructor or trainer ensures that the following actions are completed.

1. Attendance sheets from each session are reviewed for completeness and accuracy.
2. Course critiques from each session are reviewed by management and appropriate changes to course material are initiated.
3. Tests, where applicable, are scored. Participants are notified of results.
4. Prepare a summary of course critique results and test results.
5. Prepare one clean copy each of the lesson plan, participant handouts, visual aids, critique sheet, and test.
6. Assemble the materials described in Steps 4 and 5 above into a package along with the original attendance sheets from each session for training records.

STANDARD PRACTICE PROCEDURE

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SPP 3.03
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Rev. 0
Effective
Date 02/02/90

CERTIFICATION OF QUALITY ASSURANCE AUDIT PERSONNEL

1. PURPOSE:

To provide guidance and instruction for the certification of quality assurance audit personnel, which includes auditor, lead auditor, and auditor examiner.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 3.05, Administration of Personnel Certification and Qualification Records
- b. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records
- c. ANSI/ASME NQA-1-1986, Quality Assurance Program Requirements for Nuclear Facilities
1989 should be
- d. DOE Order 5700.6B, Quality Assurance

4. GENERAL:

Auditors are certified in accordance with this instruction prior to being assigned responsibility for performing quality assurance audits. The auditor examiner, as well, is certified in accordance with this instruction prior to performing auditor examiner duties.

When auditors or lead auditors from outside organizations are utilized these personnel are certified/recertified in accordance with this SPP or the assigned Quality Assurance Specialist (QAS) determines and confirms in writing that individuals have valid certifications under a system that has been accepted or is determined to be acceptable in accordance with the same or equivalent requirements. In either case, the QAS maintains supporting documentation.

5. PROCEDURE:

All actions may be performed by the Audits Coordinator when necessary.

a. Selection of Personnel and Evaluation of Qualifications

<u>Performer</u>	<u>Action</u>
Coordinator of Personnel Certification (CPC)	(1) Selects candidates to be considered for certification to quality assurance audit tasks using the Audit Task Descriptions (Attachment A) for guidance. (2) Obtains the necessary documentation which supports employee certification (e.g., standard resumes; training records, including examination results; audit participation records; communication skill letters; and appropriate forms) for each candidate. (3) Forwards documentation to the certifying official (see Attachment B for designation of the certifying official).
Certifying Official	(4) Evaluates the candidates and certifies or rejects the candidates using the criteria and guidance presented below: (a) Reviews individual qualifications against applicable auditing task qualification requirements defined in Attachment A. (b) Documents the results of the evaluation on a Certification of Qualification Form (Attachment C) for each candidate and thereafter signs and dates each form. (c) Signs the Certification Certificate (Attachment D) for each candidate.

<u>Performer</u>	<u>Action</u>
Certifying Official	(d) When a candidate is not qualified for certification completes a written justification for rejecting the certification and forwards notification to the CPC. (e) Forwards the approved certification documentation to the CPC.

b. Documentation of Personnel Certification

<u>Performer</u>	<u>Action</u>
CPC	(1) Reviews completed certification documentation for adequacy and completeness including the verification of the credit allocation of professional requirements and prepares a Notification of Certification Memorandum (Attachment E). (2) Enters the certification data and information on the Recertification Schedule (Attachment F).

c. Recertification of Personnel

<u>Performer</u>	<u>Action</u>
CPC	(1) Enters appropriate information as it becomes available and maintains the Recertification Schedule in accordance with SPP 3.05. (2) Issues a notice that recertification is required to the certifying official and the affected person at least five weeks prior to the required date for recertification.

<u>Performer</u>	<u>Action</u>
CPC	<p>Note: Where retraining or additional training is anticipated, the notice shall be issued sufficiently in advance to permit and provide for such training prior to the expiration of the certification period.</p> <p>(3) Provides the certifying official with the original certification documentation and any additional supporting documentation accumulated on an annual basis(e.g., audit participation record).</p>
Certifying Official	<p>(4) Reviews the original certification documentation and additional supporting documentation accumulated during the annual period and updates the certification form for annual evaluation or returns the form with a written explanation for not certifying.</p> <p>(5) Signs a new Certification Certificate for each recertification.</p> <p>(6) Returns the original certification documentation and any additional supporting documentation to the CPC.</p>

d. Certification Records

<u>Performer</u>	<u>Action</u>
CPC	<p>(1) Using the Notification of Certification Memorandum, transmits the Certification Certificate to the person and their supervisor.</p>

<u>Performer</u>	<u>Action</u>
Quality Assurance Specialist (QAS)	(2) Maintains the following quality records in accordance with SPP 7.01: (a) Certification Certificate (b) Certification of Auditor Qualification Form (3) Maintains the original certification documentation in the persons certification and training file in accordance with SPP 3.05.

6. ATTACHMENTS:

- a. Attachment A - Audit Task Descriptions**
- b. Attachment B - Certifying Officials for Different Audit Tasks**
- c. Attachment C - Certification of Qualification Form**
- d. Attachment D - Certification Certificate (Example)**
- e. Attachment E - Notification of Certification Memorandum (Example)**
- f. Attachment F - Recertification Schedule**

Attachment A
Audit Task Descriptions

Exhibit 1
(Page 1 of 4)

Quality Assurance Auditor Task Description

1. Functional Statement

The Quality Assurance Auditor serves as a member of a Quality Assurance Audit Team and accordingly is technically capable of performing any assigned portion of an audit.

2. Duties and Responsibilities

- a. Becomes familiar with aspects of the audit relating to the requirements and commitments and assists in preparation of the audit plan as assigned by the Team Leader.
- b. Prepares the required audit checklists as assigned by the Team Leader.
- c. Reviews the audit plan and checklist when not involved in their preparation.
- d. Participates in the pre-audit conference.
- e. Performs the audit according to the plan or as directed by the Team Leader.
- f. Describes the findings resulting from the audit investigation and provides the results to the Audit Team Leader.
- g. Assembles with the audit team at the times designated by the Team Leader.
- h. Participates in the post-audit conference.
- i. Assists in the preparation of the final audit report, reviews it for accuracy and completeness, and thereafter signs it prior to its being transmitted to the auditee.

Attachment A (Cont'd)

Exhibit 1 (Page 2 of 4)

3. Qualifications Required

The qualifications listed on this task description are intended to define the minimum capabilities that qualify personnel to perform quality assurance audits, in accordance with ANSI/ASME NQA-1.

- a. Training. Auditors shall have, or shall be given, appropriate training or orientation to develop their competence for performing required audits. Competence of personnel for performance of the various auditing functions shall be developed by:
 - (1) Training in applicable codes, standards, and regulations.
 - (2) Training in audit techniques and, if applicable, on-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor.
 - (3) Demonstrated knowledge of audit instructions and requirements as may be contained in client Quality Assurance Program Descriptions and Applicable DOE documents.
- b. Education and Experience. The prospective Auditor shall have verifiable evidence that a minimum of five (5) points under the following scoring system have been accumulated:
 - (1) Education (4 points maximum). Associate degree from an accredited institution: score one (1) point; or, if the degree is in engineering, physical sciences, mathematics, or quality assurance, score two (2) points; or, a bachelor's degree from an accredited institution: score two (2) points; or, if the degree is in engineering, physical sciences, mathematics, or quality assurance, score

Attachment A (Cont'd)

Exhibit 1
(Page 3 of 4)

three (3) points; in addition score one (1) point for a master's degree in engineering, physical sciences, business management, or quality assurance from an accredited institution.

- (2) Experience (9 points maximum). Technical experience in engineering, manufacturing, construction, operation, or maintenance: score one (1) point for each full year with a maximum of five (5) points for this aspect of experience.

If two (2) or more years of this experience have been in the nuclear field, score one (1) additional point; or,

If two (2) or more years of this experience have been in quality assurance, score two (2) additional points; or,

If two (2) or more years of this experience have been in quality assurance auditing, score three (3) additional points; or,

If two (2) or more years of this experience have been in nuclear quality assurance, score three (3) additional points; or,

If two (2) or more years of this experience have included nuclear quality assurance auditing, score four (4) additional points.

- (3) Communication Skills. The prospective Auditor shall have the capability to communicate effectively, both in writing and orally. These skills shall be attested to in writing.

Attachment A (Cont'd)

Exhibit 1 **(Page 4 of 4)**

4. Maintenance of Qualification

a. Maintenance of Proficiency

Auditors shall maintain their proficiency through one or more of the following: regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to quality assurance programs and program auditing; participation in training programs. Based on management's annual assessment, management may extend the qualification, require retraining, or require requalification. These evaluations shall be documented.

b. Requalification

Auditors who fail to maintain their proficiency for a period of two years or more shall require requalification. Requalification shall include retraining in accordance with the requirements of paragraph 3.a.

5. Certification Requirements

Each Quality Assurance Auditor shall be certified as being qualified to participate in audits and the Auditor's records shall be established and maintained in accordance with ANSI/ASME NQA-1. In addition, the certification shall specifically identify any restrictions concerning the nature of the audits or areas of auditing for which the certification shall be considered valid or areas of auditing for which the certification shall not be considered valid.

Attachment A (Cont'd)

Exhibit 2 **(Page 1 of 6)**

Quality Assurance Lead Auditor Task Description

1. Functional Statement

The Quality Assurance Lead Auditor serves primarily as the Team Leader in the conduct of quality assurance audits. This includes the detailed planning, arranging, and coordination of the activities of the quality assurance audit team.

2. Duties and Responsibilities

- a. Provides the necessary orientation for the audit team members.
- b. Prepares or assigns the audit team members to prepare the audit plan and checklists that are necessary to accomplish the audit.
- c. Reviews audit plan and checklists and prepares the audit planning package.
- d. Develops and delegates work assignments to members of the audit team.
- e. Conducts a pre-audit conference with responsible management representatives of the organizations and of the activities to be audited.
- f. Performs audit activities in accordance with the audit plan.
- g. Coordinates the audit activities of the audit team and the organization being audited.
- h. Collects the results of the audit team's investigations, and coordinates the preparation of a draft report summarizing the team's findings, both positive and negative.

Attachment A (Cont'd)

Exhibit 2 **(Page 2 of 6)**

- i. Conducts a post-audit conference according to the previously arranged schedule with attendance by the audit team, representatives of the organization being audited who can attest to the validity of the deviations, and members of management at a level that can cause corrective action.
- j. Completes preparation of the report of the audit with the audit team.
- k. Obtains signature of audit Team Members, signs and issues the audit report.

3. Qualifications Required

The qualifications listed on this task description are intended to define the minimum capabilities that qualify personnel to lead quality assurance audits, in accordance with ANSI/ASME NQA-1.

- a. **Education and Experience.** The prospective Lead Auditor shall have verifiable evidence that a minimum of ten (10) points under the following scoring system have been accumulated.
 - (1) **Education (4 points maximum).** Associate degree from an accredited institution: score one (1) point; or, if the degree is in engineering, physical sciences, mathematics, or quality assurance, score two (2) points; or, a bachelor's degree from an accredited institution: score two (2) points; or, if the degree is in engineering, physical sciences, mathematics, or quality assurance, score three (3) points; in addition score one (1) point for a master's degree in engineering, physical sciences, business management, or quality assurance from an accredited institution.

Attachment A (Cont'd)

Exhibit 2 **(Page 3 of 6)**

- (2) Experience (9 points maximum). Technical experience in engineering, manufacturing, construction, operation, or maintenance: score one (1) point for each full year with a maximum of five (5) points for this aspect of experience.

If two (2) or more years of this experience have been in the nuclear field, score one (1) additional point; or,

If two (2) or more years of this experience have been in quality assurance, score two (2) additional points; or,

If two (2) or more years of this experience have been in quality assurance auditing, score three (3) additional points; or,

If two (2) or more years of this experience have been in nuclear quality assurance, score three (3) additional points; or,

If two (2) or more years of this experience have included nuclear quality assurance auditing, score four(4) additional points.

- (3) Other Credentials of Professional Competence (2 points maximum). Certification of competency in engineering, science, or quality assurance specialties issued and approved by a State Agency, or National Professional or Technical Society, score two (2) points.
- (4) Rights of Management (2 points maximum). The Lead Auditor's employer may grant up to two (2) points for other performance factors applicable to auditing which may not be explicitly called out in this section. Examples of these factors are leadership, sound judgment, maturity, analytical ability, tenacity, past performance, quality assurance training courses.

Attachment A (Cont'd)

Exhibit 2 (Page 4 of 6)

- b. Communication Skills. The prospective Lead Auditors shall have the capability to communicate effectively, both in writing and orally. These skills shall be attested to in writing.
- c. Training. Prospective Lead Auditors shall have training to the extent necessary to assure their competence in auditing skills. As a minimum, this training shall include training in applicable codes, standards, and regulations; training in audit techniques, and demonstrated knowledge of client audit instructions. Training in the following areas shall be given based upon management evaluation of the particular needs of each prospective Lead Auditor.
- (1) Knowledge and understanding of DOE Order 5700.6, client audit instructions and requirements, ANSI/ASME NQA-1 and other nuclear-related codes, standards, regulations, regulatory guides, as applicable.
 - (2) General structure of quality assurance programs as a whole and applicable elements such as organization; design control; procurement document control; instructions; procedures and drawings; document control; control of purchased materials, parts and components; control of special processes; inspection; test control; control of measuring and test equipment; handling, storage and shipping; inspection, test, and operating status; nonconforming materials, parts, or components; corrective action; quality records; audits and quality information feedback.
 - (3) Auditing techniques of examining, questioning, evaluating and reporting audit findings; methods of identifying and following up on corrective action items for deviations; and methods of closing out audit findings.

Attachment A (Cont'd)

Exhibit 2
(Page 5 of 6)

- (4) **Audit planning in the quality-related functions for the following activities: design, purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification of nuclear facilities or associated components and safety aspects of the nuclear facility.**
 - (5) **On-the-job training to include the elements of audit activity as described in ANSI/ASME NQA-1.**
 - d. **Audit Participation. The prospective Lead Auditor shall have participated in a minimum of five (5) quality assurance audits within a period of time not to exceed three (3) years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within the year prior to qualification.**
 - e. **Examination. The prospective Lead Auditor shall pass an examination which shall evaluate comprehension of and ability to apply the body of knowledge identified in paragraph 3.c. The test may be oral, written, practical, or any combination of the three types. The development and administration of the examination shall be in accordance with Section 5.2 of ANSI/ASME NQA-1, Supplement 2S-3.**
- 4. Maintenance of Qualification**
- a. **Maintenance of Proficiency**

Lead Auditors shall maintain their proficiency through one or more of the following: regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to quality assurance programs and program auditing;

Attachment A (Cont'd)

Exhibit 2 **(Page 6 of 6)**

participation in training programs. Based on management annual assessment, management may extend the qualification, require retraining, or require requalification. These evaluations shall be documented.

b. Requalification

Lead Auditors who fail to maintain their proficiency for a period of two years or more shall require requalification. Requalification shall include retraining in accordance with the requirements of paragraph 3.c, reexamination in accordance with paragraph 3.e of this attachment, and participation as an Auditor in at least one nuclear quality assurance audit.

5. Certification Requirements

Each Quality Assurance Lead Auditor shall be certified as being qualified to lead audits, and the Lead Auditor's records shall be established and maintained in accordance with ANSI/ASME NQA-1. In addition, the certification shall specifically identify any restrictions concerning the nature of the audits or areas of auditing for which the certification shall be considered valid or areas of auditing for which the certification shall not be considered valid.

Attachment A (Cont'd)

Exhibit 3 **(Page 1 of 6)**

Auditor Examiner Task Description

1. Functional Statement

The Auditor Examiner is the designated official who evaluates each candidate for certification to perform as an Auditor or Lead Auditor in a quality assurance audit team. The Auditor Examiner evaluates prerequisite qualifications, performs examinations and certifies to the qualifications of candidates.

2. Duties and Responsibilities

- a. Establishes requirements for audit team participants.
- b. Reviews prerequisite qualifications of prospective Quality Assurance Auditors and Lead Auditors; determines the appropriateness of a candidate's credentials; identifies any areas of background qualifications needing improvement; and arranges Auditor indoctrination, or additional experience if needed to develop qualifications.
- c. Conducts interviews and/or examinations to assess qualifications of candidates for Auditor and Lead Auditor in accordance with their respective descriptions.
- d. Certifies qualified individuals in accordance with ANSI/ASME NQA-1.
- e. Conducts interviews and personnel experience reviews for the purpose of an annual recertification of the Quality Assurance Auditors and Quality Assurance Lead Auditors.

3. Qualifications Required

The qualifications listed on the task description are intended to define the minimum capabilities that qualify personnel to perform as an Auditor Examiner, in accordance with ANSI/ASME NQA-1.

Attachment A (Cont'd)

Exhibit 3 (Page 2 of 6)

a. Education and Experience. The prospective Auditor Examiner shall have verifiable evidence that a minimum of ten (10) points under the following scoring system have been accumulated.

- (1) Education (4 points maximum). Associate degree from an accredited institution: score one (1) point, or if the degree is in engineering, physical sciences, mathematics, or quality assurance, score two (2) points; or, a bachelor's degree from an accredited institution: score two (2) points or, if the degree is in engineering, physical sciences, mathematics, or quality assurance, score three (3) points; in addition score one (1) point for a master's degree in engineering, physical sciences, business management, or quality assurance from an accredited institution.
- (2) Experience (9 points maximum). Technical experience in engineering, manufacturing, construction, operation, or maintenance: score one (1) point for each full year with a maximum of five (5) points for this aspect of experience.

If two (2) or more years of this experience have been in the nuclear field, score one (1) additional point; or,

If two (2) or more years of this experience have been in quality assurance, score two (2) additional points; or,

If two (2) or more years of this experience have been in quality assurance auditing, score three (3) additional points; or,

If two (2) or more years of this experience have been in nuclear quality assurance, score three (3) additional points; or,

Attachment A (Cont'd)

Exhibit 3 (Page 3 of 6)

If two (2) or more years of this experience have included nuclear quality assurance auditing, score four (4) additional points.

- (3) Other Credentials of Professional Competence (2 points maximum). Certification of competency in engineering, science, or quality assurance specialties issued and approved by a State Agency, or National Professional or Technical Society, score two (2) points.
 - (4) Rights of Management (2 points maximum). The Auditor Examiner's employer may grant to up two (2) points for other performance factors applicable to auditing which may not be explicitly called out in this section. Examples of these factors are leadership, sound judgment, maturity, analytical ability, tenacity, past performance, quality assurance training courses.
- b. Communication Skills. The prospective Auditor Examiner shall have the capability to communicate effectively, both in writing and orally. These skills shall be attested to in writing.
- c. Training. Prospective Auditor Examiners shall have training to the extent necessary to assure their competence in auditing skills. As a minimum, this training shall include training in applicable codes, standards, and regulations; training in audit techniques, and demonstrated knowledge of client(s) audit instructions and requirements. Training in the following areas shall be given based upon management evaluation of the particular needs of each prospective Auditor Examiner.
- (1) Knowledge and understanding of ANSI/ASME NQA-1 and other nuclear-related codes, standards, regulations, regulatory guides, as applicable.

Attachment A (Cont'd)

Exhibit 3 **(Page 4 of 6)**

- (2) General structure of quality assurance programs as a whole and applicable elements such as organization; design control; procurement document control; instructions; procedures and drawings; document control; control of purchased materials, parts and components; control of special processes; inspection; test control; control of measuring and test equipment; handling, storage and shipping; inspection, test, and operating status; nonconforming materials, parts, or components; corrective action; quality records; audits and quality information feedback.
 - (3) Auditing techniques of examining, questioning, evaluating and reporting audit findings; methods of identifying and following up on corrective action items for deviations; and methods of closing out audit findings.
 - (4) Audit planning in the quality-related functions for the following activities: design, purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification of nuclear facilities or associated components and safety aspects of the nuclear facility.
 - (5) On-the-job training to include the elements of audit activity as described in ANSI/ASME NQA-1.
- d. **Audit Participation.** The prospective Auditor Examiner shall have participated in a minimum of five (5) quality assurance audits within a period of time not to exceed three (3) years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within the year prior to qualification.

Attachment A (Cont'd)

Exhibit 3 **(Page 5 of 6)**

- e. **Examination.** The prospective Auditor Examiner shall pass an examination which shall evaluate comprehension of and ability to apply the body of knowledge identified in paragraph 3.c. The test may be oral, written, practical, or any combination of the three types. The development and administration of the examination shall be in accordance with Section 5.2 of ANSI/ASME NQA-1, Supplement 2S-3.

4. Maintenance of Qualification

a. Maintenance of Proficiency

Auditor Examiners shall maintain their proficiency through one or more of the following: regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to quality assurance programs and program auditing; participation in training programs. Based on management annual assessment, management may extend the qualification, require retraining, or require requalification. These evaluations shall be documented.

b. Requalification

Auditor Examiners who fail to maintain their proficiency for a period of two years or more shall require requalification. Requalification shall include retraining in accordance with the requirements of paragraph 3.c, reexamination in accordance with paragraph 3.e of this attachment, and participation as an Auditor in at least one nuclear quality assurance audit.

Attachment A (Cont'd)

Exhibit 3
(Page 6 of 6)

5. Certification Requirements

Each Auditor Examiner shall be certified as being qualified to lead audits, and the Auditor Examiner's records shall be established and maintained in accordance with ANSI/ASME NQA-1. In addition, the certification shall specifically identify any restrictions concerning the nature of the audits or areas of auditing for which the certification shall be considered valid.

Attachment B

Certifying Officials for Different Audit Tasks

AUDIT TASKS

CERTIFYING OFFICIAL

Auditor

Auditor Examiner

Lead Auditor

Auditor Examiner

Auditor Examiner

Program Manager

Attachment C

Certification of Qualification Form

CERTIFICATION OF AUDITOR/LEAD AUDITOR/AUDITOR EXAMINER QUALIFICATIONS FOR		
A. PROFESSIONAL REQUIREMENTS		POINTS
1. EDUCATION - 4 Pts. Max. 1. Undergraduate Level 2. Graduate Level 2. EXPERIENCE - 8 Pts. Max. Industry (5 pts. max.) and Nuclear Industry (NI), or Quality Assurance (QA), or Surveillance/Auditing (AU), or Combined NI, QA, AU 3. PROFESSIONAL ACCOMPLISHMENT - 2 Pts. Max. 1. PE 2. Society/Agency 4. MANAGEMENT - 2 Pts. Max. Explain:	University/Degree/Date Company/Dates Certificate/Date Justification/Evaluator/Date	
Evaluated by: (Name & Title) _____ Date _____		
MINIMUM REQUIREMENTS: AUDITOR - 5 pts.; LEAD AUDITOR - 10 pts. Total Pts.		
B. AUDIT COMMUNICATION SKILLS Evaluated by: (Name & Title) _____ Date _____		
C. AUDIT TRAINING COURSES (or Successfully Completed Training Assignments) Course or Activity _____ Date _____ 1. 2.		
D. AUDIT PARTICIPATION <u>Location</u> _____ <u>Audit</u> _____ <u>Date</u> _____ 1. 2. 3. 4. 5.		
E. SPECIFIC EXAMINATION Passed _____ Date _____		
F. CERTIFICATION Certified as Auditor By _____ Signature/Title _____ Date Certified _____ or Certified as Lead Auditor By _____ Signature/Title _____ Date Certified _____ or Certified as Auditor Examiner By _____ Signature/Title _____ Date Certified _____		
G. ANNUAL EVALUATION Signature _____ Date _____		

Attachment D

Certification Certificate (Example)

UNITED STATES DEPARTMENT OF ENERGY OFFICE OF DEFENSE WASTE & TRANSPORTATION MANAGEMENT	
THIS IS TO CERTIFY THAT	
_____ IS HEREBY QUALIFIED AS A _____	
<p>This certification is based on an evaluation of employee qualifications in accordance with ANSI/ASME NQA-1. The effective period of certification is one year from the date of issue. The employee's education, experience, training, and ability have been evaluated and summarized on a qualification form. This form and records to substantiate qualifications are on file in the Company Certification and Training Files.</p>	
_____ Date	_____ Certifying Official - Title
_____ Date	_____ Supervisor, Certification Unit

Attachment E

Notification of Certification Memorandum (Example)

TO: (Employee)
FROM: Quality Assurance Specialist
DATE:
SUBJECT: NOTIFICATION OF CERTIFICATION

This is notification that you have met the qualification requirements for certification as a(n) _____.

Your certification document is attached. A copy of this certificate and records to substantiate qualifications are on file in the Company certification and training files. This certification is valid from (Date) to (Date). It is the responsibility of each certified auditor/lead auditor to maintain his/her qualifications for recertification purposes.

Quality Assurance Specialist

cc w/Attachment: Company Certification and Training Files
Supervisor of Employee

Attachment F

Recertification Schedule

RECERTIFICATION SCHEDULE							
Employee Name Requiring Certification	Task(s) Certified for	Certified By	Previous Cert. Date	Recert. Due Date	Notif. Ltr. Due Date	Cert. Schedule Date	Recert. Date

STANDARD PRACTICE PROCEDURE

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DOCUMENTATION OF SURVEILLANCE AND REVIEW PERSONNEL QUALIFICATIONS

1. PURPOSE:

To provide guidance and instruction for documenting the qualifications of personnel performing surveillance and conducting reviews on items and activities affecting quality.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 3.05, Administration of Personnel Certification and Qualification Records
- b. SPP 4.04, Administration and Conduct of Surveillance
- c. SPP 4.11, Review of Waste Acceptance Process Technical Documents
- d. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records
- e. ANSI/ASME NQA-1, 1986, Quality Assurance Program Requirements for Nuclear Facilities 9 Shovel BQ.

4. GENERAL:

The qualifications of personnel are documented in accordance with this instruction prior to being assigned responsibility for performing quality assurance surveillances in accordance with SPP 4.04 or reviews of technical documents in accordance with SPP 4.11. The assigned Quality Assurance Specialist (QAS) documents the qualifications of organizational candidates meeting minimum requirements. When the organization uses external personnel to perform surveillances or reviews, these personnel are qualified/requalified in accordance with this instruction. Otherwise the QAS determines and confirms in writing that the program under which their qualifications were documented is determined to be acceptable in accordance with the same or equivalent requirements. In either case, the

QAS maintains supporting documentation. Qualifications of Peer and Technical reviewers are documented in accordance with SPP 4.08 and 4.05, respectively.

a. Definitions

- (1) Surveillance - The act of monitoring or observing to verify whether an item or activity conforms to specified requirements.

5. PROCEDURE:

All actions may be performed by the Surveillance Coordinator (SC) when necessary.

a. Selection of Surveillance Personnel and Evaluation of Qualifications

<u>Performer</u>	<u>Action</u>
Surveillance Coordinator (SC)	(1) Selects a Coordinator of Personnel Certification (CPC).
CPC	(2) Selects candidates to be qualified to perform surveillance and review tasks.
	Note: Use the Surveillance and Review Task Description (Attachment A) for guidance.
	(3) Obtains the necessary documentation which supports employee qualifications (e.g., standard resumes, training records, surveillance participation records, communication skill letters, and appropriate forms) for each candidate.
	(4) Evaluates and qualifies or rejects the candidates using the criteria and guidance presented below: <ul style="list-style-type: none"> (a) Reviews individual qualifications against applicable surveillance and review task qualification requirements defined in Attachment A.

<u>Performer</u>	<u>Action</u>
CPC	<ul style="list-style-type: none"> (b) Documents the results of the evaluation on a Surveillance and Review Qualification Form (Attachment B). (c) Signs Attachment B for each candidate or completes a written justification for rejecting the qualifications of the candidate. (5) After personnel perform surveillances or reviews, documents their participation on Part IV of the Surveillance and Review Qualification Form. (6) Has the form filed in the individuals certification and training file.

b. Documentation of Qualification to Conduct Surveillances and Reviews

<u>Performer</u>	<u>Action</u>
CPC	<ul style="list-style-type: none"> (1) Reviews completed documentation for adequacy and completeness and prepares a Notification of Qualification Memorandum (Attachment C). (2) Enters the data and information on the organizational Requalification Schedule (Attachment D).

c. Requalification of Surveillance and Review Personnel

<u>Performer</u>	<u>Action</u>
CPC	<ul style="list-style-type: none"> (1) Maintains the organizational Requalification Schedule in accordance with SPP 3.05.

<u>Performer</u>	<u>Action</u>
CPC	(2) Issues a notice to the affected person at least five weeks prior to the required date that requalification is required.

Note: Where retraining or additional training is anticipated, the notice shall be issued sufficiently in advance to permit and provide for such training prior to the expiration of the qualification period.

- (3) Reviews original documentation and any additional supporting documentation accumulated on an annual basis, e.g., surveillance participation record, updates the qualification form or prepares an explanation for rejecting requalification.

d. Qualification Records

<u>Performer</u>	<u>Action</u>
Quality Assurance Specialist (QAS)	(1) Maintains the following as quality records in accordance with SPP 7.01: (a) Completed Surveillance and Review Qualification Forms. (b) Notification of Qualification Memorandum. (2) Maintains the original documentation in the employee's certification and training file in accordance with SPP 3.05.

6. ATTACHMENTS:

- a. Attachment A - Surveillance and Review Task Description
- b. Attachment B - Surveillance and Review Qualification Form
- c. Attachment C - Notification of Qualification Memorandum (Example)
- d. Attachment D - Requalification Schedule

Attachment A

Surveillance and Review Task Description

1. Functional Statement

Qualified personnel serve as members of a surveillance or review team or may perform a surveillance or review as a single individual.

Quality assurance surveillance is described as "the act of monitoring or observing to verify whether an item or activity conforms to specified requirements." In general, surveillance activities include monitoring and observing selected documents and work activities in progress to provide an effective real-time means for assessing the quality of final results (products or services) and for evaluating the adequacy and effectiveness of methods for achieving quality.

Reviews are planned and scheduled activities performed to verify whether a document conforms to specified requirements.

In general, observations of deviations identified during the conduct of surveillance activities will be brought to the attention of the appropriate level of management in the organization to take the necessary corrective action. Instances where quality is shown to be indeterminate or inadequate will be reported and acted upon in accordance with other applicable quality assurance program instructions.

Observations, comments, or concerns identified during the conduct of reviews will be brought to the attention of the responsible organization for resolution in accordance with appropriate instructions.

Surveillance activities are normally conducted by quality assurance personnel but may be performed by others, such as line personnel, particularly those who are skilled or knowledgeable in important or pertinent aspects of the activity or requirements under surveillance. Surveillance is normally performed along with other evaluation practices, such as audit or inspection.

Attachment A (Cont'd)

Review activities are conducted by personnel who possess the technical credentials equivalent to the credentials of the personnel who prepared the document under review.

Typically, surveillance activities include:

- Performing a general review of ongoing work, implementing procedures and instructions, and reviewing associated documents, to identify the requirements and acceptance criteria for which an observation will be performed.
- Observing ongoing work activities and associated quality assuring activities including inspections, examinations, and tests to verify that they are being performed in accordance with specified requirements, the results are being properly interpreted, and the documentation reflects the actual situations.
- Monitoring and review of program data, such as organizational plans and schedules, progress and status reports, open item reports, quality trend reports, quality documents, procurement documents, status review meetings, test results, personnel training, and certification activities, etc.

Typically, review activities include:

- Performing reviews of technical documents for adequacy and conformance with quality requirements.
- Performing reviews of technical documents for adequacy and conformance with quality assurance requirements.

2. Duties and Responsibilities

Surveillance

- a. Prepares or reviews the surveillance plan and becomes familiar with aspects of the surveillance relating to requirements and commitments.
- b. Prepares the required checklists or guide sheet as needed.

Attachment A (Cont'd)

- c. Conducts or participates in the pre-surveillance conference if applicable.
- d. Performs the surveillance according to the plan.
- e. Describes the findings from the surveillance activity and provides them to the Quality Assurance Specialist as appropriate.
- f. Participates in the post-surveillance conference if applicable.
- g. Prepares or assists in the preparation of the surveillance report.

Review

- a. Conducts reviews as needed.
- b. Participates in review meetings/conferences as needed.
- c. Conducts review activities in accordance with appropriate instructions.
- d. Describes the findings of the review as directed.

3. Qualifications Required

The qualifications listed on this task description are intended to define the minimum capabilities that qualify personnel to perform quality assurance surveillance activities.

Minimum qualification requirements are as follows:

- a. A B.S. degree from a four-year accredited college or university in an engineering or science field plus having satisfactorily completed at least two years of experience in either engineering, manufacturing, construction, or maintenance; or

A two-year associate degree in a non-technical field from an accredited institution plus five (5) years experience associated with design, construction, installation, maintenance, or operations preferably within the nuclear industry; or, a high school diploma with ten (10) years experience in either engineering, manufacturing, construction, or maintenance.

Attachment A (Cont'd)

Other factors which are commensurate with the scope, complexity, or special nature of the activity may provide assurance that a person can competently perform a particular task. These factors include but are not limited to previous performance, completion of capability testing, special training, or on-the-job experience. These factors and the basis for their equivalency should be documented. The limited scope and complexity of the activity to be performed should be prescribed.

- b. A demonstrated knowledge and understanding of quality assurance principles, theory, and practices and a specialized knowledge of quality assurance requirements as defined in ANSI/ASME NQA-1.

A measure of this proficiency can come from any or all of the following sources:

- 1. Quality Assurance Indoctrination
 - 2. Evaluations by management
 - 3. Existing documentation, such as reports, correspondence, etc., that provide insight into the individuals knowledge of quality assurance principles
- c. The candidate shall be able to communicate effectively in writing and orally.

Review personnel shall have technical credentials at least equivalent to the credentials of the personnel who prepare the document(s) for review.

4. Maintenance of Qualification

a. Maintenance of Proficiency

Surveillance personnel shall maintain their proficiency through one or more of the following: regular and active participation in the surveillance process; review and study of codes, standards, procedures, instructions, and other documents related to quality assurance programs and program surveillance; and participation in training programs. Based on management's annual assessment, management may extend the qualification, require retraining, or require requalification. These evaluations shall be documented.

Attachment A (Cont'd)

Review personnel shall be subjected to management's annual assessment (performance review) and based on this assessment, management may extend the qualification.

Attachment B
Surveillance and Review Qualification Form

DOCUMENTATION OF SURVEILLANCE AND REVIEW QUALIFICATIONS FOR			
I. PROFESSIONAL REQUIREMENTS			
A. EDUCATION	University/Degree/Date	SATISFACTORY	UNSATISFACTORY
	B. EXPERIENCE	Company/Dates	
C. PROFICIENCY Demonstrated knowledge and understanding of the principles, theory, and practices in the field of quality assurance. Specialized knowledge of quality assurance requirements as defined in ANS/ASME NQA-1.			
II. COMMUNICATION SKILLS			
1. Evaluated by: _____ Date _____			
III. QUALIFICATION EVALUATED BY:			
_____ Signature and Title		_____ Date Evaluated	
IV. PARTICIPATION RECORD			
V. ANNUAL EVALUATION			
	Signature		
	Date		

Attachment C

Notification of Qualification Memorandum (Example)

TO: (Employee)
FROM: Coordinator of Personnel Certification
DATE:
SUBJECT: NOTIFICATION OF QUALIFICATION

This is notification that you have been qualified to perform quality assurance surveillances and reviews. The records to substantiate your qualifications are on file in the organizational Certification and Training Files. This qualification is valid from _____ (Date) to _____ (Date).

Coordinator of Personnel Certification

cc w/Attachment: Organization Certification and Training Files
Supervisor of Employee

Attachment D

Requalification Schedule

REQUALIFICATION SCHEDULE							
Employee Name	Task(s) Qualified For	Examined By	Previous Qual. Date	Requal. Due Date	Notif. Ltr. Due Date	Schedule Date	Requal. Date

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ADMINISTRATION OF PERSONNEL CERTIFICATION AND QUALIFICATION RECORDS

1. PURPOSE:

To define actions and identify responsibilities required to establish, manage, and maintain documentation to support the personnel certification and qualification process.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 3.03, Certification of Quality Assurance Audit Personnel
- b. SPP 3.04, Documentation of Surveillance and Review Personnel Qualifications
- c. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records

4. GENERAL:

This instruction provides instructions on collection and filing of the documentation necessary to support personnel qualifications and certification for all personnel performing quality-related work.

a. Definitions

- (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.
- (2) Qualification - 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.

5. PROCEDURE:

All actions may be performed by the Manager as necessary.

a. Administration of Training, Certification, and Qualification Records

<u>Performer</u>	<u>Action</u>
Coordinator of Personnel Certification (CPC)	(1) Maintains the following documentation for each person's qualification and/or certification: <ul style="list-style-type: none"> (a) Standard Resumes (Attachment A). (b) Documentation of training activities (which support qualification or certification requirements) including results of any examinations. (c) Audit, Surveillance and Review Participation Records (Attachments B and C). (d) Verification of education documentation. (e) Job descriptions/task qualification requirement documents. (f) Physicians certification of physical ability (such as eye sight) when applicable.
Managers	(2) Provide certification or qualification support documentation for employees under their cognizance to the CPC as requested.
CPC	(3) For audit, surveillance and review personnel, receives certification and/or qualification documentation from certifying officials in accordance with SPP 3.03 and 3.04.

<u>Performer</u>	<u>Action</u>
CPC	<p>(4) For all personnel, enters the certification or qualification supporting documentation into the individual training, qualification and certification files under the appropriate tab, e.g., Certification Documentation, Training Documentation, Resume, Education Verification, Task Qualification Requirements, and Miscellaneous.</p> <p>(5) Maintains the recertification or requalification schedule (originally initiated and updated in SPP 3.03 and 3.04) to provide status of the certified or qualified personnel for audit, surveillance and review personnel.</p> <p>(6) Updates the training, qualification and certification files whenever there are annual evaluations, extensions, or changes in status.</p>

b. Training and Certification Records

<u>Performer</u>	<u>Action</u>
CPC	<p>(1) Prepares training, qualification and certification record files (including updated material) as quality records in accordance with SPP 7.01.</p> <p>(2) Maintains an updated copy of the training, qualification and certification file for working purposes.</p>

6. ATTACHMENTS:

- a. Attachment A - Standard Resume Content
- b. Attachment B - Audit Participation Record (Example)
- c. Attachment C - Surveillance Participation Record (Example)

Attachment A
Standard Resume Content

1. Name of person.
2. Disciplines or areas of expertise applicable to audits.
3. Education -List schools attended, degrees received, and last year in attendance.
4. Experience History - Each entry should include the job title; the company and organizational unit; the starting date and the ending date; and a brief summary of the duties/accomplishments in that position.
5. Licenses and Certificates - List the license or certificate, the licensing or certifying agency, their address, and the date obtained.
6. Professional Societies - List any professional societies including date of membership and position/office held (if any).
7. Technical Skills - List any technical skills applicable to audits.
8. Publication - List any technical publications.

AUDIT PARTICIPATION RECORD

Name _____ PM Approval _____ Date _____

Audit #	Audit Title/Scope	Location of Audit	Date(s) of Audit	Audit Team Status*

*e.g., Team Leader, Team Member, Audit Planner, Technical Expert, Auditor in Training

Audit Participation Record (Example)

Attachment B

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Attachment C

Surveillance Participation Record (Example)

REVIEW/SURVEILLANCE PARTICIPATION RECORD Name _____ PM Approval _____ Date _____				
Surveillance #	Title/Scope of Activity	Location	Date(s)	Function*

*e.g., Performer, Supervisor

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PLANNING AND SCHEDULING OF EVALUATION ACTIVITIES

1. PURPOSE:

To establish objectives and provide instructions for the planning and scheduling of evaluation activities, to determine that facility management controls and work activities related to quality are performed in a controlled environment, and to assess the adequacy and effectiveness of those controls.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 4.03, Conduct of Quality Assurance Audits
- b. SPP 4.04, Administration and Conduct of Surveillance
- c. SPP 4.10, Review of Operations Offices Quality Assurance Program Descriptions and Instructions
- d. SPP 4.11, Review of Waste Acceptance Process Technical Documents
- e. SPP 8.02, Quality Assurance Program Evaluation and Assessment of Adequacy and Effectiveness.
- f. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records.

4. GENERAL:

Evaluation planning and scheduling will result in an integrated structure of activities which will provide a basis for evaluating the adequacy and effectiveness of the overall Quality Assurance Program. Evaluation activities include audits, peer and technical reviews, surveillances, reviews of quality assurance program descriptions and instructions, and reviews of process or operations technical documents (see SPP 4.03, 4.04, 4.10, 4.11, and 8.02 for conduct of these evaluation activities).

Further, evaluation, planning, and scheduling is conducted in a manner that provides assurance that activities related to quality are being accomplished in accordance with approved requirements. Consequently, there is assurance that completed projects will function as required by their design and specifications.

Evaluation activities are generally combined with evaluation activities of interfacing organizations such as program operations offices in order to be most efficient and least interruptive.

a. Definitions

- (1) **Evaluation** - The act of determining or verifying through surveillance, review, audit, or other similar means the adequacy and effectiveness of a process, service, or activity in achieving its intended purpose or objective.

5. PROCEDURE:

All actions may be performed by the Program Coordinator when necessary.

a. Identification of Information, and Planning for the Evaluation Plans and Schedules

<u>Performer</u>	<u>Action</u>
Program Coordinator	(1) Authorizes the initial preparation or subsequent revision of the evaluation and assessment schedule.
Evaluation and Assessment Scheduler (EAS)	(2) Coordinates the identification of the principal evaluation activities with the Directors of Organizational Divisions on the principal evaluation activities within the overall Quality Assurance Program.

<u>Performer</u>	<u>Action</u>
EAS	<p>(3) Coordinates with the Operations or Project Office to obtain the schedules of evaluation activities to be performed by that particular office and the Operating Contractor.</p> <p>(4) Initiates correspondence to external organizations involved in the evaluation.</p> <p><u>Note:</u> This correspondence should encourage these organizations to jointly participate in evaluation Quality Assurance Program activities.</p> <p>(5) Coordinates the identification and planning of evaluation activities necessary to address the work scheduled by the Operations or Project Offices and the Operating Contractor with the principal evaluation activities identified within the overall Quality Assurance Program.</p> <p>(6) Receives correspondence with requests for participation in joint reviews or evaluations from external organizations and incorporates this information into the schedules.</p> <p>(7) Monitors Quality Assurance Planning and Scheduling Functions for Programmatic compliance and advises the Program Coordinator accordingly.</p>

b. Preparation and Review of The Long-Range Evaluation Plan and Schedule

<u>Performer</u>	<u>Action</u>
EAS	<p>(1) Prepares and maintains the long-range evaluation plan and schedule (Attachment A) which covers the subsequent three fiscal years.</p>

<u>Performer</u>	<u>Action</u>
EAS	(2) Submits the long-range Evaluation Plan and Schedule to the appropriate organizational Directors and the Program Coordinator for review.
Organizational Directors/Program Coordinator	(3) Review the long-range evaluation plan and schedule and provide feedback to the EAS.
EAS	(4) Finalizes the long-range evaluation plan and schedule.

c. Approval of the Long-Range Evaluation Plan and Schedule

<u>Performer</u>	<u>Action</u>
EAS	(1) Recommends approval of the long-range evaluation plan and schedule by submitting to the Program Coordinator.
Program Coordinator	(2) Approves the long-range evaluation plan and schedule by signing and dating, then forwards to the EAS for distribution.

d. Distribution of the Long-Range Plan and Schedule

<u>Performer</u>	<u>Action</u>
EAS	(1) Distributes the long-range evaluation plan and schedule by September 15 of each year to Organizational Directors, and the Program Coordinator.
	(2) Distributes any updated revisions of the Long-Range Evaluation Plan and Schedule which are required to maintain it in current condition.

Performer

Action

EAS

Note: Distribution of approved Long-Range Evaluation Plans and Schedules, approved Annual and Quarterly Plans, and Schedules to DOE or sponsor organizations shall be through the Program Coordinator.

e. Preparation, Review, and Revision of the Annual Evaluation Plan and Schedule

Performer

Action

EAS

- (1) Coordinates the establishment of specific evaluation activities, evaluation activity scope(s), tentative personnel who will perform the evaluation, and schedule for implementation.
- (2) Prepares or revises (to maintain current) the annual evaluation plan and schedule (Attachment B) by defining the upcoming fiscal year from the long-range evaluation plan and schedule, and taking into account previous years experience and any changes to imposed requirements.
- (3) Submits the annual evaluation plan and schedule to the Organizational Directors and the Program Coordinator for review.

Organizational
Directors/Program
Coordinator

- (4) Review the annual evaluation plan and schedule and provide feedback to the EAS.

EAS

- (5) Coordinates the activities identified in the annual evaluation plan and schedule with the Organizational Directors and Program Coordinator.

<u>Performer</u>	<u>Action</u>
EAS	(6) Finalizes the annual evaluation plan and schedule.

f. Approval of the Annual Evaluation Plan and Schedule

<u>Performer</u>	<u>Action</u>
EAS	(1) Recommends approval of the annual evaluation plan and schedule by submitting to the Program Coordinator.
Program Coordinator	(2) Approves the annual evaluation plan and schedule by signing and dating and then forwards to the EAS for distribution.

g. Distribution of the Annual Evaluation Plan and Schedule

<u>Performer</u>	<u>Action</u>
EAS	(1) Distributes the annual evaluation plan and schedule by September 15 of each year to the Program Coordinator and Organizational Directors.
	(2) Distributes any updated revisions of the annual evaluation plan and schedule which are required to maintain it in current condition.

h. Preparation, Review, and Revision of The Quarterly Evaluation Plan and Schedule

<u>Performer</u>	<u>Action</u>
EAS	(1) Selects and recommends an evaluation team for each evaluation to be listed on the quarterly evaluation plan and schedule, (Attachment C) ensuring evaluation personnel are qualified and, if appropriate, certified.

<u>Performer</u>	<u>Action</u>
EAS	<p>Note: The evaluation team and leader shall be listed under the "Evaluation Activity Description" on Attachment C.</p> <p>(2) Assigns a unique identification number to the specific evaluation activity.</p> <p>(3) Prepares a draft quarterly evaluation plan and schedule, and correlates it against the annual plan and schedule.</p> <p>(4) Finalizes the quarterly evaluation plan and schedule.</p>

I. Approval of The Quarterly Evaluation Plan and Schedule

<u>Performer</u>	<u>Action</u>
EAS	(1) Recommends approval of the quarterly evaluation plan and schedule by submitting to the Program Coordinator.
Program Coordinator	(2) Approves quarterly evaluation plan and schedule by signing and dating and then forwards to the EAS for distribution.

J. Distribution of The Quarterly Evaluation Plan and Schedule

<u>Performer</u>	<u>Action</u>
EAS	(1) Distributes the initial issue by the first day of each quarter and any subsequent revisions of the quarterly evaluation plan and schedule to the Program Coordinator and Organizational Directors.

<u>Performer</u>	<u>Action</u>
EAS	(2) Coordinates with the evaluator(s) and Program Coordinator to establish details of each scheduled evaluation activity.

Note: The schedule shall be prepared and issued by the first day of each quarter beginning in January, April, July, and October and shall be revised thereafter to maintain a current schedule.

k. Records

<u>Performer</u>	<u>Action</u>
EAS	(1) Prepares each issued long-range, annual, and quarterly evaluation plan and schedule as a quality record in accordance with SPP 7.01.

6. ATTACHMENTS:

- a. Attachment A - Long-Range Evaluation Plan and Schedule (Example)
- b. Attachment B - Annual Evaluation Plan and Schedule (Example)
- c. Attachment C - Quarterly Evaluation Plan and Schedule (Example)

LONG-RANGE EVALUATION PLAN & SCHEDULE			
	Prepared by:		
	Approved by:		Date:
Principal Activities	FY 89 O N D J F M A M J J A S	FY 90 O N D J F M A M J J A S	FY 91 O N D J F M A M J J A S
Organization Adequacy			
Planning and Preparation Adequacy			
Implementation Adequacy			
Results Adequacy			
Management Control Effectiveness			

LEGEND: AU=Audit S=Surveillance R=Review I=Inspection, Examination, or Test A=Assessment

Long-Range Evaluation Plan and Schedule (Example)

Attachment A

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Attachment B

Annual Evaluation Plan and Schedule (Example)

Annual Evaluation Plan & Schedule		Prepared by: _____										
		Approved by: _____										
		Date: _____										
Principal Activities	<u>Fiscal Year 1989</u>											
	O	N	D	J	F	M	A	M	J	J	A	S
Organization Adequacy												
Planning and Preparation Adequacy												
Implementation Adequacy												
Results Adequacy												
Management Control Effectiveness												

LEGEND: AU=Audit S=Surveillance R=Review I=Inspection, Examination, or Test A=Assessment

Attachment C

Quarterly Evaluation Plan and Schedule (Example)

QUARTERLY EVALUATION PLAN & SCHEDULE			
Evaluation Period: _____		Prepared by: _____	Approved by: _____
		Date Approved: _____	
Evaluation Identification Number	Organization to be Evaluated	Evaluation Activity	Scheduled Date

STANDARD PRACTICE PROCEDURE

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ADMINISTRATION OF QUALITY ASSURANCE AUDITS

1. PURPOSE:

To provide instructions for initiating, planning, follow-up, close-out, and documenting of quality assurance audits.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

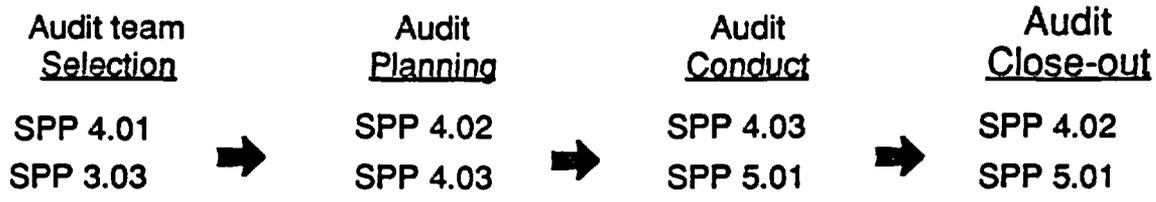
3. REFERENCES:

- a. SPP 3.03, Certification of Quality Assurance Audit Personnel
- b. SPP 4.01, Planning and Scheduling of Evaluation Activities
- c. SPP 4.03, Conduct of Quality Assurance Audits
- d. SPP 5.01, Deviation Reporting and Disposition
- e. SPP 5.02, Management Action Request
- f. SPP 7.01, Preparation, Transfer and Receipt of Quality Records

4. GENERAL:

This instruction applies to the administration of quality assurance audits.

The chronological sequence of the audit process involves four steps. They are: Selection of the audit team; planning of the audit; conduct of the audit; and audit closure. The audit process is accomplished through the use of five SPPs: SPP 3.03, Certification of Quality Assurance Audit Personnel; SPP 4.01, Planning and Scheduling of Evaluation Activities; SPP 4.02, Administration of Quality Assurance Audits; SPP 4.03, Conduct of Quality Assurance Audits; and SPP 5.01, Deviation Reporting and Disposition. Their sequence in the audit process is as follows:



a. Definitions

- (1) 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 the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.
- (2) 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.
- (3) Internal Audit - An audit of those portions of an organization's quality assurance program retained under its direct control and within its organizational structure.

5. PROCEDURE:

All actions may be performed by the Program Coordinator when necessary.

a. Audit Preparation Activities

<u>Performer</u>	<u>Action</u>
Audits Coordinator (AC)	(1) Coordinates the assignment of the audit team leader and team members in accordance with the plans developed under SPP 4.01. (2) Confirms the audit schedule from the quarterly evaluation plan and schedule with the management of the organization to be audited.

<u>Performer</u>	<u>Action</u>
AC	<p>Note: The audit schedule may be dependent on the work schedule for certain activities.</p> <p>(3) Prepares an audit notification letter that includes as a minimum: the scope of audit, the dates scheduled, the location of the pre-audit conference, and the names of audit team members.</p> <p>(4) Forwards the audit notification letter to the Program Coordinator (PC) for signature and issue.</p>
PC	<p>(5) Signs and distributes the audit notification letter to the following as a minimum: the audit team, the cognizant field office, and management of the organization to be audited including appropriate quality assurance personnel.</p> <p>Note: The referenced management should be the lowest level which could implement effective corrective action.</p>
AC	<p>(6) Establishes a working file for the audit and places a copy of the audit notification letter in the audit working file.</p> <p>(7) Collects or identifies input data to be used by the audit team in planning and conducting the audit.</p> <p>Note: Input data may include but is not limited to:</p> <p>(a) The audit scope as defined on the quarterly evaluation plan and schedule.</p> <p>(b) Previous evaluation results that are within the scope of the audit.</p>

<u>Performer</u>	<u>Action</u>
AC	<ul style="list-style-type: none">(c) Open and closed deviations from previous evaluation activities that are within the scope of the audit.(d) Other data from sources such as the appropriate Division Director, the organization to be audited, and other interfacing organizations.(e) List of policies and requirements, codes, standards, regulatory requirements, and implementing procedures and instructions that are within the scope of the audit. <ul style="list-style-type: none">(8) Prepares the draft audit scope and planning document (Attachment A) based on information provided in the quarterly evaluation plan and schedule.(9) Provides to the audit team leader the draft audit scope and planning document, the input data, and the list of audit team members.(10) Ensures the audit team leader understands the scope of the audit and the purpose of the audit in the overall program evaluation process as described in the quarterly evaluation plan and schedule.
Audit Team Leader	<ul style="list-style-type: none">(11) Prepares the final audit scope and planning document in accordance with SPP 4.03, paragraph 5a.
AC	<ul style="list-style-type: none">(12) Obtains the final audit planning package as prepared by the audit team leader in accordance with SPP 4.03.(13) Reviews the final audit planning package for completeness, approves it, and returns a copy to the audit team leader.

<u>Performer</u>	<u>Action</u>
AC	(14) Retains the original audit planning package in the audit working file, including the draft audit scope and planning document.
Audit Team Leader	(15) Conducts audit in accordance with SPP 4.03 (starting with paragraph 5b)

b. Post-Audit Activities

<u>Performer</u>	<u>Action</u>
AC	<p>(1) Obtains the completed audit report, audit checklists, and any deviation reports compiled during the audit from the audit team leader as specified in SPP 4.03.</p> <p>Note: Deviation and Corrective Action Reports shall be completed and distributed as a part of the audit report in accordance with SPP 5.01, "Deviation Reporting and Disposition," Attachment A.</p> <p>(2) Reviews each deviation report prepared by the audit team to assure proper reporting and characterization of deviations and processes deviation reports in accordance with SPP 5.01.</p> <p>(3) Reviews the audit report and audit checklist(s) for completeness and consistency and identifies input for future evaluation planning and scheduling in accordance with SPP 4.01.</p> <p>(4) Ensures the issuance of audit reports within thirty days of completion of the post-audit conference.</p>

<u>Performer</u>	<u>Action</u>
AC	(5) Prepares an audit report transmittal letter (see Attachment B) which transmits the results of the audit. (6) Requests the participating organization to provide a formal response to each Deviation and Corrective Action Report receipt of the audit report, the date identified prior to or during the post-audit conference, or as specified in the audit report. Note: Organizations should not wait for receipt of the audit report to begin corrective actions (see SPP 4.03). (7) Forwards the audit report transmittal letter to the PC for approval and signature.
PC	(8) Signs the audit report transmittal letter and returns it to the QAS for dispositioning.
AC	(9) Dates and distributes copies of the audit report and transmittal letter to the following as a minimum: the organizational staff, the audit team, the cognizant field office, the overall management and the quality assurance management of the origination unit to be audited. (10) Files the original of the audit report, the final audit planning package, and a copy of the transmittal document in the audit working file.

c. Audit Follow-up and Closure

<u>Performer</u>	<u>Action</u>
AC	(1) Obtains corrective action responses to deviations identified in the audit report in accordance with SPP 5.01.

<u>Performer</u>	<u>Action</u>
AC	<ul style="list-style-type: none">(2) Coordinates evaluation of the corrective action responses and verification of corrective actions in accordance with SPP 5.01.(3) Reviews the audit working file to ensure all deviations have been dispositioned, pertinent documentation is complete and on file, and the file contains, as a minimum:<ul style="list-style-type: none">(a) Audit Letter Notification.(b) Original audit planning package and supporting materials including the audit scope and planning documents.(c) Pre-audit correspondence.(d) Audit report and transmittal letter.(e) Deviation reports and a copy of the transmittal letter.(f) Management Action Requests, if used (see SPP 5.02).(g) Post-audit correspondence.(4) Prepares and issues an audit closure letter officially closing the audit including as a minimum: the audit scope and number, dates of the audit, deviations involved, and issues it to the organizational staff, the audit team, the cognizant field office, the responsible management including quality assurance of the audited organization.(5) Places a copy of the audit closure letter in the audit working file.

d. Records

<u>Performer</u>	<u>Action</u>
AC	(1) Prepares the audit working file (upon audit closure) as a quality record in accordance with SPP 7.01.

6. ATTACHMENTS:

- a. Attachment A - Audit Scope and Planning Document
- b. Attachment B - Audit Report Transmittal Letter (Example)

Attachment A

Audit Scope and Planning Document

AUDIT SCOPE & PLANNING DOCUMENT		Audit No. _____
I. ORGANIZATION BEING AUDITED _____		Scheduled Date _____
II. AUDIT SCOPE		
III. PREVIOUS EVALUATION ACTIVITIES OF SAME OR SIMILAR AREAS FOR FOLLOW-UP		
IV. TEAM MEMBERS		
V. SEE BACK FOR LIST OF CONTROLLING DOCUMENTS AND REVISIONS		
Prepared by: _____	Date: _____	
Approved by: _____	Date: _____	

Attachment B

Audit Report Transmittal Letter (Example)

(Date) _____

(addressee) _____

(title) _____

(audited organization) _____

(address) _____

(city, state and zip code) _____

Quality Assurance Audit of _____ (audited organization)

Audit Number _____

Dear _____:

The attached report presents the results of the subject audit conducted at your facility on _____ (date). The results of the audit were discussed with _____ (audited organization's name) representatives at the post-audit meeting held on _____ (date).

The cooperation and responsiveness of your personnel during the conduct of the audit and during the post-audit meeting are noted and appreciated. (This may be modified at the discretion of the Audit Team Leader depending on the results of the audit.)

You are requested to reply to this report within 30 days of receipt. Address your reply to _____ (Audits Coordinator) and identify: (1) The actions to be taken to correct the reported deviations; (2) Actions taken to investigate situations similar to that identified in the deviation; (3) Actions to be taken to preclude recurrence of similar deficiencies, and a determination of the root cause of the deficiency; and (4) A schedule for completion of all involved actions.

Please document your response(s) on the attached Deviation and Corrective Action Report(s) (DCAR) and return the originals.

If you have any questions, please contact _____ (audit team leader) at _____

Sincerely,

Program Coordinator

cc: (Audited Organization Senior Management) _____
(Audited Organization Quality Assurance Manager) _____

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CONDUCT OF QUALITY ASSURANCE AUDITS

1. PURPOSE:

To provide instructions for conducting and reporting quality assurance audits.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 4.02, Administration of Quality Assurance Audits
- b. SPP 3.03, Certification of Quality Assurance Audit Personnel
- c. SPP 5.01, Deviation Reporting and Disposition

4. GENERAL:

The administration and follow-up of quality assurance audits is covered in SPP 4.02 and the certification of quality assurance audit team leaders and audit team members is addressed in SPP 3.03. Deviations, their corrective actions and closure are covered in SPP 5.01.

This SPP covers the conduct of both internal and external audits.

a. Definitions

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

- (2) 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.
- (3) Internal Audit - An audit of those portions of an organization's quality assurance program retained under its direct control and within its organizational structure.
- (4) 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.
- (5) Item - An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit.

Note: The focus of audits performed will be mostly programmatic but may also include hardware.

5. PROCEDURE:

All actions may be performed by the organizational manager who has been certified to conduct audits in accordance with SPP 3.03.

a. Preparation of Final Audit Planning Package

<u>Performer</u>	<u>Action</u>
Audit Team Leader	<ul style="list-style-type: none">(1) Receives the draft audit scope and planning document, input data pertinent to the specific audit activity and the list of audit team members from the assigned Quality Assurance Specialist (QAS) per SPP 4.02.(2) Reviews the draft audit scope and planning document with respect to the ongoing work within the organization to be audited and if necessary further defines the specific reviews and investigations to be made during the audit to match the status of the activity.

<u>Performer</u>	<u>Action</u>
Audit Team Leader	<p>(3) Prepares the final audit scope and planning document, which includes the list of requirements and implementing procedures determined to be within the scope of the audit and determines the extent and depth of the audit (e.g., projected sample sizes, resources to be expended, etc.)</p> <p>(4) Discusses the final audit scope and planning document with the audit team.</p> <p>(5) Develops and delegates specific assignments for the audit activities to team members.</p> <p>(6) Prepares or assigns the audit team members to prepare the audit checklist(s) that is necessary to accomplish the audit. See Attachment A. The checklist(s) shall contain the following (as a minimum):</p> <ul style="list-style-type: none">(a) Audit identification number which will also be the unique checklist number.(b) Detailed identification of attributes and items to be verified (in DESCRIPTION column).(c) Identification of the requirements to which the activity is being audited (in REFERENCES column).(d) Spaces to be filled in during the course of the audit for:<ul style="list-style-type: none">1 Names and titles of personnel contacted during the performance of the audit (to be entered under RESULTS/REMARKS column).

<u>Performer</u>	<u>Action</u>
Audit Team Leader	2 Specific identification of items, objective evidence, or activities examined (to be entered under RESULTS/REMARKS column). 3 Observations of conformance or nonconformance (SAT, UNSAT, N/A columns). 4 Checklist additions (Continuation on back side of form). (7) Reviews the audit checklist(s) for appropriateness as to the scope of the audit, clarity, and relative importance. (8) Assembles the final audit scope and planning document and audit checklist(s) into the final audit planning package. (9) Forwards the final audit planning package to the QAS who reviews and approves it in accordance with SPP 4.02.
Audit Team Leader and Team Members	(10) Receive a copy of the final audit planning package from the QAS.

b. Pre-audit Team Meeting

<u>Performer</u>	<u>Action</u>
Audit Team Leader	(1) Schedules and arranges for the pre-audit team briefing ensuring that audit team members and others, as deemed necessary by the Audit Team Leader, are present.

<u>Performer</u>	<u>Action</u>
Audit Team Leader	<p>(2) Meets with the Audit Team (see SPP 4.02) to discuss:</p> <ul style="list-style-type: none">(a) Approved audit scope.(b) Deviations and corrective action commitments from previous audits.(c) Status of the activity to be audited.(d) Specific instructions under which the audit team members are to function. Examples include methods of reviewing results and progress made during the audit and expectations regarding documentation of findings.

c. Pre-audit Conference

<u>Performer</u>	<u>Action</u>
Audit Team Leader	<p>(1) Holds a pre-audit conference with the management of the organization being audited to introduce the audit team members; to discuss the scope, plan, and schedule of the audit; to establish the necessary channels of communication; and to identify facilities to be used.</p> <p>(2) Identifies any assistance needed from the organization being audited, including knowledgeable personnel to accompany the audit team to provide information and confirmation of observations.</p> <p>(3) Discusses methods by which management of the audited organization desires to be apprised of findings during the audit.</p> <p>(4) Obtains commitments for access to organizational areas and personnel and confirms the schedule for the post-audit conference.</p>

<u>Performer</u>	<u>Action</u>
Audit Team Leader	(5) Initiates an attendance roster for the pre-audit conference.

d. Conduct of the Audit

<u>Performer</u>	<u>Action</u>
Audit Team Leader	(1) Leads the conduct of the audit using the approved audit planning package.
Audit Team Member	(2) Evaluates the methods used to implement the requirements.
	(3) Ensures requirements are fulfilled by proper methods of implementation using selective examination of representative quality records, personnel interviews, observations of work activities, and objective evidence.
	(4) Determines the effectiveness and implementation of audited procedures.
	(5) Discusses possible deviations with the team leader and obtains his or her concurrence.

Note: Auditors should exercise care to ensure that deviations are departures from specific requirements and not the opinions of the auditors or others.

- (6) Contacts the QAS to ascertain if an identified possible deviation has been previously reported and is still pending.
- (7) For deviations previously documented, makes a note for inclusion into the audit report.
- (8) For deviations not previously documented, assigns deviation report numbers in accordance with SPP 5.01.

<u>Performer</u>	<u>Action</u>
Audit Team Member	<p>(9) Records observations determined to be deviations on a Deviation and Corrective Action Report (DCAR) (see Attachment A of SPP 5.01 for an example of a DCAR form) and support them with sufficient data and specific examples to adequately substantiate the observation with regard to its importance.</p> <p><u>Note:</u> Each observation should be referenced to a specific requirement or commitment.</p>
Audit Team Leader	<p>(10) Request the audited organization to sign each deviation report form.</p> <p><u>Note:</u> The signature attests only that the representative understands the deviation and not that he or she agrees with the finding.</p>
Audit Team Members	<p>(11) Using an audit checklist, document the names and titles of contacts, identification of items/activities examined, observations of conformance, and checklist deletions or additions.</p> <p>(12) Note on the audit checklist and/or audit scope and planning document any changes (additions or deletions) made in the conduct of the audit and the reason for changes.</p>

<u>Performer</u>	<u>Action</u>
Audit Team Leader	<p>(13) Assembles the audit team at appropriate times during the audit and:</p> <ul style="list-style-type: none"> (a) Identifies the observations from the audit performed - this includes observations of conformance as well as those determined to be deviations. All observations shall be cross-checked for validity and consistency. (b) Ranks the deviations as major or minor for presentation purposes at the post-audit conference. <p>(14) Prepares a draft summary of audit observations as part of the audit report which is to be delivered at the post-audit conference.</p>

e. Post-audit Conference

<u>Performer</u>	<u>Action</u>
Audit Team Leader	<p>(1) Arranges for and conducts the post-audit conference ensuring the attendance of the audit team, representatives of the audited organization who can attest to the validity of the observations, and members of management at a level that can cause corrective action.</p> <p>(2) Initiates an attendance roster during the post-audit conference.</p> <p>(3) Presents an overall summary of the audit observations (as well as each individual deviation) in the form of a draft audit report (as complete as time permits).</p> <p>(4) Discusses or has the appropriate audit team member discuss each deviation sufficiently to ensure an understanding of the requirement and the deviation.</p>

<u>Performer</u>	<u>Action</u>
Audit Team Leader	(5) Informs the audited organization that they will be required to respond to each deviation reported upon receipt of the formally transmitted audit report but corrective action should be initiated upon completion of the audit.

Note: Explicit commitments to corrective action or action to prevent recurrence from the audited organization are not required at the post-audit conference.

f. Audit Report

<u>Performer</u>	<u>Action</u>
Audit Team Leader	(1) Completes preparation of or assigns the final preparation of the formal audit report to an audit team member in accordance with the audit report format (see Attachment B).
Audit Team Leader and Audit Team Members	(2) Conducts a review of the report with the audit team and ensures all deviations are defined in sufficient detail to place each problem in proper perspective and facilitate ease of response, resolution, and follow-up for close-out.
Audit Team Leader and Audit Team Members	(3) Sign and date the audit report, signifying concurrence.

<u>Performer</u>	<u>Action</u>
Audit Team Leader and Audit Team Members	Note: The audit team leader tries to resolve any comments by audit team members with dissenting opinions. If the dissenting opinion(s) cannot be resolved by the audit team leader, the audit team member should document the dissenting opinion and reference the document in the audit report. The dissenting opinion is then elevated through the appropriate management chain(s) independent of the audit report until resolution is obtained and documented.
Audit Team Leader	(4) Ensures audit documentation references the audit number. (5) Forwards the audit report, including deviation reports, completed audit check lists, and final audit planning package to the QAS in a timely manner to ensure issue of the final audit report within 30 days of the post-audit conference.

6. ATTACHMENTS:

- a. Attachment A - Quality Assurance Checklist Form
- b. Attachment B - Audit Report Format

Attachment B

Audit Report Format

The cover sheet or at least the first page of the audit report should, as a minimum, include:

- a. Identification of the Audit Coordinator
- b. Audit title and number or unique identification
- c. Dates the audit was conducted
- d. Identification of the audited organization
- e. An abbreviated scope of the audit
- f. Names of the audit team leader and team members
- g. Audit report completion date

The body of the audit report should include the following sections:

a. SCOPE

The audit scope is to be a statement of the audit purpose, the activities audited, and the requirements under which the audit was conducted.

b. AUDIT RESULTS SUMMARY

The summary should be an "executive summary" and is to make a statement as to the "adequacy" and "effectiveness" of the quality assurance program as determined by the results of the audit. Both positive and negative observations are to be highlighted including identified deviations.

c. PARTICIPANTS IN THE AUDIT

The names of the audit team members are to be included.

The names of personnel from the audited organization who attended the pre-audit and post-audit conference are to be listed. Their position titles are not to be abbreviated. Indicate which conference was attended if the person did not attend both conferences.

The names of personnel interviewed during the conduct of the audit who provided input pertaining to information reflected in the audit report are to be listed.

Attachment B (Cont'd)

d. PRE-AUDIT CONFERENCE

Identify the audited organization's senior management representative who attended the conference; that a review of the audit purpose, scope, and schedule took place; and that the arrangements for the post-audit conference were made.

e. OBSERVATIONS

This section is to provide a brief description of each procedural requirements audited, specific examples or activities which were examined, areas of conformance, and areas of deviation. If quantity prohibits specific listings, then summary statements may be substituted. Any observation of deviation is to be entered on a deviation report form and is to be referenced in this section and attached as part of the audit report.

f. POST-AUDIT CONFERENCE

Identify the senior management representative of the audited organization and summarize the audit results and discussions that occurred. If appropriate, express the appreciation of the team members for cooperation given by the audited organization.

g. DEVIATION REPORTS

This section contains a brief description of the deviations found as a result of the audit.

h. AUDIT TEAM MEMBER CONCURRENCE

This section contains spaces for signatures of audit team members and date of signing denoting concurrence with results of the audit as reported. In the event of a dissenting opinion, this section is to contain reference to a separate document describing the dissenting opinion.

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ADMINISTRATION AND CONDUCT OF SURVEILLANCE

1. PURPOSE:

To provide instructions for the administration and conduct of surveillance activities involving monitoring or observing to verify if an activity or item conforms to specified requirements.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 3.04, Documentation of Surveillance and Review Personnel Qualifications
- b. SPP 4.01, Planning and Scheduling of Evaluation Activities
- c. SPP 5.01, Deviation Reporting and Disposition
- d. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records

4. GENERAL:

Surveillance activities include monitoring or observing to verify conformance of an item or process. Monitoring involves the verification of day to day activities. Observations are more formal in that the activity is usually scheduled and scoped for a particular item or process. This instruction covers the detail planning and conduct of surveillance observation activities.

Consistent with the projected activities of organizations to be evaluated (participating organizations), the Surveillance Coordinator plans and schedules those activities to be subjected to surveillance in accordance with SPP 4.01. The need for unscheduled surveillance is determined on the basis of changes in the participating organizations schedule of activities or the results of previous evaluations.

The qualifications of personnel performing surveillance are documented in accordance with SPP 3.04. A description of the surveillance process is contained in Attachment A.

a. Definitions

- (1) **Surveillance** - The act of monitoring or observing to verify whether an item or activity conforms to specified requirements.
- (2) **Item** - An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit.

5. **PROCEDURE:**

All actions except those that involve the organizational Division Directors may be performed by the Surveillance Coordinator when necessary.

a. Preparation for Surveillance

<u>Performer</u>	<u>Action</u>
Surveillance Coordinator	<ul style="list-style-type: none"> (1) Ensures evaluators are aware of assigned surveillance activities. (2) Determines the need for unscheduled surveillance activities based on the results of current evaluation activities and the participating organizations latest schedule of work activities.
Evaluator	<ul style="list-style-type: none"> (3) Identifies and collects input material pertaining to the activity to be monitored or observed. Input material may include but is not limited to: <ul style="list-style-type: none"> (a) Previous evaluation results that are within the scope of the surveillance. (b) Open and closed deviations from previous evaluation activities that are within the scope of the surveillance.

<u>Performer</u>	<u>Action</u>
Evaluator	<p>(c) Other data from sources such as the Program Coordinator, the organization under surveillance, and other interfacing organizations.</p> <p>(d) List of policies and requirements, codes, standards, regulatory requirements, and implementing procedures and instructions that are within or are applicable to the scope of the surveillance.</p> <p>(4) Prepares a surveillance guide sheet (Attachment B) or identifies the requirements and acceptance criteria for a specific surveillance activity based on a review of the input material collected in step 5.a.(3).</p> <p>Note: A guide sheet is normally used for a scheduled surveillance; however, there may not be time to prepare a guide sheet for an unscheduled surveillance.</p> <p>(5) Monitors specific work activities and associated data within the scope of the surveillance activity on an ongoing basis and determines the need for further observations.</p> <p>Note: The basis for determining the need for additional observation includes an assessment of the activities importance to quality and problem areas previously identified by evaluation activities. Observations are performed in accordance with Section 5.b.</p>

<u>Performer</u>	<u>Action</u>
Evaluator	(6) Establishes a file for each surveillance activity and assigns a unique surveillance report number [obtained from the Surveillance Coordinator] and logs the activity on a surveillance activity status log (Attachment C).

b. Conduct of Observation

<u>Performer</u>	<u>Action</u>
Evaluator	(1) Observes the chosen quality related activities to ensure they are being performed in accordance with specified requirements using the prepared guide sheet or identified requirements. Note: The evaluator is not restricted by the predefined scope of scheduled surveillances. Additional areas should be included as necessary.
	(2) Evaluates the results of the observations considering the following points as applicable and formulates conclusions. (a) The conformance of the activity or item with quality and quality assurance requirements. (b) The adequacy of the quality assurance practices observed. (c) The need for corrective action. (d) The need to assign follow-up performance dates for verification of corrective action. (e) The need for an independent inspection, examination, or test.

<u>Performer</u>	<u>Action</u>
Evaluator	<p>(f) The need for additional evaluation of the activity or program.</p> <p>(g) The effectiveness of implementation of controlling procedures.</p> <p>(3) Documents the results of each observation activity or groups of observation activities on a surveillance report (Attachment D) upon their completion.</p> <p>(4) If any potential deviations are identified, contacts the Surveillance Coordinator to determine if the deviation has been previously identified and is still pending.</p> <p>(5) For potential deviations previously documented, and still pending, makes a note in the surveillance report and proceeds to step 5.c.(1).</p> <p>(6) Discusses potential deviations during the surveillance with the first-line individual responsible for the activity being evaluated in an attempt to resolve the problem and ensure there are no misunderstandings.</p> <p>(7) Documents any deviations on a deviation report in accordance with SPP 5.01 and cross references the deviation report and surveillance report numbers on each other.</p>

Note: Deviation reports are processed in accordance with SPP 5.01.

c. Processing Surveillance Results

<u>Performer</u>	<u>Action</u>
Evaluator	<p>(1) Completes the surveillance report by noting that no deviations were identified or by documenting the deviation report number that requests corrective action.</p> <p><u>Note:</u> Corrective action will be tracked and closed out in accordance with SPP 5.01.</p> <p>(2) Attaches surveillance notes, completed guide sheets (if used), and other pertinent data to the surveillance report.</p> <p>(3) Upon completion of the report, closes out the file on the surveillance activity and updates the surveillance activity status log.</p> <p>(4) Prepares and transmits the results of surveillance activities considered particularly noteworthy and which may warrant special attention to the management of the organization being evaluated and the Surveillance Coordinator. Cognizant field offices receive a copy of reports concerning contractor activities.</p> <p><u>Note:</u> These are normally discussed with the Program Coordinator prior to transmittal.</p>

d. Records

<u>Performer</u>	<u>Action</u>
Evaluator	<p>(1) Prepares surveillance reports as quality records in accordance with SPP 7.01. Forwards to the Surveillance Coordinator.</p>

<u>Performer</u>	<u>Action</u>
Surveillance Coordinator	(2) Maintains the following records for working and historical purposes: <ul style="list-style-type: none">(a) Surveillance guide sheets.(b) Surveillance activity status log.(c) Surveillance reports.

6. ATTACHMENTS:

- a. Attachment A - Description of the Surveillance Process**
- b. Attachment B - Surveillance Guide Sheet**
- c. Attachment C - Surveillance Activity Status Log**
- d. Attachment D - Surveillance Report**

Attachment A

Description of the Surveillance Process

Surveillance activities will be conducted in conjunction with other evaluation practices in order to determine the status and assess the adequacy and effectiveness of Quality Assurance Program Participants. Surveillance activities will not be performed in lieu of audits.

Surveillance activities may be either formally scheduled or unscheduled. In either case, surveillance of activities affecting quality will be planned and executed to ensure optimum results.

Surveillance will be performed by the evaluators through selected activities such as:

- Monitoring of program material such as participating organization plans and schedules, progress and status reports, correspondence, deviation reports, inspection reports, open item reports, quality trend reports, quality documents, procurement documents, configuration control actions, status review meetings, documentation system utilization and maintenance, test results, personnel training and certification activities.

Note: Monitoring will be performed in conjunction with other evaluation activities to validate the accomplishment of program activities and to collect data for and to identify activities and actions requiring observation.

- Performing a general review of ongoing work, implementing procedures and instructions, and associated documents to identify the requirements and acceptance criteria for which an observation will be performed.
- Observing ongoing work activities as well as associated quality assurance activities including inspections, examinations and tests to verify they are being performed in accordance with specified requirements.

Based on results of surveillance activities, the Surveillance Coordinator will:

- Determine if the activities are acceptable or unacceptable.
- Determine if the surveillance sample, frequency, or depth is adequate.

Attachment A (Cont'd)

- **Determine if particular evaluations of quality assurance activities should be performed and plan the conduct of those evaluations.**
- **Determine if independent inspections, examinations, or tests should be performed and plan conduct of same.**
- **Initiate request for actions to correct deviations.**

Deviations identified during the conduct of surveillance activities will be brought to the attention of the appropriate level of personnel in the participating organization to afford them the opportunity to take the necessary corrective actions.

Surveillance will be executed to a planned guide sheet (as necessary) in accordance with the objectives and criteria that have been assigned or that have been identified by the general review of the participating organization's schedule and implementing procedures and instructions.

When guide sheets are used, they are to be prepared by the quality assurance evaluator prior to the commencement of the surveillance activity.

Attachment D

Surveillance Report

SURVEILLANCE REPORT		
(1) ORGANIZATION BEING EVALUATED _____	(2) DATE _____	(3) SURVEILLANCE REPORT NO. _____
(4) TYPE OF SURVEILLANCE ACTION _____	(5) LOCATION _____	
(6) OBSERVED ACTIVITY		
(7) SURVEILLANCE RESULTS		
		DEVIATION REPORT(S) INITIATED (If None, So State) _____ _____ _____ _____
Evaluator Signature _____ Date _____		

STANDARD PRACTICE PROCEDURE

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ADMINISTRATION OF TECHNICAL REVIEWS

1. PURPOSE:

To define the responsibilities and actions required in the Administration of Technical Reviews conducted by a Technical Review Group.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. DOE/RW-0214, Quality Assurance Requirements Program for the Civilian Radioactive Waste Management Program
- b. SPP 4.06, Conduct of Technical Reviews
- c. SPP 7.01, Preparation, Transfer and Receipt of Quality Records

4. GENERAL:

This instruction covers the administrative functioning of Technical Review activities to include:

- Review Group composition and qualifications
- Review Group funding
- Initiation of Reviews
- Processing of Review Reports
- Records Control

Technical reviews are conducted by a Technical Review Group (TRG) in accordance with SPP 4.06 and a Charter for a Technical Review Group.

A TRG is organized to directly support the DOE-HQ Program Manager in the technical review of work associated with the High-Level Waste Program, including the Defense Waste Processing Facility's Waste Qualification Report (WQR). The TRG has administrative ties with the Defense High-Level Waste Technology Program Office (DHLW TPO) and the Materials Integration Office (MIO). Communication links are maintained to transmit

technical information or to report progress of the reviews to external organizations.

The Review Coordinator is responsible for interface activities between the Operations Offices and a Technical Review Group. Requests for Technical Reviews are directed to the Review Coordinator who, in turn, arranges for the requested service. Correspondingly, the review results are directed to the Review Coordinator who, in turn, notifies and directs the Operations Offices of the results of the review and corresponding actions needed.

a. Definitions

- (1) 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 evaluations 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--DOE/RW-0214.
- (2) Technical Review Group (TRG) - A review group consisting of a chairman, an executive secretary, a core group of reviewers and, as necessary, technical consultants. The TRG performs technical reviews of work associated with the High-Level Waste Program, including the Defense Waste Processing Facility's Waste Qualification Report. The group reports through its Chairman to the Review Coordinator.
- (3) 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.
 - (c) They do not report directly to the immediate supervisors who are responsible for performing the activity or work being evaluated--DOE/RW-0214.

- (4) TRG preliminary review report - A report prepared by a TRG which contains a description of the review performed, consensus comments, majority reports, and minority reports--TRG Charter.
- (5) TRG final review report - The TRG preliminary review report plus the document generator's responses to the comments, the TRG assessment of those responses, and final recommendations by the TRG Chairman--TRG Charter.

5. PROCEDURE:

a. Establishment of the Technical Review Group

<u>Performer</u>	<u>Action</u>
Review Coordinator	(1) Appoints Technical Review Group (TRG) Chairman.
Materials Integration Office (MIO)	(2) Appoints Executive Secretary (ES).
Review Coordinator	(3) Approves appointment of the ES.
TRG Chairman, ES	(4) Recommend members for TRG core group. (See Attachment A.)
Review Coordinator	(5) Approves appointment of TRG core group membership.
TRG Chairman, ES	(6) Appoint technical consultants to the TRG as needed.
Review Coordinator	(7) Arranges for adequate funding to support TRG activities throughout the year.

b. Documentation of TRG Qualification

<u>Performer</u>	<u>Action</u>
TRG Chairman	(1) Obtains documentation from each review group member to include: <ul style="list-style-type: none"> (a) Resume (see Attachment B).

<u>Performer</u>	<u>Action</u>
TRG Chairman	(b) Statement of independence (see Attachment C). (c) Qualification information (see Attachment D).
ES	(2) Forwards qualification statements to the ES for incorporation into the technical document review file.
Review Coordinator	(3) Maintains qualification statements and provides a copy of them to the Review Coordinator as they are generated. (4) Assures that the minimum qualifications described in Attachment E are met. (5) Issues Reviewer Certification Certificate (see Attachment F).

c. Initiation of Technical Review

<u>Performer</u>	<u>Action</u>
Operations Office	(1) Forwards package of work to be reviewed to the Review Coordinator. (2) Provides input to Statement of Work (SOW) for the Review Coordinator's use.
Review Coordinator	(3) Prepares and approves finalized SOW for the TRG. (4) Authorizes the review of the package by the TRG. (5) Logs the documents on the Review Log (Attachment G). (6) Transmits the SOW and package of work to be reviewed to the TRG Chairman.

<u>Performer</u>	<u>Action</u>
TRG Chairman	(7) Forwards the SOW and package of work to be reviewed to the ES.
ES	(8) Establishes a technical review document file and a reviewer's data package for each review.
TRG Chairman	(9) Initiates the technical review in accordance with SPP 4.06

d. Processing of the Preliminary Review Report

<u>Performer</u>	<u>Action</u>
TRG Chairman	(1) Transmits preliminary review report [see paragraph 4.a(4)] to the Review Coordinator.
Review Coordinator	(2) Reviews and transmits the preliminary review report to the Operations Office and document generator.
Operations Office	(3) Responds to the comments contained in the preliminary review report and forwards the responses to the Review Coordinator.
Review Coordinator	(4) Reviews and transmits the responses received by the TRG Chairman.
TRG Chairman	(5) Coordinates response resolution with the Operations Office through the Review Coordinator.
	(6) Concurs with responses after resolution.
Review Coordinator	(7) Ensures that all comments are closed out and that the TRG concurs with the resolution of the comments.

Performer

Action

e. Processing of the Final Review Report

- | | |
|--------------------|--|
| TRG Chairman | (1) Transmits the final review report [see paragraph 4.a.(5)] to the Review Coordinator. |
| Review Coordinator | (2) Transmits the final review report and the corresponding revised materials (or section thereof) through appropriate channels. |
| | (3) Records any comments and date complete on the Review Log (Attachment G). |

f. Records

Performer

Action

- | | |
|--------------------|---|
| Review Coordinator | (1) Prepares the Technical Review Record files in accordance with SPP 7.01 to include the following: <ul style="list-style-type: none">(a) Package being submitted for review.(b) SOW.(c) Final review report.(d) Reviewer qualification statements. |
|--------------------|---|

The overall flow diagram for the review process is illustrated in Attachment H which is extracted from the TRG Charter.

6. ATTACHMENTS:

- a. Attachment A - Technical Review Group Composition**
- b. Attachment B - Standard Resume Content**
- c. Attachment C - Statement of Reviewer Independence (Example)**
- d. Attachment D - Reviewer Qualification Form (Example)**
- e. Attachment E - Minimum Qualifications for the Technical Review Group**
- f. Attachment F - Certification Certificate (Example)**
- g. Attachment G - Review Log (Example)**
- h. Attachment H - Simplified Flow Diagram for Package Review**

Attachment A

Technical Review Group Composition

1. Permanent Membership (all voting members)

- a. Chairman
- b. Executive Secretary
- c. Core Group Members

The following areas of technical expertise shall be represented by the Core Group:

- (1) **Waste Form:** For the review of material related to the formulation and evaluation of vitrified high-level nuclear waste forms.
- (2) **Repository:** For the evaluation of materials related to repository issues, especially with respect to the controlling parameters for DHLW disposal.
- (3) **Mechanical:** For the review of material related to highly radioactive facility/equipment design and operation of vitrification and nuclear waste handling facilities.
- (4) **Metallurgical:** For the review of information on use of materials for nuclear waste processing and storage, on DHLW canister designs, and on corrosion mechanisms related to geologic repositories.
- (5) **HLW Process and Its Control:** For the review of information on vitrification process design and operation, processing equipment, and process control parameters.

Note: The Chairman has the authority to change the above list as needed to provide the necessary technical expertise.

2. Technical Consultants (non-voting members)

Consultants shall be appointed by the Chairman in consultation with the Executive Secretary on a case-by-case basis. They will provide specialized expertise to review specific aspects of the submitted material.

Attachment B
Standard Resume Content

1. Name of person.
2. Disciplines or areas of expertise applicable to a specific technical review.
3. Education - List schools attended, degrees received, and last year in attendance.
4. Experience History - Each entry should include the job title; the company and organizational unit; the starting date and the ending date; and a brief summary of the duties/accomplishments in that position.
5. Licenses and Certificates - List the license or certificate, the licensing or certifying agency, their address, and the date obtained.
6. Professional Societies - List any professional societies including date of membership and position/office held (if any).
7. Technical Skills - List any technical skills applicable to the specific technical reviews.
8. Publication - List any technical publications.

Attachment C

Statement of Reviewer Independence (Example)

For the subject activity or work that I am to review, I:

- a) have not had any direct responsibility for or involvement in performing the activity or work.
- b) am not accountable for the activity or work result.
- c) do not report directly to the immediate supervisors who are responsible for performing the activity or work being evaluated.

Reviewer Signature/Date

Attachment D

Reviewer Qualification Form (Example)

DOCUMENTATION OF REVIEWER QUALIFICATIONS FOR _____		
I. PROFESSIONAL EXPERIENCE:		
A. EDUCATION:		
<u>High School/University</u>	<u>Degree</u>	<u>Date</u>
B. EXPERIENCE:		
<u>Experience</u>	<u>Company</u>	<u>Dates</u>
C. PROFICIENCY AND SKILLS:		
II. QUALIFICATION IS VALIDATED BY:		
_____ Signature and Title	_____ Date	
III. APPROVAL OF APPOINTMENT		
_____ Signature and Title	_____ Date	

Attachment E

Minimum Qualifications for the Technical Review Group

- 1. TRG Chairman - The Chairman must have a broad technical understanding of HLW management issues ranging from an understanding of the waste solidification process, waste form, and waste-form/canister specifications to repository disposal concepts, and institutional requirements for the waste acceptance process. The Chairman must also understand the scheduling demands of the waste acceptance process and be able to work effectively with and manage professionals of varying technical backgrounds to establish acceptability of multidisciplinary technical work. He must have excellent verbal and written communication skills. The Chairman must have a technical degree and at least 10 years experience in nuclear waste management.**
- 2. Executive Secretary - The Executive Secretary must have at least 10 years experience in the nuclear waste field, as well as strong administrative skills and an understanding of the institutional requirements for HLW disposal. He must have excellent verbal and written communication skills.**
- 3. Core Group Members - These are technical experts in selected functional areas involved with waste form acceptance. Each member must have a technical degree and a minimum of 5 years experience in the nuclear waste field. Each member should be generally familiar with the Waste Acceptance Process.**
 - a. Waste Form: A chemist, ceramist, or equal with extensive experience in formulating and evaluating vitrified high-level nuclear waste forms.**
 - b. Repository: A physical scientist or engineer with broad experience in evaluating repository sites, especially with respect to the controlling parameters for HLW disposal. He should be able to review the material relative to issues of concern to the repository program.**
 - c. Mechanical: An engineer whose experience base includes involvement with highly radioactive facility/equipment design and operation including vitrification facilities and nuclear waste handling facilities.**

Attachment E (Cont'd)

- d. **Metallurgical:** A metallurgist or equal familiar with material selection requirements for nuclear waste processing and storage, knowledgeable in HLW canister design criteria, and corrosion mechanisms related to geologic repositories.
 - e. **HLW Process and Its Control:** A chemical engineer or equal whose experience includes chemical process design and operation in a highly radioactive environment with specific knowledge of vitrification processes, processing equipment and process control parameters.
4. **Lead Reviewer** - a member of the Core Group who is designated by the Chairman to lead a specific review based on his recognized expertise relative to the document contents. If one is not designated, the Chairman is the Lead Reviewer. A Lead Reviewer shall be a Core Group member with a technical expertise directly related to the material being reviewed.
5. **Technical Consultants** - They will provide specialized expertise to review specific aspects of the submitted material. The Executive Secretary will maintain a record of their participation in the reviews.

Attachment F

Certification Certificate (Example)

THIS IS TO CERTIFY THAT

***IS HEREBY QUALIFIED TO PERFORM AS A
TECHNICAL REVIEWER***

This certification is based on an evaluation of employee qualifications in accordance with SPP 4.05. The effective period of certification is one year from the date of issue. The employee's education, experience, training, and ability have been evaluated and summarized on a qualification form. This form and records to substantiate qualifications are on file in the Certification and Training Files.

Date

Certifying Official - Title

REVIEW LOG

LOG FOR _____ PAGE _____

Item No.	Document No. & Title	Rev. & Addendum	Date Rec	Date Req	Reviewer	Guide Sheet No.	Comments	Date Comp.
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

(1) Item No. - Sequential number with prefixes as follows:
 D=Design; P=Procurement; PE=Peer; Q=Quality Assurance ;
 R=Readiness; T=Technical
 (2) Document No. & Title - Number and title of document to be reviewed
 (3) Rev. & Addendum - Revision and addendum of (2)
 (4) Date Rec. - Date document received for review
 (5) Date Req. - Date document review is to be completed (assigned by Supervisor, OPS)

(6) Reviewer - Individual within that section assigned to perform the review
 (7) Guide Sheet No. - Identification of guide sheet if a standard guide sheet is used
 (8) Comments - Pertinent information from the review; attach notes if necessary
 (9) Date Comp. - Date the document review completed

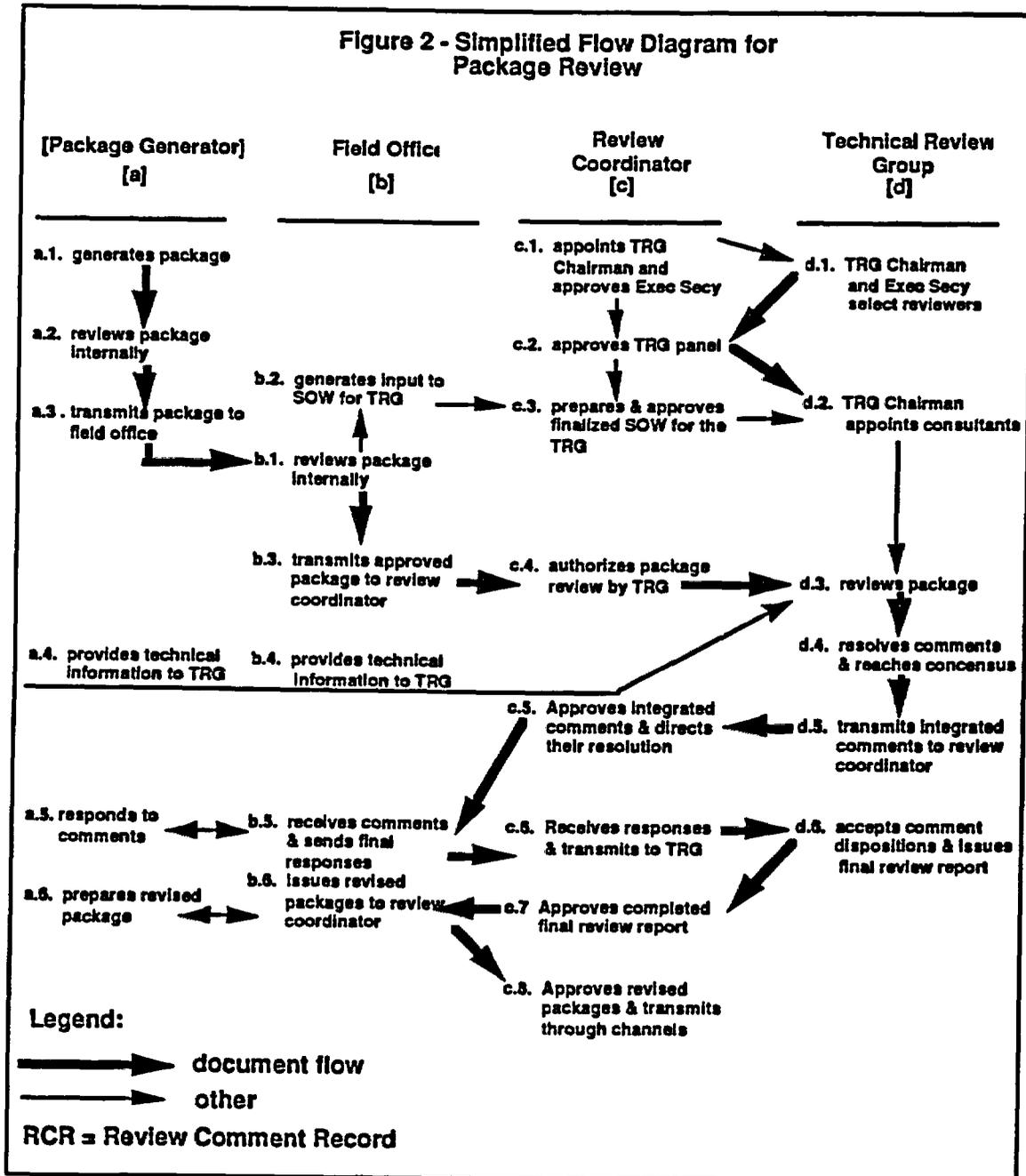
Review Log (Example)

Attachment G

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Attachment H

Simplified Flow Diagram for Package Review



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CONDUCT OF TECHNICAL REVIEWS

1. PURPOSE:

To define the responsibilities and actions required to conduct technical reviews.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. DOE/RW-0214 Quality Assurance Requirements for the Civilian Radioactive Waste Management Program
- b. SPP 4.05, Administration of Technical Reviews
- c. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records

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4. GENERAL:

Technical Reviews are an effective way for DOE to assess whether a large, complex project complies with the technical requirements.

Technical Reviews are conducted by Technical Review Groups made up of individuals independent of the work to be reviewed, and at least technically competent enough to perform the original work. The findings of the reviewer are documental in the Technical Review Group's preliminary and final reports.

a. Definitions

- (1) Technical Review - A documented, traceable, in-depth, critical review, analysis, or evaluation of documents, materials, or data that falls within the state of the art conducted to verify or validate or both its applicability, correctness, adequacy, and completeness. Technical reviews are performed by qualified personnel with technical expertise at least equivalent to those who conducted the original work, and who are independent of those who conducted the work being reviewed.--DOE/RW-0214.

- (2) Technical Review Group (TRG) - A review group consisting of a chairman, an executive secretary, a core group of reviewers, and, as necessary, technical consultants. The TRG performs technical reviews of work associated with the High-Level Waste Program, including the Defense Waste Processing Facility's Waste Qualification Report. The group reports through its Chairman to the Review Coordinator.

- (3) 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.
 - (c) They do not report directly to the immediate supervisors who are responsible for performing the activity or work being evaluated--DOE/RW-0214.

- (4) TRG preliminary review report - A report prepared by the TRG which contains a description of the review performed, consensus comments, majority reports, and minority reports--TRG Charter.

- (5) TRG final review report - The TRG preliminary review report plus the document generator's responses to the comments, the TRG assessment of those responses, and final recommendations by the TRG Chairman--TRG Charter.

5. PROCEDURE:

a. Preparation for Technical Reviews

<u>Performer</u>	<u>Action</u>
Review Coordinator	(1) Receives package of work to be reviewed from responsible Operations Office. (2) Initiates the technical review in accordance with SPP 4.05.

b. Performance of Technical Review

<u>Performer</u>	<u>Action</u>
Technical Review Group (TRG) Chairman	(1) Directs the TRG members to perform the review as noted in the Statement of Work (SOW).
TRG Members	(2) Conduct review in accordance with established policy and within identified time constraints.
	(3) Document the review results on a Review Comment Record (RCR): (Attachment A) by categorizing the review results as follows: <ul style="list-style-type: none"> (a) Acceptance with no comments. (b) Acceptance with comment(s). (c) Non-acceptance with comment(s).

c. Processing Review Results

<u>Performer</u>	<u>Action</u>
TRG Chairman	(1) Collects all TRG member's comments and writes a single set of integrated comments on the RCR Form.
	(2) Obtains written concurrence from TRG Members for integrated comments, or
	(3) Documents majority and minority positions.
TRG Members	(4) Sign RCR indicating concurrence with consensus comments or documenting majority and minority positions.
TRG Chairman	(5) Prepares the preliminary review report [see 4.a.(4)] and forwards it to the Review Coordinator.

d. Processing Responses to Review Report Comments

<u>Performer</u>	<u>Action</u>
Review Coordinator	(1) Forwards the Responses from the Operations Office and document generator to the TRG Chairman.
TRG Chairman	(2) Coordinates response resolution with the Operations Office through the Review Coordinator. (3) Prepares the final review report [see 4.a.(5)]. (4) Forwards the final review report to the Review Coordinator.

e. Quality Records

<u>Performer</u>	<u>Action</u>
Review Coordinator	(1) Prepares the technical review file in accordance with SPP 4.05.

6. ATTACHMENTS:

- a. Attachment A - Review Comment Record (RCR) (Example)
- b. Attachment B - Simplified Flow Diagram For Package Review

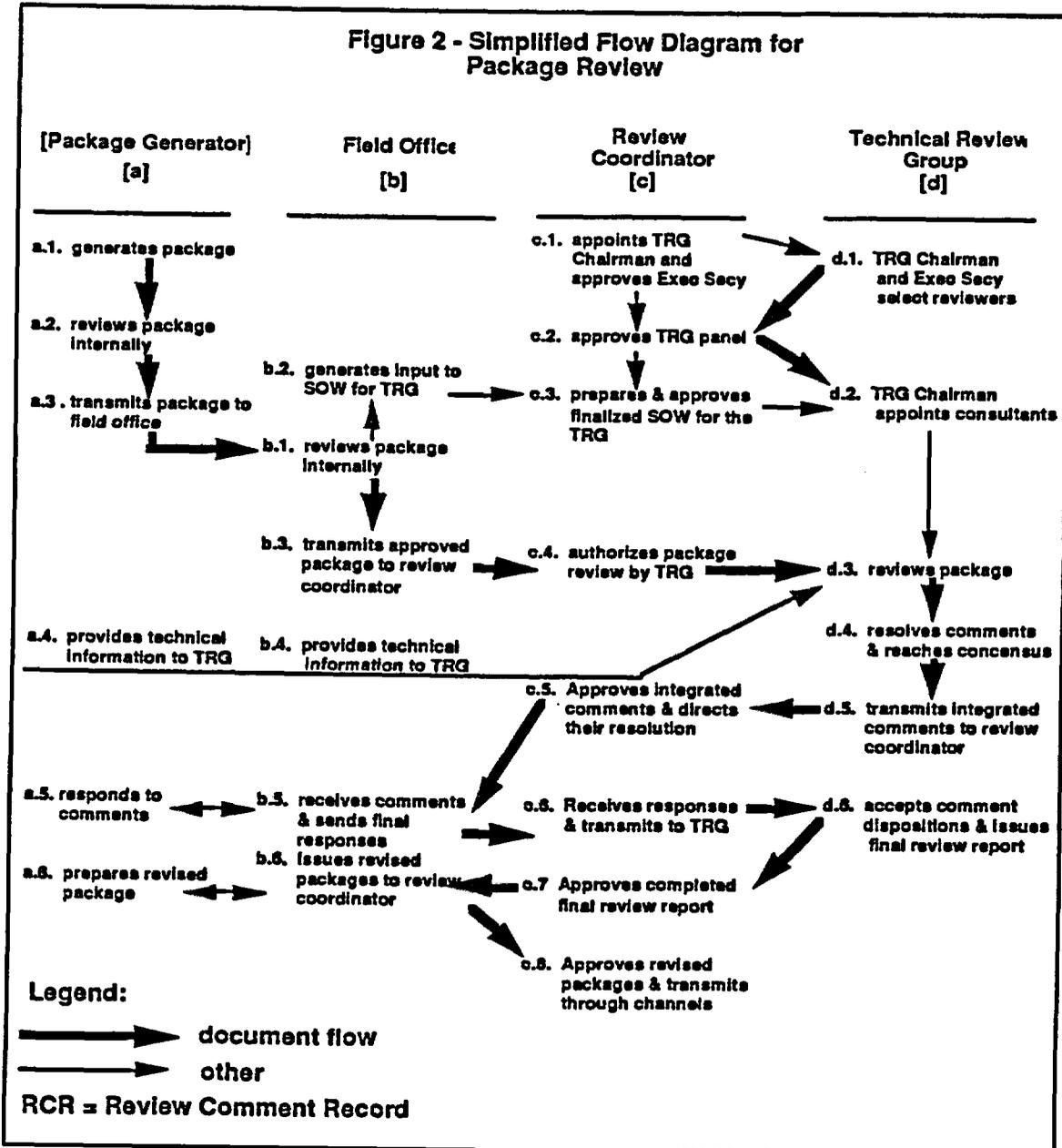
Attachment A (Cont'd)

Review Comment Record Continuation Sheet

Reviewer	REVIEW COMMENT RECORD (RCR)			Review No.	Page ____ of ____
Item	Comments(s)/Discrepancy(s) (Provide technical justification for the comment and detailed recommendation of the action required to correct/resolve the discrepancy/problem indicated.)	Non Mandatory Comment	Mandatory Comment	Disposition (provide justification if NOT accepted)	

Attachment B

Simplified Flow Diagram For Package Review



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ADMINISTRATION OF PEER REVIEWS

1. PURPOSE:

To define the responsibilities and actions required in the Administration of Peer Reviews conducted by the Peer Review Group.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. NUREG-1297, Peer Review for High-Level Nuclear Waste Repositories
- b. DOE/RW-0214 Quality Assurance Requirements for the Civilian Radioactive Waste Management Program 47 CFR - 2
- c. SPP 4.09, Conduct of Peer Reviews
- d. SPP 7.01, Preparation, Transfer and Receipt of Quality Records

4. GENERAL:

This SPP covers the administrative functioning of Peer Review activities to include:

- Review Group composition and qualifications
- Review Group funding
- Initiation of Reviews
- Processing of Peer Review Reports
- Records Control

Peer reviews are conducted by the Peer Reviewer or Review Group (PRG) in accordance with SPP 4.09. The PRG is organized to directly support the Review Coordinator in the peer review of work associated with the High-Level Waste Program. Communication links are maintained to transmit technical information or to report progress of the reviews to external organizations.

The Review Coordinator is responsible for interface activities between the Operations Offices and the Peer Reviewer or Review Group. Requests for Peer Reviews are directed to the Review Coordinator who, in turn, contracts or otherwise arranges for the requested service.

Correspondingly, the review results are directed to the Review Coordinator who, in turn, notifies and directs the Operations Offices of the results of the review and corresponding actions needed.

a. Definitions

- (1) Peer - A peer is a person having technical expertise in the subject matter to be reviewed (or a critical subset of the subject matter to be reviewed) to a degree at least equivalent to that needed for the original work--NUREG 1297.
- (2) Peer Review Group - A peer review group is an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed, and should vary in size based on the subject matter and importance of the subject matter to safety or waste isolation--NUREG 1297.
- (3) 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--DOE/RW-0214.
- (4) Preliminary Peer Review Report - A report prepared by the PRG which contains a description of the review performed, consensus comments, majority reports, and minority reports.
- (5) Final Peer Review Report - The Preliminary Peer Review Report plus the document generators responses to the comments, the PRG assessment of those responses, and final recommendations by the PRG Chairman.

- (6) 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.
 - (c) They do not report directly to the immediate supervisors who are responsible for performing the activity or work being evaluated--DOE/RW-0214.

5. PROCEDURE:

a. Establishment of the Peer Review Group

<u>Performer</u>	<u>Action</u>
Review Coordinator	(1) Appoints Peer Review Group (PRG) Chairman.
PRG Chairman	(2) Appoints PRG Secretary.
Review Coordinator	(3) Approves appointment of the PRG Secretary.
PRG Chairman, Secretary	(4) Recommend members for PRG, including any needed technical consultants.
Review Coordinator	(5) Approves appointment of PRG membership.
	(6) Arranges for adequate funding to support PRG activities throughout the year.

b. Documentation of PRG Qualification

<u>Performer</u>	<u>Action</u>
TRG Chairman	(1) Obtains written statements from each review group member attesting to their qualifications including support for independence requirements. [See paragraph 4.a.(6).] (2) Forwards qualification statements to the PRG Secretary for incorporation into the peer review document file.
PRG Secretary	(3) Maintains qualification statements and provides a copy of them to the Review Coordinator as they are generated.

c. Initiation of Peer Review

<u>Performer</u>	<u>Action</u>
Operations Office	(1) Forwards package of work to be reviewed to the Review Coordinator. (2) Provides input to Statement of Work (SOW) for the Review Coordinator's use.
Review Coordinator	(3) Prepares and approves finalized SOW for the PRG. (4) Authorizes the review by the PRG. (5) Logs the documents on the Review Log (Attachment A). (6) Transmits the SOW and package of work to be reviewed to the PRG Chairman.
PRG Chairman	(7) Forwards the SOW and package of work to be reviewed to the PRG Secretary.

<u>Performer</u>	<u>Action</u>
PRG Secretary	(8) Establishes a peer review document file and a reviewers data package for each review.
PRG Chairman	(9) Initiates the technical review in accordance with SPP 4.09

d. Processing of the Preliminary Review Report

<u>Performer</u>	<u>Action</u>
PRG Chairman	(1) Transmits the Preliminary Peer Review Report to the Review Coordinator.
Review Coordinator	(2) Reviews and transmits the Preliminary Peer Review Report to the Operations Office and work performer.
Operations Office	(3) Responds or obtains responses to the comments contained in the Preliminary Peer Review Report and forwards the responses to the Review Coordinator.
Review Coordinator	(4) Reviews and transmits the responses received to the PRG Chairman.
PRG Chairman	(5) Coordinates response resolution with the Operations Office and work performer through the Review Coordinator.
	(6) Concurs with responses after resolution.
Review Coordinator	(7) Ensures that all comments are closed out and that the PRG concurs with the resolution of the comments.

e. Processing of the Final Review Report

<u>Performer</u>	<u>Action</u>
PRG Chairman	(1) Transmits the Final Peer Review Report to the Review Coordinator.

<u>Performer</u>	<u>Action</u>
Review Coordinator	(2) Transmits the Final Peer Review Report through appropriate channels.
PRG Chairman	(3) Records any comments and date complete on the Review Log (Attachment A).

f. Records

<u>Performer</u>	<u>Action</u>
Review Coordinator	(1) Prepares the Peer Review Record files in accordance with SPP 7.01 to include the following: <ul style="list-style-type: none">(a) Work package being submitted for review(b) SOW(c) Final Peer Review Report(d) Reviewer qualification statements

6. ATTACHMENTS:

- a. Attachment A - Review Log (Example)

REVIEW LOG

LOG FOR _____ PAGE _____

Item No.	Document No. & Title	Rev. & Addendum	Date Rec	Date Req	Reviewer	Guide Sheet No.	Comments	Date Comp.
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

- (1) Item No. - Sequential number with prefixes as follows:
D=Design; P=Procurement; PE=Peer; Q=Quality Assurance ;
R=Readiness; T=Technical
- (2) Document No. & Title - Number and title of document to be reviewed
- (3) Rev. & Addendum - Revision and addendum of (2)
- (4) Date Rec. - Date document received for review
- (5) Date Req. - Date document review is to be completed (assigned by Supervisor, OPS)

- (6) Reviewer - Individual within that section assigned to perform the review
- (7) Guide Sheet No. - Identification of guide sheet if a standard guide sheet is used
- (8) Comments - Pertinent information from the review; attach notes if necessary
- (9) Date Comp. - Date the document review completed

Review Log (Example)

Attachment A

SPP 4.08
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Effective
Date 02/02/90

CONDUCT OF PEER REVIEWS

1. PURPOSE:

To define the responsibilities and actions required to conduct peer reviews.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. ~~NUREG-1297, Peer Review for High-Level Nuclear Waste Repositories~~
- b. ~~DOE/RW-0214 Quality Assurance Requirements for the Civilian Radioactive Waste Management Program~~ *see app D.02*
- c. SPP 4.08, Administration of Peer Reviews
- d. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records

4. GENERAL:

Applicability of Peer Reviews:

A peer review should be used when the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods essential to showing that the repository system meets or exceeds its performance requirements with respect to safety and waste isolation cannot otherwise be established through testing, alternate calculations, or reference to previously established standards and practices.

In general, the following conditions are indicative of situations in which a peer review should be considered:

- Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing.

- Decisions or interpretations having significant impact on performance assessment conclusions will be made.
- Novel or beyond the state-of-the-art testing, plans and procedures, or analyses are, or will be utilized.
- Detailed technical criteria or standard industry procedures do not exist or are being developed.
- Results of tests are not reproducible or repeatable.
- Data or interpretations are ambiguous.
- Data adequacy is questionable--such as, data may not have been collected in conformance with an established Quality Assurance program.

A peer review should be used when the adequacy of a critical body of information can be established by alternate means, but there is disagreement within the cognizant technical community regarding the applicability or appropriateness of the alternate means--NUREG 1297.

a. Definitions

- (1) **Peer** - A peer is a person having technical expertise in the subject matter to be reviewed (or a critical subset of the subject matter to be reviewed) to a degree at least equivalent to that needed for the original work--NUREG 1297.
- (2) **Peer Review Group** - A peer review group is an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed, and should vary in size based on the subject matter and importance of the subject matter to safety or waste isolation--NUREG 1297.
- (3) **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--DOE/RW-0214.

- (4) Preliminary Peer Review Report - A report prepared by the Peer Review Group (PRG) which contains a description of the review performed, consensus comments, majority reports, and minority reports.
- (5) Final Peer Review Report - The Preliminary Peer Review Report plus the document generators responses to the comments, the PRG assessment of those responses, and final recommendations by the PRG Chairman.
- (6) 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 of work.
 - (b) They are not accountable for the activity or work result.
 - (c) They do not report directly to the immediate supervisors who are responsible for performing the activity or work being evaluated--OGR/B-14.

5. PROCEDURE:

a. Preparation for Peer Reviews

<u>Performer</u>	<u>Action</u>
Review Coordinator	(1) Receives package of work to be reviewed from responsible Operations Office. (2) Initiates the peer review in accordance with SPP 4.08.

b. Performance of Peer Reviews

<u>Performer</u>	<u>Action</u>
Peer Review Group (PRG) Chairman	(1) Directs the PRG members to perform the review as noted in the Statement of Work (SOW).
PRG Members	(2) Conduct review in accordance with established policy and within identified time constraints. (See Attachment A). (3) Document the review results on a Review Comment Record (Attachment B) by categorizing the review results as follows: (a) Acceptance with no comments. (b) Acceptance with comment(s). (c) Non-acceptance with comment(s).

c. Processing Peer Review Results

<u>Performer</u>	<u>Action</u>
PRG Chairman	(1) Collects all PRG members' comments and writes a single set of integrated comments on the Review Comment Record (RCR) Form. (2) Obtains written concurrence from PRG Members for integrated comments, or (3) Documents majority and minority positions.
PRG Members	(4) Sign RCR indicating concurrence with consensus comments or documenting majority and minority positions.
PRG Chairman	(5) Prepares the Preliminary Peer Review Report [see 4.a.(4)] and forwards it to the Review Coordinator.

d. Processing Responses to the Preliminary Peer Review Report Comments

<u>Performer</u>	<u>Action</u>
Review Coordinator	(1) Forwards the responses from the Operations Office and work performer to the PRG Chairman.
PRG Chairman	(2) Coordinates response resolution with the Operations Office or work performer through the Review Coordinator.
	(3) Prepares the Final Peer Review Report [see 4.a.(5) and Attachment C].
	(4) Forwards the Final Peer Review Report to the Review Coordinator.

e. Quality Records

<u>Performer</u>	<u>Action</u>
Review Coordinator	(1) Prepares the technical review file in accordance with SPP 4.08.

6. ATTACHMENTS:

- a. Attachment A - Areas to Be Addressed in Peer Reviews
- b. Attachment B - Review Comment Record (RCR) (Example)
- c. Attachment C - Content of a Final Peer Review Report

Attachment A

Areas to Be Addressed in Peer Reviews

From NUREG-1297

1. Validity of assumptions.
2. Alternate interpretations.
3. Uncertainty of results and consequences if wrong.
4. Appropriateness and limitations of methodology and procedures.
5. Adequacy of application.
6. Accuracy of calculations.
7. Validity of conclusions.
8. Adequacy of requirements and criteria.

From RW 0214

1. Validity of basic assumptions, data and functional requirements.
2. Appropriateness of methodology.
3. Verifications of calculations or computer software.
4. The review process and reviewer responsibilities.
5. Handling of comment resolution.
6. Reporting minority positions.
7. Involvement of the quality assurance organization.

Attachment A (Cont'd)

8. Review of new documents and changes to previously peer reviewed documents.
9. Re-review of revised documents.
10. Records of revised documents.
11. Review individual(s) qualifications for the review(s).

Attachment B (Cont'd)

Review Comment Record (RCR) (Example) (Back Side)

REVIEW COMMENT RECORD (RCR)		BLOCK NO.	RESPONSIBILITY	INSTRUCTIONS
<p>The review comment record (RCR) is a multipurpose review form to be utilized to accumulate review comments, receive recommendations, and document subsequent dispositions associated with the process of review. Unique form preparation instructions will be defined by governing procedures within individual programmatic areas. General instructions are provided herein to ensure uniform usage and establish basic requirements for RCR initiation and control.</p>		11	Reviewer and Document Preparer	CLOSED date - When all comments have been dispositioned to the satisfaction of the reviewer and verified by the reviewer as incorporated, or otherwise resolved, the reviewer and Document Preparer shall sign and date this block.
RCR FORM PREPARATION				
BLOCK NO.	RESPONSIBILITY			INSTRUCTIONS
1	Reviewer		Date - Enter date this form is completed.	
2	Reviewer		Review No. - Enter Review Number indicated on Notice of Design/Document Review form.	
3	Reviewer		Project No. - Enter the Project Number if the documents apply to a construction project; otherwise, leave blank.	
4	Reviewer	14	Page (Number) - Assigned sequentially. The total number of pages (if continuation pages are used) shall be noted on Page 1.	No Comment - Mark if no comments.
5	Reviewer		Document Number(s)/Title(s) - Enter the number(s) and title(s) of document(s) being reviewed. If too numerous to list, indicate the primary document and number.	Nonmandatory Comment - Mark if comment is not significant and disposition acceptance not required. Mandatory Comment - Mark if comment and disposition acceptance is required.
6	Reviewer	15	Program/Project - Enter name of Program or Project to which the document(s) being reviewed apply (FFTF, N Reactor, Tank Farms, PUREX, Z Plant, etc.).	Disposition - Upon completion of discussion with the reviewer, the Document Preparer finalizes the disposition of each comment indicating "accept" or "reject." Should a comment be rejected, a written justification shall be provided to the reviewer. After the reviewer has verified that the original agreed upon disposition of comments (block No. 10) have been incorporated or a satisfactory justification provided for rejection, the reviewer and the Document Preparer shall sign this block and enter a "closed date."
7	Reviewer		Reviewer - Enter name of individual preparing the RCR form.	
8	Reviewer		Organization/Group - Enter the functional organization or group being represented by the reviewer (preparer of the RCR form).	
9	Reviewer	16	Location/Phone - Enter the current work location and telephone number of the reviewer/preparer.	Status - The Document Preparer shall use this column to indicate the status of each comment (open, closed, etc.).
10	Reviewer and Document Preparer	17	Agreement with indicated comment/disposition(s) - Upon reaching a satisfactory agreement between the reviewer and the Document Preparer as to the intended disposition of comments submitted by the reviewer, the reviewer and Document Preparer shall sign and date this block.	Approval - Ensure credible representation of the group.

Attachment B (Cont'd)

Review Comment Record Continuation Sheet

Reviewer		REVIEW COMMENT RECORD (RCR)			Review No.	Page ____ of ____
Item	Comments(s)/Discrepancy(s) (Provide technical justification for the comment and detailed recommendation of the action required to correct/resolve the discrepancy/problem indicated.)	Non Mandatory Comment	Mandatory Comment	Disposition (provide justification if NOT accepted)		

Attachment C

Content of a Final Peer Review Report

1. Clearly state the subject peer reviewed
2. Conclusions reached and recommendations given as a result of the peer review
3. A listing of the peers and the general facet(s) each reviewed
4. As appropriate, references to documented dissenting views or additional comments.
5. Include as attachments:
 - a. Peer Review Scope and Planning Document
 - b. Logs of activities, minutes of meetings, and records of deliberations
 - c. General identification of materials reviewed and persons contacted
 - d. Dispositioned RCR Forms with document generators' and reviewers' concurrences.

STANDARD PRACTICE PROCEDURE

UNCONTROLLED COPY

SPP 4.10
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Date 02/02/90

REVIEW OF OPERATIONS OFFICES QUALITY ASSURANCE PROGRAM DESCRIPTIONS AND PROCEDURES

1. PURPOSE:

To establish objectives and provide instructions for review of operations offices quality assurance program descriptions and procedures to determine their adequacy and acceptability for use on the HLW Program.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 4.01, Planning and Scheduling of Evaluation Activities
- b. SPP 4.11, Review of Waste Acceptance Process Technical Documents
- c. SPP 5.01, Deviation Reporting and Disposition
- d. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records

4. GENERAL:

DOE Headquarters, as a part of its evaluation practice, performs reviews of the Operations Offices quality assurance program descriptions and procedures. These reviews are planned and scheduled in accordance with SPP 4.01.

Reviews of quality assurance program descriptions and procedures should be planned and executed to determine that:

- Quality-related activities are adequately identified.
- Organizational responsibilities for the performance of quality assurance tasks are established and can be implemented.
- Organizational freedom has been provided to identify and cause corrective action on quality-related problems.

- Preparation, review, and approval is in accordance with established requirements and fully conforms with the governing upper-tier requirements.

The guide sheet referred to in this instruction pertains to a guide or checklist for each technical or programmatic document. It is used to facilitate and standardize the review process and provide and document review acceptance criteria.

a. **Definitions**

- (1) **Mandatory Comment** - A comment that identifies a significant problem regarding technical content, concept, practice, implementation, or responsibilities that render a document unacceptable or out of compliance with established requirements. All mandatory comments must be resolved with the evaluator and the resolution documented.
- (2) **Nonmandatory Comment** - A comment that is a suggestion regarding the organization or content of the document or that provides helpful additions or deletions, typographical corrections, punctuation, etc., but does not constitute a significant problem or weakness. Nonmandatory comments shall be dispositioned and may be incorporated at the discretion of the originator.

5. PROCEDURE:

a. Preparation for Reviews of Program Descriptions and Procedures

<u>Performer</u>	<u>Action</u>
Quality Assurance Specialist (QAS)	<ol style="list-style-type: none"> (1) Receives a request for assistance from a DOE-HLW Program as needed to perform reviews. (2) Locates and ensures receipt of the descriptions and procedures from the Operations Offices and logs the descriptions and procedures in the Quality Assurance descriptions and Procedures Review Log (Attachment B to SPP 4.11).

<u>Performer</u>	<u>Action</u>
QAS	<p><u>Note:</u> The program descriptions and procedures may be identified individually, by tier level, or some other grouping.</p> <p>(3) Secures approval of the list and obtains program execution guidance, if necessary, to compile all descriptions and procedures for review.</p> <p>(4) Identifies and provides to the HLW Program a list of quality assurance program descriptions and procedures requiring routine review.</p> <p>(5) Establishes a review file for each description or procedure to be reviewed.</p> <p>(6) Identifies additional documents for selected review based on the document's importance to quality, extent of revision, and content.</p> <p>(7) Coordinates with the HLW Program Manager and Division Managers, if appropriate, the assignment of the program descriptions or procedures to receive review.</p> <p>(8) Assigns the description or procedure to the appropriate reviewer for review.</p>

b. Performance of Quality Assurance Description and Procedure Reviews

<u>Performer</u>	<u>Action</u>
Evaluator	<p>(1) Identifies quality assurance requirements applicable to the description or procedure to be reviewed.</p>

<u>Performer</u>	<u>Action</u>
Evaluator	<p>(2) Prepares a review guide sheet or obtains a previously prepared standard guide sheet that can be used for the review</p> <p>(3) Reviews the assigned description or procedure for content, completeness, and incorporation of applicable quality assurance requirements and controls in accordance with the established guide sheet.</p> <p><u>Note:</u> The evaluator should not be restricted by the content of the guide sheet but should expand it to encompass additional areas as necessary.</p> <p>(4) Evaluates the results of the review and formulates conclusions as to the need for corrective action or improvements, including an assessment of the description or procedure's potential for success if properly implemented or executed.</p> <p><u>Note:</u> If no deviations are identified during the review, the processing of the description or procedure proceeds in accordance with Section 5.d. If deviations are identified, proceed with Section 5.c.</p>

c. Disposition of Deviations

<u>Performer</u>	<u>Action</u>
Evaluator	<p>(1) Contacts the QAS to ascertain if the possible deviation has been previously identified and disposition is still pending.</p>

<u>Performer</u>	<u>Action</u>
Evaluator	<ul style="list-style-type: none">(2) Proceeds with step 5.d.(1) for deviations previously documented, makes a note for inclusion into the report.(3) Proceeds with Section 5.c.(4) for deviations not previously documented.(4) Initiates a deviation report in accordance with SPP 5.01.

d. Processing Review Results

<u>Performer</u>	<u>Action</u>
Evaluator	<ul style="list-style-type: none">(1) Documents the review results on a Review Comment Record form, see SPP 4.11. Optional actions are as follows:<ul style="list-style-type: none">(a) Acceptance with no comment(s).(b) Acceptance with non-mandatory comment(s).<p>Note: Non-mandatory comments must be either listed or identified on the review report form.</p><ul style="list-style-type: none">(c) Non-acceptance with mandatory comment(s).<p>Note: Each mandatory comment must be: 1) uniquely identified, 2) listed or attached to the review report form, and 3) coordinated with the QAS.</p><ul style="list-style-type: none">(d) Non-acceptance with deviation(s).<p>Note: Deviations identified shall be tracked in accordance with SPP 5.01.</p>(2) Attaches review notes, review guide sheet and pertinent data to the report and submits it to the QAS.

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<u>Performer</u>	<u>Action</u>
QAS	(3) Consolidates review comments, prepares correspondence transmitting the results of the reviews, as appropriate, to the Operations Office responsible for the preparation of the description or procedure. (4) Files the report, review notes, and other pertinent data in the review file. (5) Updates the Quality Assurance Descriptions and Procedures Review Log to indicate review completion.

e. Quality Records

<u>Performer</u>	<u>Action</u>
QAS	(1) Prepares the review file as a quality record in accordance with SPP 7.01.

6. ATTACHMENTS:

None

REVIEW OF WASTE ACCEPTANCE PROCESS TECHNICAL DOCUMENTS

1. PURPOSE:

To establish objectives and provide instructions for review and evaluation of selected Operations Office and contractor technical documents for compliance to applicable quality and quality assurance requirements.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 3.04, Documentation of Surveillance and Review Personnel Qualifications
- b. SPP 4.01, Planning and Scheduling of Evaluation Activities
- c. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records
- d. ~~DOE/RW-0214, Quality Assurance Requirements for the Civilian Radioactive Waste Management Program~~ SPP 02

4. GENERAL:

The DOE-HLW Program, as a part of its evaluation practice, performs reviews of the Operations Office and its contractor's (participating organization) technical and programmatic documents. These reviews are planned and scheduled in a general sense in accordance with SPP 4.01.

Technical reviews are in-depth, critical reviews, analyses, and evaluations 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. Technical documents will also be reviewed to determine if quality and quality assurance requirements are complete, correctly stated, inspectable, and controlled, if requirements and acceptance criteria are established, and if preparation, review and approval is in accordance with the established requirements.

Reviews of programmatic documents are performed to determine that quality related activities are identified, that organizational responsibilities are established and can be implemented, that organizational freedom is provided to identify and cause corrective action, and that preparation, review, and approval is in accordance with established requirements.

A review guide sheet (Attachment A) is prepared for each technical or programmatic document and is used to facilitate and standardize the review process and to provide and document review acceptance criteria.

a. Definitions

- (1) **Mandatory Comment** - A comment that identifies a significant problem regarding technical content, concept, practice, implementation, or responsibilities that render a document unacceptable or out of compliance with established requirements. All mandatory comments must be resolved and the resolution documented.
- (2) **Nonmandatory Comment** - A comment that is a suggestion regarding the organization or content of the document or that provides helpful additions or deletions, typographical corrections, punctuation, etc., but does not constitute a significant problem or weakness. Nonmandatory comments shall be dispositioned and may be incorporated at the discretion of the originator.
- (3) **Programmatic Documents** - Those documents which define and describe the quality related aspects and also identify the requirements for quality related work. These documents include the implementing plans, procedures, and instructions, and other supporting documentation which describe the methods for performing each quality related activity, assign authorities and responsibilities for doing so, and provide a means for measuring performance.
- (4) **Technical documents** - Those engineering, design, construction, procurement, and operations documents which define and specify the attributes, parameters, or characteristics that are to be achieved for each item or service. These documents include drawings, specifications, plans, instructions, and other such documents which collectively contribute to an item or service's ability to satisfy the requirements of its intended purpose.

5. PROCEDURE:

a. Preparation for Reviews

<u>Performer</u>	<u>Action</u>
Quality Assurance Specialist (QAS)	<p>(1) Identifies and lists the documents for which reviews are either required or recommended.</p> <p><u>Note:</u> The identification may be a specific technical document, the documents on a specific subject or item or some other grouping.</p> <p>(2) Locates and ensures receipt of the documents after approval of the listing from the participating organizations and logs the documents on the Review Log (Attachment B).</p> <p>(3) Establishes a document review file for each document to be reviewed.</p> <p>(4) Assigns the document for review and assures that selected reviewers are qualified in accordance with SPP 3.04.</p>

b. Performance of Reviews

<u>Performer</u>	<u>Action</u>
Reviewer	<p>(1) Identifies requirements applicable to the document to be reviewed.</p> <p>(2) Prepares a review guide sheet which incorporates applicable requirements including those from DOE/RW-0214, or obtains a previously prepared standard guide sheet that can be used for the review.</p>

<u>Performer</u>	<u>Action</u>
Reviewer	<p>(3) Reviews the assigned document for content, completeness, and incorporation of applicable requirements and controls in accordance with the established DOE/RW-0214 compatible guide sheet.</p> <p><u>Note:</u> The reviewer should not be restricted by the content of the guide sheet but should expand it to encompass additional areas as necessary.</p> <p>(4) Evaluates the results of the review and formulates conclusions as to the need for corrective action or improvements including an assessment of the document's potential for success if properly implemented or executed.</p>

c. Processing Review Results

<u>Performer</u>	<u>Action</u>
Reviewer	<p>(1) Documents the review results on a Review Comment Record (Attachment C) by categorizing the review results as follows:</p> <p>(a) No comments.</p> <p>(b) Nonmandatory comment(s).</p> <p><u>Note:</u> Non-mandatory comments must be either listed or identified on the Review Comment Record.</p> <p>(c) Mandatory comment(s).</p> <p><u>Note:</u> Each mandatory comment must be 1) uniquely identified, 2) listed or attached to the Review Comment Record, and 3) coordinated with the Document Preparer.</p>

<u>Performer</u>	<u>Action</u>
Reviewer	(2) Attaches review notes and pertinent data to the Document Review Form and forwards to the document preparer for resolution.

Note: Based upon the comments submitted by the reviewers, the document shall be dispositioned as follows:

- Document Accepted - no review comments.
- Document Accepted - minor review comments noted.
- Document unacceptable - mandatory review comments noted.
- The disposition shall be stated in the transmittal letter.

QAS	(3) Files the Review Comment Record, review notes, and other pertinent data in the document review file.
	(4) Updates the Review Log to indicate review completion.

d. Quality Records

<u>Performer</u>	<u>Action</u>
QAS	(1) Prepares the document review file as a quality record in accordance with SPP 7.01, Preparation, Transfer and Receipt of Quality Records.

6. ATTACHMENTS:

- a. Attachment A - Review Guide Sheet for Technical and Programmatic Documents (Example)
- b. Attachment B - Review Log (Example)
- c. Attachment C - Review Comment Record (RCR) (Example)

Attachment A (Cont'd)

Review Guidesheet for Technical and Programmatic Documents (Back Side)

Reviews of technical documents should be planned and executed to determine that:

- a. Quality and quality assurance requirements are complete, correctly stated, and applicable to the activity being reviewed.
- b. Sequential and procedural requirements and acceptance criteria are established to adequately control the performance of the activity.
- c. Preparation, review, and approval is in accordance with established requirements and fully conforms with the governing upper-tier requirements.

Attachment B

Review Log (Example)

REVIEW LOG								
LOG FOR _____					PAGE _____			
Item No.	Document No. & Title	Rev. & Addendum	Date Rec	Date Req	Reviewer	Guide Sheet No.	Comments	Date Comp.
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

(1) Item No. - Sequential number with prefix as follows: D-Design; P-Procurement; PE-Peer; Q-Quality Assurance; R-Readiness; T-Technical
 (2) Document No. & Title - Number and title of document to be reviewed
 (3) Rev. & Addendum - Revision and addendum of (2)
 (4) Date Rec. - Date document received for review
 (5) Date Req. - Date document review is to be completed (assigned by Supervisor, OPS)

(6) Reviewer - Individual within that section assigned to perform the review
 (7) Guide Sheet No. - Identification of guide sheet if a standard guide sheet is used
 (8) Comments - Pertinent information from the reviewer; attach notes if necessary
 (9) Date Comp. - Date the document review completed

Attachment C

Review Comment Record (RCR) (Example)
(Front Side)

REVIEW COMMENT RECORD (RCR)						1 Date	2 Review No.		
						3 Project No.	4 Page 1 of		
5 Document Number(s) / Title(s)		6 Program/Project/Building Number		7 Reviewer		8 Organization/Group		9 Location/Phone	
17 Comment Submittal Approval DWTM-HEW-PM		10 Agreement with indicated comment disposition(s) _____ Reviewer _____ Date _____ Document Preparer			11 CLOSED _____ Reviewer _____ Date _____ Document Preparer				
12 Item	13 Comment(s) Discrepancy(s) (Provide technical justification for the comment and detailed recommendation of the action required to correct/resolve the discrepancy/problem indicated)	14 No Comments	14 Non Mandatory Comments	14 Mandatory Comments	15 Disposition (provide justification if not accepted)			16 Status	

Attachment C (Cont'd)

Review Comment Record (RCR) (Example)
(Back Side)

REVIEW COMMENT RECORD (RCR)		BLOCK NO.	RESPONSIBILITY	INSTRUCTIONS
<p>The review comment record (RCR) is a multipurpose review form to be utilized to accumulate review comments, receive recommendations, and document subsequent dispositions associated with the process of review. Unique form preparation instructions will be defined by governing procedures within individual programmatic areas. General instructions are provided herein to ensure uniform usage and establish basic requirements for RCR initiation and control.</p>				
RCR FORM PREPARATION				
BLOCK NO.	RESPONSIBILITY			INSTRUCTIONS
1	Reviewer	11	Reviewer and Document Preparer	CLOSED date - When all comments have been dispositioned to the satisfaction of the reviewer and verified by the reviewer as incorporated, or otherwise received, the reviewer and Document Preparer shall sign and date this block.
2	Reviewer	12	Reviewer	Yes - Enter the number of each comment being listed.
3	Reviewer	13	Reviewer	Comment(s) - A detailed explanation of the discrepancy or item requiring attention. Provide an exact location, zone, view, page, paragraph number, including technical justification for the comment, e.g., applicable procedure(s), regulation(s), code(s), and/or specification.
4	Reviewer	14	Reviewer	Recommendation - A detailed recommendation by the reviewer of the action required to correct/resolve the discrepancy/problem indicated.
5	Reviewer			No Comment - Mark if no comments.
6	Reviewer			Nonmandatory Comment - Mark if comment is not significant and disposition acceptance not required.
7	Reviewer			Mandatory Comment - Mark if comment and disposition acceptance is required.
8	Reviewer	15	Document Preparer	Disposition - Upon completion of discussion with the reviewer, the Document Preparer finalizes the disposition of each comment indicating "accept" or "reject." Should a comment be rejected, a written justification shall be provided to the reviewer. After the reviewer has verified that the original agreed upon disposition of comments (block No. 10) have been incorporated or a satisfactory justification provided for rejection, the reviewer and the Document Preparer shall sign this block and enter a "closed date."
9	Reviewer	16	Document Preparer	Status - The Document Preparer shall use this column to indicate the status of each comment (open, closed, etc.).
10	Reviewer and Document Preparer	17	DWTM-HLN-PM	Approval - Ensure credible representation of the group.

Attachment C (Cont'd)

Review Comment Record Continuation Sheet

Reviewer	REVIEW COMMENT RECORD (RCR)			Review No.	Page ___ of ___
Item	Comments(s)/Discrepancy(s) (Provide technical justification for the comment and detailed recommendation of the action required to correct/resolve the discrepancy/problem indicated.)	Non Mandatory Comment	Mandatory Comment	15 Disposition (provide justification if NOT accepted)	

REVIEW OF PROGRAM EXECUTION GUIDANCE DOCUMENTS

1. PURPOSE:

To define the responsibilities and actions required to review HLW Program Execution Guidance documents for adequacy and to document the review findings.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. DOE Order 5820.2A, Radioactive Waste Management
- b. DOE Order 5700.6B, Quality Assurance
- c. DOE Order 5000.3, Unusual Occurrence Reporting System
- d. ANSI/ASME NQA-1, 1986 Quality Assurance Program Requirements for Nuclear Facilities
- e. DOE/RW-0214, Quality Assurance Requirements for the Office of Civilian Radioactive Waste Management Program
- f. SPP 5.01, Deviation Reporting and Disposition
- g. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records

4. GENERAL:

The Program Senior Official for HLW programs, projects and activities specifies and passes down applicable quality assurance requirements for implementation.

DOE Order 5820.2A establishes that requirements of ANSI/ASME NQA-1 are applicable to all Radioactive Waste Management activities. It also provides supplemental requirements and directs that each participant in HLW programs, projects and activities review these requirements and

incorporate them into their Quality Assurance programs and into the applicable defining and implementing documentation. Reference 3.e. is specifically required for High-Level Waste Management Programs, which mandates ANSI/ASME NQA-1 and additional requirements.

Quality assurance program activities that are to be implemented on defense high-level waste processing are initially specified in HLW program execution guidance documents to the Operations Offices. The position of the HLW program execution guidance documents within the hierarchy of quality assurance requirements is illustrated in Attachment A.

The quality assurance requirements may be specified, along with other technical direction or funding authorizations, in program direction letters or by other means. Quality assurance requirements may be specified directly in contract scope of work statements; or the appropriate documents may be referenced as applicable.

5. PROCEDURE:

a. Preparation for Review of Program Execution Guidance

<u>Performer</u>	<u>Action</u>
Requestor	(1) Requests review of program execution guidance document.
Quality Assurance Specialist (QAS)	(2) Obtains current copies of existing program execution guidance documents.
	(3) Establishes a review file for the identification and control of each document to be reviewed.
	(4) Coordinates the assignment of the appropriate document reviewer(s).
	(5) Enters document data onto a Review Log (see Attachment B).
	(6) Forwards the document(s) to be reviewed to the appropriate evaluator for review.

b. Performance of Program Execution Guidance Review

<u>Performer</u>	<u>Action</u>
Evaluator	<ul style="list-style-type: none"> (1) Identifies quality assurance requirements applicable to the document to be reviewed. (2) Prepares a review guide sheet (Attachment C) or obtains a previously prepared standard guide sheet that can be used for the review. (3) Reviews the assigned document for content, completeness, and incorporation of applicable quality assurance requirements and controls in accordance with the established guide sheet. <p><u>Note:</u> The evaluator should not be restricted by the content of the guide sheet but should expand it to encompass additional areas as necessary. Additions or deviations are to be documented along with the results obtained.</p> <ul style="list-style-type: none"> (4) Evaluates the results of the review and formulates conclusions as to the need for correction or improvement in the HLW program execution guidance document, including an assessment of the document's potential for success if properly implemented or executed.

c. Processing Review Results

<u>Performer</u>	<u>Action</u>
Evaluator	<ul style="list-style-type: none"> (1) Documents the "results of review" on a review report form (see Attachment D) as: <ul style="list-style-type: none"> (a) Recommend acceptance with no comments

<u>Performer</u>	<u>Action</u>
Evaluator	(b) Recommend acceptance with comment(s) Note: Comments must be either listed or identified on the review report form. (c) Recommend non-acceptance Note: Each comment must be; 1) uniquely identified, 2) and listed or attached to the review report form, and 3) coordinated with the QAS. (d) Recommend non-acceptance with inadequacy
QAS	(2) Attaches review notes and pertinent data to the report and submits it to the QAS. (3) Forwards results of the review to the Requestor. (4) Follows up and notes when corrections are made for identified problems. (5) Files the report, review notes, and other pertinent data in the review file. (6) Updates the Review Log (Attachment B) to indicate review completion.

d. Quality Records

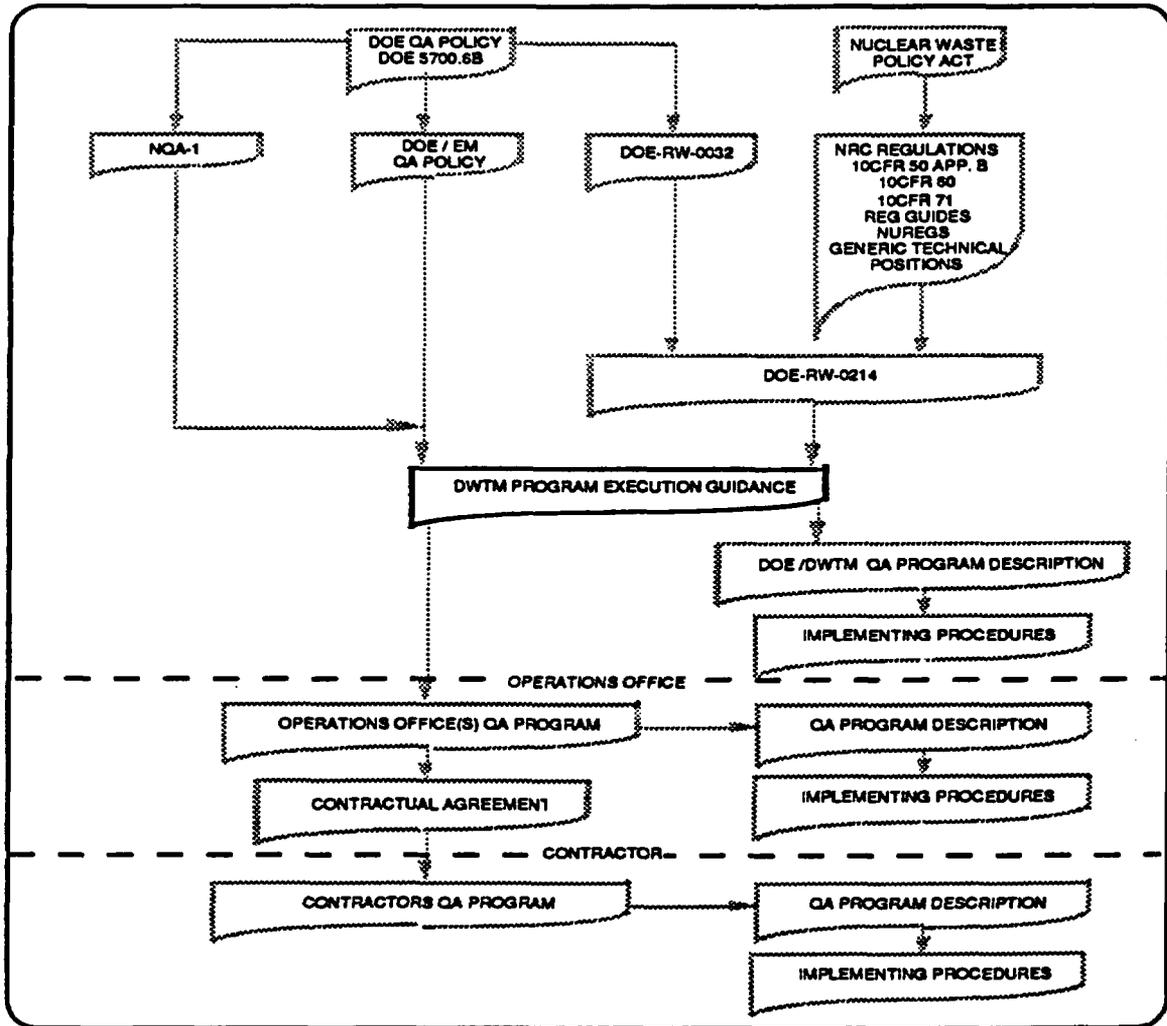
<u>Performer</u>	<u>Action</u>
QAS	(1) Prepares the review file as a quality record in accordance with SPP 7.01.

6. ATTACHMENTS:

- a. Attachment A - Quality Assurance Hierarchy for HLW Program**
- b. Attachment B - Review Log (Example)**
- c. Attachment C - Review Guide Sheet for Program Execution Guidance**
- d. Attachment D - Review Report (Example)**

Attachment A

Quality Assurance Hierarchy for HLW Program



Attachment B
Review Log (Example)

REVIEW LOG								
LOG FOR _____					PAGE _____			
Item No.	Document No. & Title	Rev. & Addendum	Date Rec	Date Req	Evaluator	Guide Sheet No	Comments	Date Comp.
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

(1) Item No. - Sequential number with prefixes as follows: D-Design; P-Procurement; PE-Peer; Q-Quality Assurance; R-Readiness; T-Technical
 (2) Document No. & Title - Number and title of document to be reviewed
 (3) Rev. & Addendum - Revision and addendum of (2)
 (4) Date Rec. - Date document received for review
 (5) Date Req. - Date document review is to be completed (assigned by Supervisor, OPS)

(6) Evaluator - Individual within that section assigned to perform the review
 (7) Guide Sheet No. - Identification of guide sheet if a standard guide sheet is used
 (8) Comments - Pertinent information from the reviewer, attach notes if necessary
 (9) Date Comp. - Date the document review completed

STANDARD PRACTICE PROCEDURE

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SPP 4.13
Page 1 of 4
Rev. 0
Effective
Date 02/02/90

PARTICIPATION IN EVALUATION ACTIVITIES LED BY EXTERNAL ORGANIZATIONS

1. PURPOSE:

To establish objectives and define instructions and actions for participating in evaluation activities led by external organizations and using those evaluations in lieu of internal duplicate evaluations.

) bad premise

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 4.01, Planning and Scheduling of Evaluation Activities
- b. SPP 7.01, Preparation, Transfer and Receipt of Quality Records
- c. SPP 8.01, Coordination of Reviews and Evaluations by Outside Organizations

4. GENERAL:

To ensure efficient use of DOE resources, the HLW program participates in selected external organizations evaluations involving activities within the scope of the HLW Quality Assurance Program in lieu of performing their own duplicate evaluations. Participation in evaluation activities led by such external organizations as the Operations Office and the Operating Contractor is facilitated through SPP 8.01 and planned through SPP 4.01.

5. PROCEDURE:

a. Initiating Participation

<u>Performer</u>	<u>Action</u>
Quality Assurance Specialist (QAS)	(1) Identifies participation in external organizations evaluations from the evaluation plan and schedule based on activity scope and scheduled evaluations.

<u>Performer</u>	<u>Action</u>
Quality Assurance Specialist (QAS)	<ul style="list-style-type: none"> (2) Confirms schedule date with the organization leading the evaluation activity. (3) Contacts the evaluation candidate. (4) Obtains cognizant management concurrence on participation in external evaluation activities and the selection of the participant(s). (5) Completes Part 1 of the External Evaluation Participation Record (see Attachment A), and submits for approval.

b. Participation in External Evaluation Activities

<u>Performer</u>	<u>Action</u>
Participant(s)	<ul style="list-style-type: none"> (1) Participates in the evaluation activity in accordance with the external organizations procedures. (2) Documents participation using Part 2 of the External Evaluation Participation Record and referencing any deviation report(s) initiated. (3) Signs and dates Part 2 of the External Evaluation Participation Record, ensuring that each deviation is identified.

c. Evaluation of Performance

<u>Performer</u>	<u>Action</u>
Participant(s)	<ul style="list-style-type: none"> (1) Evaluates the performance of the External Evaluation. (2) Documents the evaluation in an Audit Summary Report per SPP 4.03.

<u>Performer</u>	<u>Action</u>
Participant(s)	(3) Any deviations identified will be documented and tracked according to SPP 5.01.

d. Records

<u>Performer</u>	<u>Action</u>
QAS	(1) Prepares the External Evaluation Participation Record as a quality record in accordance with SPP 7.01.

6. ATTACHMENTS:

- a. Attachment A - External Evaluation Participation Record (Example)

Attachment A

External Evaluation Participation Record (Example)

EXTERNAL EVALUATION PARTICIPATION RECORD	
Page 1 of	
PART 1 - Identification of Participation	
Evaluation Type _____	
Evaluation Title _____	
External Organization Evaluation Number _____	
Dates of Evaluation _____ Procedures Used _____	
DWTM Participants _____	
Other Team Members _____	
Used in lieu of Internal Duplicate Evaluation _____	
Comments _____	
QAS _____	Date _____
<small>Signature</small>	
PM _____	Date _____
<small>Signature</small>	
PART 2 - Evaluation Results	
Evaluation Report Title _____	
Report Number _____ Report Date _____	
Deviation(s) _____	
<small>List each deviation</small>	

Corrective Actions _____	

Comments _____	

Participant(s) _____	
<small>Signature</small>	Date _____
<small>Signature</small>	Date _____

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DEVIATION REPORTING AND DISPOSITION

1. PURPOSE:

To provide instructions for reporting, disposition, and closure of deviations and the initiation, processing, and closure of corrective actions for those deviations considered to be significant conditions adverse to quality (CAQ).

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 5.02, Management Action Request
- b. SPP 5.03, Control of Unsatisfactory Conditions (Stop Work Orders)
- c. SPP 4.02, Administration of Quality Assurance Audits
- d. SPP 4.03, Conduct of Quality Assurance Audits
- e. DOE Order 5000.3, Unusual Occurrence Reporting System
- f. SPP 5.05, Review of Unusual Occurrence
- g. SPP 7.01, Preparation, Transfer and Receipt of Quality Records

4. GENERAL:

The Deviation and Corrective Action Report consists of two sections. The first section is the Deviation Report section, and is where the deviation is identified and detailed. Also, in this section the actions to correct the immediate problem are requested, responses are evaluated and accepted or rejected. The second section is the Corrective Action Report section, and is used to formally request and document corrective action for those deviations classified as being significant conditions adverse to quality and/or those deviations discovered during quality assurance audits.

In the event an organization responsible for providing corrective action for a deviation is nonresponsive or untimely, the implementing organization will evaluate the deviation to determine the need for escalated management attention and will proceed accordingly (see SPP 5.02 and SPP 5.03).

a. Definitions

- (1) Condition Adverse to 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, operability, or reliability.
- (2) Corrective Action - Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition. For the purposes of this instruction, corrective action is associated with measures taken to rectify significant conditions adverse to quality or to rectify deviations found during audit activities.
- (3) Deviation - A departure from specified requirements.
- (4) Disposition - The action taken to correct the immediate condition adverse to quality, ignoring the underlying, or root, cause.
- (5) Nonconformance - A deficiency in characteristic, documentation, or instruction that renders the quality of an item or activity unacceptable or indeterminate.
- (6) 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.
- (7) Rework - The process by which an item is made to conform to original requirements by completion or correction.
- (8) Use-as-is - A disposition permitted for a nonconforming item when it can be established that the item is satisfactory for its intended use.

5. PROCEDURE:

a. Identification and Documentation of Deviations

<u>Performer</u>	<u>Action</u>
Evaluator	<p>(1) Promptly identifies any deviations discovered whether they were found during a review, a surveillance action, an audit, or during any other kind of evaluation activity.</p> <p>(2) Discusses the deviation with the organization responsible for the item or activity in which the deviation exists, confirms its existence and ensures that the condition has not been documented.</p> <p>(3) Documents the deviation on the Deviation Report Section (Sections 1 and 2 on page 1) of the Deviation and Corrective Action Report (DCAR) (Attachment A), if not already documented.</p>

Note: Instructions for completing DCARs are also included in Attachment A.

(4) Initiates a nonconforming item tag for deviations in hardware (see Attachment B).

Note: Instructions for completing nonconforming item tags are also included in Attachment B.

If the hardware item is the responsibility of another organization, the tagging may be done under the other organization's tagging program. Should this be done, then the tag removal must be contingent upon the Evaluator's acceptance of the resolution.

DCAR Administrator	(5) Establishes a working file for the DCAR.
--------------------	--

b. Evaluation of Deviations for Corrective Action Reporting (Significance)

<u>Performer</u>	<u>Action</u>
Evaluator	<p>(1) Evaluates the deviation against the criteria of Attachment C to determine if corrective action reporting is necessary.</p> <p><u>Note:</u> Deviations discovered during a quality assurance audit (see SPP 4.02 and SPP 4.03.) always require corrective action.</p> <p>(2) Documents if a corrective action report is required in Section 3 of the DCAR.</p> <p>(3) If a corrective action report is required, initiates the request on page 2 of the DCAR (Section 7).</p> <p>(4) Ensures the responsible organization is notified of the adverse condition requiring control in order that they may take appropriate actions, such as work stoppage or immediate control of further processing or performance.</p> <p>(5) If appropriate controls are not established, obtains guidance from the Manager on the course of action to take.</p>

c. Deviation and Corrective Action Report (DCAR)

<u>Performer</u>	<u>Action</u>
Evaluator	<p>(1) Prepares a memorandum or letter as appropriate (see Attachment D) to transmit the DCAR, request disposition, and request corrective action if corrective action is indicated in Section 3.</p>

<u>Performer</u>	<u>Action</u>
Evaluator	<p>Note: The responsible organization is to complete Section 4 (and if corrective action is required, Section 8) of the DCAR form.</p>
Manager	<p>(2) Concurs that corrective action is required and with the statement of the request for corrective action by signing in Section 7 of the DCAR form.</p> <p>(3) Issues the DCAR to the organization responsible for the item or activity in which the deviation exists.</p> <p>(4) Forwards a copy of the DCAR and transmittal document to the DCAR Administrator.</p>
DCAR Administrator	<p>(5) Enters items 1 through 8 on a DCAR Log (Attachment E) for tracking purposes.</p> <p>(6) Files the DCAR copy and transmittal document in the DCAR working file.</p> <p>(7) Keeps the Evaluator informed as to status.</p>
Evaluator	<p>(8) When nonconforming items are involved, verifies items containing deviations are segregated (if practical) or other actions are taken to preclude inadvertent installation or use and attaches a nonconforming item tag, if possible.</p> <p>(9) Monitors the requested response date(s) and initiates actions to expedite responses when necessary.</p>

d. Receipt of Proposed Dispositions/Corrective Action

<u>Preparer</u>	<u>Action</u>
Evaluator	(1) Receives the DCAR with proposed disposition and corrective action (if requested) from the organization responsible for disposition (and corrective action). <u>Note:</u> Receipt of proposed dispositions and corrective action may occur simultaneously or they may occur separately.
DCAR Administrator	(2) Enters dates disposition and corrective action notification are received in item 9 and 10 respectively of DCAR Log (Attachment E).

e. Evaluation of Proposed Dispositions

<u>Performer</u>	<u>Action</u>
Evaluator	(1) Evaluates the proposed disposition to determine its adequacy for solving the specific problem identified in the deviation report portion of the DCAR and records acceptance or rejection in Section 5 of the DCAR. (2) For those deviations determined to be reportable as unusual occurrences by the responsible organization, ensures that the appropriate organization is notified so that an unusual occurrence report can be initiated in accordance with DOE Order 5000.3 (see SPP 5.05). (3) Upon receipt of the proposed disposition action, notifies the responsible organization of acceptance or rejection. If necessary, discusses with the organization the preparation of a revised response.

<u>Performer</u>	<u>Action</u>
Evaluator	<p>Note: This may be done with the evaluation of corrective action.</p> <p>(4) If resolution of a rejected disposition action cannot be obtained, elevates the problem to the next higher level of management (per SPP 5.02).</p> <p>(5) Forwards a copy of the DCAR that was evaluated to the DCAR Administrator.</p>
DCAR Administrator	<p>(6) Enters date disposition accepted in item 11 of DCAR Log (Attachment E).</p> <p>(7) Places a copy in the DCAR working file.</p>

f. Evaluation of Proposed Corrective Action

<u>Performer</u>	<u>Action</u>
Evaluator	<p>(1) When corrective action was requested, evaluates proposed corrective action which normally includes an evaluation of the following (see Section 8 of the DCAR):</p> <ul style="list-style-type: none"> (a) Reason for the deviation (root cause). (b) Action taken/proposed to investigate and correct any similar work in which the same deviation may exist and was not previously identified. (c) Action taken to prevent recurrence. (d) Date(s) action will be complete. <p>(2) Documents acceptance or rejection of the proposed corrective action response in Section 9 of the DCAR.</p>

<u>Performer</u>	<u>Action</u>
Evaluator	(3) Obtains Manager approval of the evaluation of proposed corrective action in Section 9 of the DCAR. (4) Forwards a copy of the DCAR to the organization responsible for corrective action with a copy going to the DCAR Administrator.
DCAR Administrator	(5) Enters date the correction action was evaluated in item 12 of DCAR Log (Attachment E). (6) Places a copy in the DCAR working file.
Evaluator	(7) When the proposed corrective action is unacceptable issues a revision to the DCAR (Corrective Action Report section only) and coordinates with the organization responsible for corrective action to obtain a revised response.
	<p><u>Note:</u> Revisions to DCARs should use the same DCAR number; revisions will be indicated by an "R1," "R2," etc. after the DCAR number. When a revised response is obtained, go back to the start of this section and proceed again. If resolution is not obtained, elevate the problem to the next higher level of management for resolution (according to SPP 5.02).</p>
	(8) Forwards two copies of the revised DCAR to the DCAR Administrator.
DCAR Administrator	(9) When a DCAR is revised opens a new entry in the DCAR log (Attachment E).
	<p><u>Note:</u> The original DCAR remains open and the original and all revisions thereto are closed simultaneously.</p>

<u>Performer</u>	<u>Action</u>
DCAR Administrator	(10) Places a copy of the revised DCAR in the working file.

g. Verification and Closure of Disposition Action

<u>Performer</u>	<u>Action</u>
Evaluator	<p>(1) During disposition monitors progress and when complete verifies that the actions taken to correct the deviation have been completed satisfactorily and as scheduled.</p> <p><u>Note:</u> When the proposed disposition or completed actions are unsatisfactory, the evaluator initiates correspondence to that effect through the Manager.</p> <p>(2) Ensures the removal of any nonconforming item tag(s) only after verifying satisfactory completion of all disposition actions.</p> <p>(3) Approves acceptance of verified disposition in Section 6 of the DCAR.</p> <p>(4) Forwards the closed out deviation report portion of the DCAR to the DCAR Administrator.</p>
DCAR Administrator	(5) Enters date disposition verified in item 13 of DCAR Log (Attachment E).
Evaluator	(6) Issues correspondence to inform involved parties of the closure of the deviation.

h. Verification and Closure of Corrective Action

<u>Performer</u>	<u>Action</u>
Evaluator	(1) If corrective action is required and when proposed corrective action has been accepted, monitors the corrective action to ensure completion and acceptance are as scheduled.

<u>Performer</u>	<u>Action</u>
Evaluator	(2) Verifies the action taken to prevent recurrence is satisfactorily complete. (3) Verifies the action taken to investigate and correct any similar work is satisfactorily complete. (4) Documents the verification activities in Section 10 of the DCAR by signature and date and forwards the DCAR to the Manager for concurrence and closure.
Manager	(5) Formally closes the Corrective Action Report section of the DCAR by concurring with the verification of corrective action in Section 11 of the DCAR and forwards to the DCAR Administrator.
Evaluator	(6) When corrective action taken is unacceptable issues a revision to the DCAR and coordinates with the organization responsible for corrective action to obtain further action (see Section 5.f.(7) for instructions on revisions to DCARs). Note: The original DCAR remains open and the original and all revisions thereto are closed simultaneously. (7) When further action has been agreed upon, goes back to the start of this section and proceeds again. If resolution is not obtained, elevates the problem to the next higher level of management for resolution (per SPP 5.02).
DCAR Administrator	(8) Enters date corrective action verified in item 14 of DCAR Log (Attachment E).
Evaluator	(9) Issues correspondence to inform involved parties of the closure for the corrective action.

i. Records

<u>Performer</u>	<u>Action</u>
DCAR Administrator	(1) Updates the DCAR Log to reflect the closure of the deviation report/ corrective action report portions of the DCAR as applicable and retains for working and historical purposes.
	(2) Prepares DCAR working files as quality records in accordance with SPP 7.01.

6. ATTACHMENTS:

- a. **Attachment A - Deviation and Corrective Action Report (DCAR) (Example)**
- b. **Attachment B - Nonconforming Item Tag (Example)**
- c. **Attachment C - Criteria to Determine if Corrective Action Reporting is Required**
- d. **Attachment D - DCAR Transmittal Document Content (Example)**
- e. **Attachment E - DCAR Log (Example)**

Attachment A (Con't)

Deviation and Corrective Action Report (DCAR) Page 1 Back

Deviation and Corrective Action Report (DCAR)

Instructions - Deviation Report Portion

The purpose of the deviation report side of the DCAR is to formally request and document dispositioning actions(s) from the responsible organization.

DCAR NUMBER - The unique number assigned to the DCAR. The Evaluator obtains this number from the DCAR Administrator. The DCAR number on the deviation report section shall be followed with a "-1" and the DCAR number on the corrective action report section shall be followed with "-2" for tracking purposes.

Section 1

Date of Discovery - The date the deviation was discovered.

Responsible Organization - The organization determined to be responsible for the item or activity in which a deviation is discovered. This is normally the participating organization on which the evaluation activity was performed.

Responsible Organizations Representative - Representative of the responsible organization who is responsible for disposition/corrective action (if applicable).

Activity - Activity to which the deviation/corrective action pertains.

Location - Primary location of the activity related to the deviation/corrective action.

Section 2

Requirements - Identifies the procedure, instruction, standard, or code which establishes the acceptance criteria for the activity or item being evaluated.

Deviation - Fully describe the deviation discovered as it relates to the requirements. Personnel opinions are not to be expressed.

Note: Deviations should be described in a way that will allow closure of the deviation with remedial action (action which will correct the immediate problem). Deviations in need of programmatic corrective action receive additional processing on the corrective action report portion of the DCAR.

Provide Disposition By Date - A formal request to the responsible organization to provide a date for the completion of actions to disposition the deviation.

Current Status - If material/hardware is involved in the deviation, provide a description of the status of that material/hardware.

Evaluator - Signature of the evaluator who discovered the deviation. Indicates the assigned evaluator has discussed the deviation with the responsible organization's representative. It does not necessarily reflect concurrence with the deviation by the participating organization's representative.

Section 3

Is a Corrective Action Report Required - The evaluator checks "Yes" if a Corrective Action Report is required per Attachment C of the procedure.

Section 4

Is the Deviation Reportable - The responsible organization evaluates for reportability in accordance with DOE Order 5000.3 for unusual occurrence reporting.

Note: If the "Yes" box is checked, the responsible organization proceeds with the reportability process in accordance with its internal procedure.

Disposition - Completed by the responsible organization as requested by the OAS including a scheduled completion date and signed and dated by the organization's representative. Check off the appropriate block; Accept-As-Is, Rework, Repair, or Reject. For Accept-As-Is/Repair, - complete the technical justification portion Section 4.

Section 5

Evaluation of Disposition - The evaluator originating the deviation report evaluates the disposition to ensure the actions or proposed actions will fix the immediate problem discovered. The appropriate block is checked and the evaluator signs and dates to authenticate. For those deviations involving nonconformances with the Waste Acceptance Specification or the repository license application, forwards an information copy of the DCAR to the appropriate DOE organization.

Section 6

Disposition Action Complete - The Evaluator signs and dates to verify disposition actions are complete.

Attachment A (Con't.)

Deviation and Corrective Action Report (DCAR) (Example) Page 2 Back

Deviation and Corrective Action Report (DCAR)

Instructions - Corrective Action Portion

The purpose of the corrective action report portion of the DCAR is to formally request and document corrective action for those deviations classified as being significant conditions adverse to quality and/or those discovered during quality assurance audits.

Section 7

Request for Corrective Action - A request for corrective action worded in terms of the root cause rather than the specific problem as described on the accompanying deviation report.

Concurrence - Signature of the person concurring that corrective action is required.

Section 8 - Completed by the Organization Responsible for Corrective Action

- A. Reason for Deviation - Section provided to outline the reason (root cause) of the significant deviation when requested in accordance with Section 7.
- B. Action Taken/Proposed to Investigate and Correct Any Similar Work - Section provided to outline action taken/proposed to correct work previous to or similar to the discovery of the significant deviation. This section is completed when requested in accordance with Section 7.
- C. Action Taken to Prevent Recurrence - Section provided to outline the specific action to be taken or completed to prevent this significant deviation or other significant deviations of this kind from recurring. This section is completed when requested in accordance with Section 7.
- D. Date(s) Action(s) will be Complete - Section provided for the date or dates action(s) are completed or scheduled to be completed.

Signature of Organization's Representative - Signature of the representative of the organization responsible for the proposed or implemented corrective action described in this section.

Section 9

Evaluation of Corrective Action Response - Documented results of the evaluator's appraisal to ensure the proposed action adequately addresses the significant deviation. This section also contains the signature of the evaluator performing the evaluation. If the Corrective Action Response is deemed not acceptable, complete the justification section.

Approval - Signature of the person approving the evaluation results.

Section 10

Corrective Action Verification - Documentation that actions outlined in Section 9 have been taken or completed as scheduled and are adequate and acceptable. This verification may be in the form of a review, observation, or other means. This section also contains the signature of the evaluator performing the verification.

Section 11

Closure of Corrective Action - Signature indicating concurrence with the corrective action verification and formally closing the corrective action report side of the DCAR.

Attachment B

Nonconforming Item Tag (Example)
(Front Side)

**NONCONFORMING ITEM
HOLD TAG**

DCAR No. _____

Tag No. ____ of _____

Item Description _____

Reason for Hold _____

Initiator _____

Signature _____

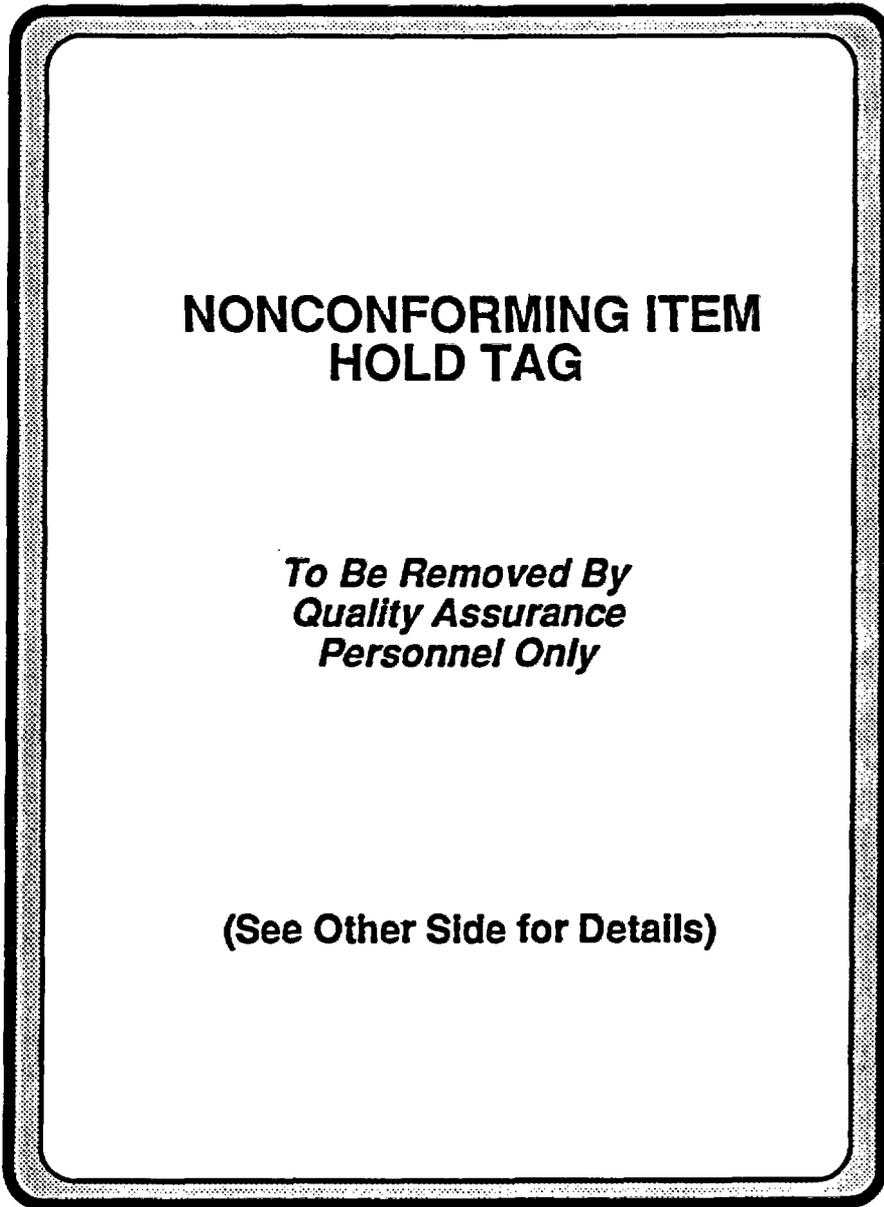
Telephone No. _____

Date _____

Attachment B (Con't)

Nonconforming Item Tag (Example)

(Back Side)



Attachment B (Con't)

Nonconforming Item Tag

Instructions for Use

- 1) Use black ink only.
- 2) Enter the DCAR number that identifies the deviation.
- 3) When multiple tags are required, number sequentially and enter total number. If only one tag enter 1 of 1.
- 4) Describe the item being held, i.e., the subsystem, the component, the part name.
- 5) Summarize the reason for the hold.
- 6) Print the name of the Initiator.
- 7) Signature of the Initiator.
- 8) Telephone number of Initiator.
- 9) Enter the date tagged.
- 10) Securely attach the tag to the nonconforming item in a visible location.
- 11) If the tagging of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be tagged.
- 12) When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of a nonconforming item.
- 13) Tag is not to be removed until after disposition of DCAR has been evaluated to be acceptable.

Attachment C

Criteria to Determine if Corrective Action Reporting is Required

Evaluators shall issue a Request For Corrective Action for all deviations as a result of audit findings and deviations involving significant or repetitive noncompliance with quality requirements based on surveillance and trend analysis efforts.

Determination will be based on:

- **Significance** - Deviations which have, or may have, serious effect on safety, or operability, or reliability.
- **Quantity/Frequency** - Repetitive deviations or similar deviations resulting from activities or conditions which are common to the deviations.
- **Ineffective Implementation of Dispositions** - Deviations which have not been properly or promptly dispositioned or resolved and which if uncorrected could result in other deviations or significant conditions adverse to quality.

The following are examples of significant conditions adverse to quality and shall be processed in accordance with this instruction:

- **Approved and released documents such as design documents, procurement documents, procedures, instructions, reports, and data found to contain significant errors or to be inadequate for their intended function.**
- **Failure to comply with quality assurance program requirements and procedures.**
- **In-process checks that indicate process or test limits may be exceeded.**
- **Quality violations related to handling, shipping, and storage of materials or items.**
- **Out-of-calibration standards or instruments used to verify process limits.**
- **Significant adverse trend analysis results.**

Attachment D

DCAR Transmittal Document Content (Example)

**SUBJECT: DEVIATION AND CORRECTIVE ACTION REPORT (DCAR)
TRANSMITTAL - DCAR REPORT NO(s). _____**

The purpose of this memorandum is to provide you with the attached DCAR(s) and request disposition action for the deviation(s) detailed on page 1 of the DCAR form. Corrective action is not (is) required. You do not need to (are requested) to complete page 2 of the DCAR form (defining the corrective action).

You are requested to provide your proposed or completed actions to disposition the deviation (and provide corrective action) within _____ days from the date of this memorandum. Please provide your response(s) in Section 4 (and in Section 9) of the DCAR form. You will find directions for filling out the forms on their reverse side. Include your expected completion date(s) for accomplishing the disposition (and corrective actions). In the event the accomplishment of disposition (and corrective action) will take more than 30 days from the date of this memorandum, please provide a justification.

Please return the original DCAR with Section 4 (and Section 9) completed to the DCAR Administrator. When disposition (and corrective actions) is complete, please notify me for verification.

Evaluator

XXX:XXX

Attachment(s)

cc: Attachment(s)

Deviation Report Working File

Attachment E
DCAR Log (Example)

DEVIATION AND CORRECTIVE ACTION REPORT LOG	
DCAR Number	(1)
Responsible Organization	(2)
Summary of Condition	(3)
Evaluator	(4)
Date Discovered	(5)
Tag Issued	(6)
CAR Required	(7)
Audit or Memo ID	(8)
Date Corrective Action Received	(10)
Date Disposition Accepted	(11)
Date Corrective Action Accepted	(12)
Date Disposition Verified	(13)
Date Corrective Action Verified	(14)
Date DCAR Closed	(15)

MANAGEMENT ACTION REQUEST

1. PURPOSE:

To provide instructions for bringing to the attention of higher management deviations or other problems identified during quality assuring activities. This includes the responsibilities and actions required to initiate, process, and follow-up on Management Action Requests (MARs).

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 5.01, Deviation Reporting and Disposition
- b. SPP 5.03, Control of Unsatisfactory Conditions (Stop Work Orders)
- b. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records

4. GENERAL:

Deviations identified in accordance with SPP 5.01 for which routine resolution actions have been ineffective in achieving corrective action will be escalated to higher levels of management. The escalation document is a memorandum or letter identified as a MAR. If adequate resolution is not achieved by the first MAR, additional MARs will be escalated to appropriate levels of management until resolution is achieved.

Internal MARs are escalated along the following levels:

Level 1 - When deviations and quality problems are not resolved in a timely and satisfactory manner, a MAR is sent to the manager within the organization who is directly responsible for the corrective action for the deviation.

Level 2 - When deviations and quality problems are not resolved by a Level 1 MAR, a second MAR is sent to the manager over the person directly responsible.

Level 3 - When deviations and quality problems cannot be resolved at Level 2, then a MAR is sent to the person within the organization who has the final decision authority.

External MARs are escalated along the following levels:

Level 1 - When deviations and quality problems are not resolved in a timely and satisfactory manner, a MAR is sent to the manager directly responsible for the corrective action for the deviation.

Level 2 - When deviations and quality problems are not resolved by a Level 1 MAR, a second MAR is sent to a person higher in the responsible organization.

Level 3 - When deviations and quality problems cannot be resolved at Level 2, then a new MAR is sent to the person who has the final decision authority.

a. Definitions

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

(2) Deviation - A departure from specified requirements.

(3) Management Action Request (MAR) - A written communication by which the issuing organization informs responsible management that efforts to secure a responsible and timely disposition of a deviation or resolution of a quality problem have been unsuccessful and therefore attention by higher level management is requested. The MAR requests immediate resolution of the deviation or quality problem, a management analysis of the circumstances that led or contributed to this unresolved condition, and actions to assure timely and responsive dispositions in the future.

(3.a) Internal MAR - A MAR escalating an unsatisfactory quality condition that exists within the organization using SPPs.

(3.b) External MAR - A MAR escalating an unsatisfactory quality condition in an organization being evaluated by an organization using SPPs.

5. PROCEDURE:

a. Initiating an Internal MAR

<u>Performer</u>	<u>Action</u>
Evaluator	(1) Initiates a MAR in the form of a memorandum with a content similar to Attachment A when a responsive and timely disposition of a deviation or resolution of a quality problem cannot be secured.
DCAR Administrator	(2) Assigns a unique number to the MAR which will tie the MAR to the related deviation report or quality problem and enters number on the MAR Log (Attachment B).
Evaluator	(3) Signs and issues the MAR. <u>Note:</u> 1) Attaches a copy of the deviation report and other pertinent correspondence to the MAR. 2) A MAR response is required within 15 calendar days of the issue date of the MAR.
DCAR Administrator	(4) Files a copy of the MAR in the deviation report working file (see SPP 5.01).

b. Following Up on Internal MARs

<u>Performer</u>	<u>Action</u>
Evaluator	(1) Monitors the MAR response due date using the MAR Log (or commitment control system) and follows up verbally or decides if escalation of the MAR if necessary.

<u>Performer</u>	<u>Action</u>
Evaluator	(2) Evaluates the MAR response as a part of deviation report closure per SPP 5.01. (3) If the response to the MAR is acceptable, notifies the manager who responded. (4) If escalation is needed, proceeds to the next escalation level listed in Section 4 and repeats steps 5.a.(1) through 5.a.(4). (5) If stop work is needed, refers to SPP 5.03.
DCAR Administrator	(6) Files a copy of the response in the deviation report working file. (7) Enters receipt of the response in the MAR Log.

c. Initiating an External MAR

<u>Performer</u>	<u>Action</u>
Evaluator	(1) When a responsive and timely disposition of a deviation or resolution of a quality problem cannot be secured from the organization responsible for corrective action to the deviation or quality problem, initiates a MAR in the form of a letter with a content similar to Attachment A.
DCAR Administrator	(2) Assigns a unique number to the MAR which will tie the MAR to the related deviation report and enters number on the MAR Log.
Manager	(3) Signs the MAR and sends to the organization responsible for the corrective action.
DCAR Administrator	(4) Updates the deviation status log (from SPP 5.01) with applicable MAR information.

<u>Performer</u>	<u>Action</u>
DCAR Administrator	(5) Files the MAR in the deviation report file (see SPP 5.01).

d. Following Up on External MARs

<u>Performer</u>	<u>Action</u>
Evaluator	(1) Monitors the MAR response due date using the MAR Log. (2) Evaluates the MAR response as part of deviation report closure per SPP 5.01. (3) If the response to the MAR is acceptable, notifies the manager who responded. (4) If no response is received within 15 days, obtains status information from the organization responsible.
Evaluator and Manager	(5) Evaluate the status information on late responses and decide if escalation of the MAR or stop work is needed.
Evaluator	(6) If escalation is needed proceeds to the next escalation level listed in Section 4 and repeats the actions listed in Sections 5.c.(1) through 5.c.(5).
	Note: The concurrence and approval process described in Section 5.c. will differ with the level of escalation, as noted in Section 4.
	(7) If stop work is needed, refers to SPP 5.03.
DCAR Administrator	(8) Files a copy of the response in the deviation report working file. (9) Enters receipt of the response in the MAR Log.

e. Closure

<u>Performer</u>	<u>Action</u>
DCAR Administrator	(1) Upon closure of the DCAR, records the closure date in the MAR Log.

f. Records

<u>Performer</u>	<u>Action</u>
DCAR Administrator	(1) Maintains a copy of each MAR in the deviation report working file which is prepared as a quality record in accordance with SPP 7.01.

6. ATTACHMENTS:

- a. Attachment A - Management Action Request (MAR) Content (Example)
- b. Attachment B - Management Action Request (MAR) Log (Example)

Attachment A

Management Action Request (MAR) Content (Example)

SUBJECT: MANAGEMENT ACTION REQUEST NO. _____

Reference: Deviation Report No. _____/Management
Action Request No. _____ [number(s)] of
previous transmittal(s) of the Management Action
Request

This is to inform you that a deviation (or a quality problem) has been identified in the performance of your organization and efforts to date have been unsuccessful in attaining a satisfactory disposition of the deviation (quality problem). (Describe previous attempts to resolve the deviation; e.g., untimeliness of response, inadequate response, inadequate corrective action; and include previous escalated management actions taken, as appropriate.)

You are requested to forward your plan of action to resolve this deviation (quality problem), the results of your management analysis of the circumstances that led or contributed to the exclamation of this deviation (quality problem), and actions to assure timely and responsive dispositions in the future within 15 days from the date of Management Action Request.

We appreciate your attention to the timely resolution of this deviation (quality problem). In the event you require our assistance or have any questions on this matter, please contact _____
at extension _____.

(As outlined in Section 4)

Attachment B

Management Action Request (MAR) Log (Example)

MANAGEMENT ACTION REQUEST (MAR) LOG							
Deviation Report No.	Associated MAR/ Escalated MAR ID No.	MAR Issue Date	MAR Responses	Date MAR Response Rec'd	To:	From:	Deviation Report Closure Date

STANDARD PRACTICE PROCEDURE

SPP 5.03
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Rev. 0
Effective
Date 02/02/90

CONTROL OF UNSATISFACTORY CONDITIONS (STOP WORK ORDERS)

1. PURPOSE:

To provide instructions for issuing and processing Urgent Action Directives (stop work orders) which notify responsible management of unsatisfactory work or unapproved practices; and if necessary, to stop unsatisfactory work or control further processing, delivery, installation, or operation of nonconforming items or services.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 5.01, Deviation Reporting and Disposition
- b. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records

4. GENERAL:

Persons having quality assurance responsibility have the authority to initiate actions to control or to stop an activity identified as an unsatisfactory condition. Conditions requiring such intervention are serious and discretion should be used.

Normal actions to identify unsatisfactory conditions include audits, surveillance, testing, and various kinds of reviews in conjunction with the deviation reporting system. This instruction covers additional actions to control unsatisfactory conditions which may include directives to:

- Stop the activity in question.
- Change the way the activity is being performed.
- Start an activity not previously initiated.

a. Definitions

- (1) **Unsatisfactory Condition** - A condition adverse to quality which, if allowed to continue, could affect the end use of an item, the safe operation of a facility, or the health and safety of personnel or the public.
- (2) **Evaluator** -The person who discovers a deviation during an evaluation activity; then documents, follows up, and closes out the deviation.

5. PROCEDURE:

a. Initiation of Control Action

<u>Performer</u>	<u>Action</u>
Evaluator	<ul style="list-style-type: none"> (1) After identifying an unsatisfactory condition, obtains documentation and information necessary to support evaluation of the condition. (2) Discusses the condition with the individual responsible for the activity to inform them and provides them an opportunity to correct the condition. (3) If resolution is obtained, documents the condition and corrective action on the appropriate evaluation report (e.g., audit report, surveillance report, etc.). (4) If resolution is not obtained, discusses the situation, as appropriate, and obtains guidance on the course of action to be taken, including stopping the work.

Note: The evaluator and others may discuss the situation with higher levels of management responsible for the activity in another attempt to resolve the problem. If the problem is resolved, documents per step 5.a.(3) above.

<u>Performer</u>	<u>Action</u>
Evaluator	<ul style="list-style-type: none"> (5) If resolution is still not be obtained, initiates an Urgent Action Directive (Attachment A), by obtaining a unique number from the DCAR Administrator. (6) Prepares the Urgent Action Directive identifying unsatisfactory conditions and detailing action called for in either letter or memorandum form, as appropriate. (7) Initiates a deviation report in accordance with SPP 5.01. <p><u>Note:</u> Tracking, follow-up, and closure of the deviation report are done in accordance with SPP 5.01.</p>

b. Approval and Notification of the Urgent Action Directive

<u>Performer</u>	<u>Action</u>
Manager	<ul style="list-style-type: none"> (1) Signs and issues the Urgent Action Directive. (2) Transmits copies of the Urgent Action Directive to management of the organization responsible for the activity within one working day.
DCAR Administrator	<ul style="list-style-type: none"> (3) Logs the Urgent Action Directive on the Urgent Action Directive Log (Attachment B). (5) Establishes an Urgent Action Directive working file with a copy of the directive and returns the original to the Evaluator.

c. Urgent Action Directive Closure

<u>Performer</u>	<u>Action</u>
Evaluator	(1) Following receipt of notification, follows up on the Urgent Action Directive and verifies the unsatisfactory condition has been corrected. (2) Documents verification results on an Urgent Action Directive Closure Record (Attachment C). (3) Signs the Urgent Action Directive Closure Record to denote acceptance and forwards to the Manager.
Manager	(4) Concurs in the Urgent Action Directive Closure Record. (5) Transmits copies of the Urgent Action Directive Closure Record to the management of the organization responsible for the activity.
DCAR Administrator	(6) Records closure on the Urgent Action Directive Log. (7) Files the original of the Urgent Action Directive Closure Record in the working file.

d. Records

<u>Performer</u>	<u>Action</u>
DCAR Administrator	(1) Prepares the Urgent Action Directive working file as a quality record in accordance with SPP 7.01.

6. ATTACHMENTS

- a. Attachment A - Content (Body) of an Urgent Action Directive**
- b. Attachment B - Urgent Action Directive Log (Example)**
- c. Attachment C - Urgent Action Directive Closure Record (Example)**

Attachment A

Content (Body) of an Urgent Action Directive

Subject: URGENT ACTION DIRECTIVE NO. _____
LOCATION, PROJECT, OR FACILITY - SUBJECT OR DESCRIPTION

Provide an overall description of the unsatisfactory condition. Include background information and a description of the events leading to the unsatisfactory condition. Discuss previous actions taken as appropriate. List the areas evaluated and associated results as follows:

1. Discuss in detail the area that was found to be unsatisfactory and provide evaluation results with sufficient evidence supporting the evaluation. Provide an apparent cause of the condition if possible.
2. Same as 1 for each area.

Based on the results discussed above, we conclude that:

- A. Provide conclusions as to what actions are required to correct the area evaluated. Be as specific as possible.
- B. Same as A for each area.
- C. Provide overall conclusions and requested corrective actions as appropriate. Request the management of the participating organization initiate and complete the necessary corrective actions by month, day, or year or halt the activities in question. Request the management of participating organization to notify the organization issuing the urgent Action Directive when corrective actions have been completed.

(Title)

Attachment B

Urgent Action Directive Log (Example)

URGENT ACTION DIRECTIVE LOG							
Number	To	From	Originator	Description of Unsatisfactory Condition and Location	Date Issued	Date Closed	Comments

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DISPOSITION OF DEVIATIONS IDENTIFIED BY OUTSIDE ORGANIZATIONS

1. PURPOSE:

To provide instructions for evaluating and developing dispositions and corrective actions identified by an organization other than the organization invoking the Standard Practice Procedures (SPPs).

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 6.04, Commitment Control
- b. SPP 5.01, Deviation Reporting and Disposition
- c. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records

4. GENERAL:

This SPP addresses the evaluation of deviation(s) identified against the organization using the SPPs. The deviation(s) may be identified by the organization invoking the SPPs or by any other organization authorized to audit or evaluate the user of the SPPs. These outside organizations may have audit findings or other types of deviations against the organization using these SPPs.

The organization invoking the SPPs may incur deviations and request assistance from the user of the SPPs in dispositioning the deviation and in defining corrective action. The steps for providing that assistance are addressed in this procedure.

In the event the SPPs are being applied to defense high level waste form, the disposition of any deviation involving the waste form product must have approval of other organizations. Deviations involving nonconformance with the Waste Acceptance Specification (WAS) or the Federal Repository License Application must be concurred in by DOE/DP Defense Waste and

Transportation Management (DWTM) and approved by the DOE Office of Civilian Radioactive Waste Management (OCRWM).

a. Definitions

- (1) Deviation - A departure from specified requirements.
- (2) Disposition - The action taken to correct a deviation.

5. PROCEDURE:

a. **Processing of Deviations Against the User of the SPPs**

<u>Performer</u>	<u>Action</u>
Manager	<ul style="list-style-type: none"> (1) Receives the deviation from the evaluating organization. (2) Identifies the disposition as a commitment in the Commitment Control Log. (See SPP 6.04). (3) Assigns an Evaluator to review and resolve the deviation.
Evaluator	<ul style="list-style-type: none"> (4) Determines if corrective action is required using the criteria in SPP 5.01. (5) Evaluates the deviation and proposes disposition. (6) When corrective action is required, proposes corrective action. (7) Prepares a response to the identifying organization defining the disposition, when the disposition will be complete and when required, defines the corrective action and when the corrective action will be complete.

<u>Performer</u>	<u>Action</u>
Evaluator	Note: In the event the deviation involves defense high level waste form, includes a notation that the disposition must be approved by OCRWM.
Manager	(8) Approved the proposed response and issues. (9) Ensures the Commitment Control Log entry is updated. (10) Upon notification that the disposition and, if required, that the corrective action is acceptable, closes the Commitment Control Log entry. (11) In the event the response is not acceptable, repeat steps (3) through (10).

b. Processing Deviations Against Other Organizations

<u>Performer</u>	<u>Action</u>
Manager	(1) Receives the request for assistance in defining the disposition to the identified deviation. (2) Identifies the request as a commitment in the Commitment Control Log (see SPP 6.04). (3) Assigns an Evaluator to review and propose disposition for the deviation. (4) Determines if corrective action is required using the criteria in SPP 5.01.

<u>Performer</u>	<u>Action</u>
Manager	(5) Evaluated the deviation and proposes disposition. (6) When corrective action is required, proposes corrective action. 7) Prepares a response to the organization requesting assistance. Note: In the event the deviation involves defense high level waste form, includes a notation that the disposition must be approved by OCRWM. (8) Approves the proposed response and issues. (9) Ensures the Commitment Control Log entry is updated. (10) Upon notification that the disposition, and, if corrective action is required, that the corrective action is acceptable, closes the Commitment Control Log entry. (11) In the event the response is not acceptable, repeat steps (3) through (10).

c. Records

<u>Performer</u>	<u>Action</u>
Evaluator	(1) Prepares the incoming and outgoing correspondence as quality records in accordance with SPP 7.01

6. ATTACHMENTS:

None

REVIEW OF UNUSUAL OCCURRENCES

1. PURPOSE:

To provide instructions for reviewing Unusual Occurrence Reports. The reviews are for generic applicability, quality implications, or other stated purposes.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. DOE Order 5000.3, Unusual Occurrence Reporting System
- b. SPP 5.01, Deviation Reporting and Disposition
- c. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records

4. GENERAL:

The requirements for Unusual Occurrence Reports (UORs) are defined in DOE Order 5000.3. The DOE Operations Office and responsible operating contractor are charged with the responsibility for notifying DOE Headquarters. The UOR notification includes the definition and evaluation of the occurrence and the corrective action.

These UORs may be forwarded to the organization using these SPPs with a request to evaluate the UOR. The request may be to evaluate the UOR for generic implications on projects or programs other than where the UOR happened. The request may be to review the UOR for adequately describing the event, for the adequacy of the analysis and definition of corrective action or a review for some other stated purpose. This procedure defines the process for conducting the requested reviews.

a. Definitions

- (1) Unusual Occurrence - Any unusual or unplanned event having programmatic significance such that it adversely affects or potentially affects the performance, reliability, or safety of a facility.
- (2) Unusual Occurrence Report (UOR) - A written description of an unusual occurrence that is prepared in sufficient detail to enable the reviewer to assess its significance, consequences, or implications and to determine the means of avoiding a recurrence with minimal additional inquiry.
 - (a) Initial UOR - A formal written report describing the occurrence and is issued within a period of time established by the field organization. (The initial report may be combined with the final report into a single report when the full requirements of a final report can be defined within the established time frame).
 - (b) Interim UOR - An interim report may be issued to provide current status and progress achieved when all information required for a final report is not available. Interim reports should include the schedule for completion.
 - (c) Final UOR - A final UOR is issued when corrective action has been completed. The final UOR retains information provided in the initial and interim UORs as necessary to provide a complete description of the occurrence, an evaluation (including a determination of cause), and action taken to prevent recurrence. A final UOR is revised and reissued if it is determined to be incomplete or requires clarification.

5. PROCEDURE:

a. Review of UORs

<u>Performer</u>	<u>Action</u>
Manager	<ul style="list-style-type: none"> (1) Receives the UOR with the request for review or evaluation. The UOR may be the initial, an interim, or a final UOR. (2) Assigns the UOR to an Evaluator knowledgeable in the disciplines involved.

<u>Performer</u>	<u>Action</u>
Evaluator	<ul style="list-style-type: none">(3) Reviews UOR to ensure the report adequately describes the occurrence.(4) If an interim UOR, reviews to ensure the report reflects the current status and includes a schedule for the final UOR.(5) Reviews final UORs to ensure the reports correctly retain the information provided in the initial and any interim reports and properly address:<ul style="list-style-type: none">(a) Determination of cause.(b) Adequacy of disposition action.(c) Adequacy of action to prevent recurrence.(d) Generic applicability to other features or facilities internal or external to within DOE.(6) Reviews the UOR for the purpose requested.(7) Documents the review on a memorandum or letter ensuring the response fully addresses the request. <p>Note: The memorandum or letter should clearly state if there are no comments. If there are comments, they should be specific with the action items clearly stated.</p> <ul style="list-style-type: none">(8) If there are deviations that are not documented, then a DCAR should be initiated. See SPP 5.01.
Manager	<ul style="list-style-type: none">(9) Upon concurrence sign and issue the memorandum or letter.

b. Records

<u>Performer</u>	<u>Action</u>
Evaluator	(1) Prepares the following as quality records in accordance with SPP 7.01: <ul style="list-style-type: none">• Copies of the UORs.• Correspondence related to the review.• Key working papers from the review, such as documentation of actions taken by others, basis for decision, and related information.

6. ATTACHMENTS:

None

STANDARD PRACTICE PROCEDURE

SPP 5.06
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CONTROL AND DISPOSITION OF DEVIATIONS AND RECOMMENDATIONS FOR IMPROVEMENT BY OUTSIDE ORGANIZATIONS

1. PURPOSE:

To provide instructions for the control and disposition of deviations and recommendations for improvement identified by outside organizations.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a SPP 8.01, Coordination of Reviews and Evaluations by Outside Organizations
- b SPP 6.04, Commitment Control
- c SPP 5.01, Deviation Reporting and Disposition
- d SPP 7.01, Preparation, Transfer, and Receipt of Quality Records

4. GENERAL:

Deviation reports and recommendations for improvement are a likely result of reviews and evaluations by external organizations. The reports and recommendations may be received in various formats; however, for the purposes of this instruction, they are referred to generically as external program evaluation reports. The coordination of these external evaluations are addressed in SPP 8.01.

Each deviation and recommendation for improvement will be evaluated and an appropriate response will be prepared in the time frame requested.

a. Definitions

- (a) Deviation - A departure from specified requirements.

- (b) Recommendations for Improvement - Suggestions for improvement of a program that are based on observations.

5. PROCEDURE:

a. Receipt and Processing of Deviation and Recommendation for Improvement Documents from External Organizations

<u>Performer</u>	<u>Action</u>
Manager	(1) Receives the external program evaluation report and assigns it to an Evaluator with a copy to the DCAR Administrator.
DCAR Administrator	(2) Establishes a working file for each external program evaluation report. (3) Enters the external program evaluation report in the Commitment Control Log. See SPP 6.04.
Evaluator	(4) Reviews external program evaluation and identifies and reports any deviations. See SPP 5.01.

b. Evaluating, Responding, and Following-Up on Deviations and Recommendations for Improvement

<u>Performer</u>	<u>Action</u>
Evaluator	(1) Evaluates the deviation or recommendation for improvement for appropriateness. (2) Develops an appropriate course of action in response to the deviation or recommendation for improvement.

Note: The course of action should either outline actions taken or proposed to be taken in response to the deviation or reject the deviation or recommendation.

<u>Performer</u>	<u>Action</u>
Evaluator	<p>(3) Documents the course of action in the initial response to the originator of the external evaluation report.</p> <p>Note: If the deviation or recommendation is rejected or disputed, the response should give the specific reasons.</p> <p>(4) Forwards the initial response to the Manager for concurrence.</p>
Manager	<p>(5) Concurs in the initial response, signs, and transmits the response to the originating external organization for acceptance.</p>
DCAR Administrator	<p>(6) Updates the Commitment Tracking Log.</p> <p>Note: If the response to the deviation or recommendation for improvement is rejection or if the response has already been implemented, the entry in the Commitment Control Log may be closed.</p>
Evaluator	<p>(7) Initiates action to implement dispositions, corrective actions or recommendations for improvements in accordance with the response.</p> <p>(8) Monitors implementation of the disposition, corrective action or recommendations for improvements using the Commitment Control Program and keeps the Manager informed as a part of normal progress reporting.</p> <p>(9) Verifies the implementation in accordance with the response to the originator.</p>

<u>Performer</u>	<u>Action</u>
Evaluator	(10) Documents the implementation in a letter or memorandum as appropriate to notify the external originating organization and forwards to the Manager.
Manager	(11) Signs and transmits the final correspondence to the appropriate external organization.
DCAR Administrator	(12) Closes the entry in the Commitment Control Log.

c. Records

<u>Performer</u>	<u>Action</u>
DCAR Administrator	(1) Ensures the following are in the external program evaluation report file: <ul style="list-style-type: none">(a) External program evaluation report.(b) All response correspondence (initial, interim, and final).
	(2) Prepares the external program evaluation report file as a quality record in accordance with SPP 7.01.

6. ATTACHMENTS:

None

STANDARD PRACTICE PROCEDURE

UNCONTROLLED SPP

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OFFICIAL HLW OFFICE FILES

1. PURPOSE:

To provide instructions for the operation of a filing and storage system to maintain official HLW office documentation and to preserve those documents which will become quality records upon completion.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means. This SPP applies to all HLW office files including those that will be declared quality records upon completion.

3. REFERENCES:

- a. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records
- b. DOE Order 1324.3, Files Management
- c. DOE Order 0000.1A, Subject Classification System

4. GENERAL:

The HLW office files include documents that eventually will be completed and then declared quality records in accordance with SPP 7.01. These quality records are identified in SPP 7.01.

a. Definitions

File Administrator - The person within each organizational unit charged with the responsibility of collecting and maintaining the files.

5. PROCEDURE:

a. Establishment of HLW Office File

<u>Performer</u>	<u>Action</u>
Program Coordinator	(1) Designates, in writing, File Administrator(s) responsible for administration of the file.

<u>Performer</u>	<u>Action</u>
File Administrator	(2) Organizes the files, including file equipment and work space, in accordance with the guidelines in DOE Order 1324.3 and the SPP Office File Guide (Attachment A).

Note: Attachment A is an extraction of Attachment 2 of DOE Order 0000.1A.

b. Maintaining the HLW Office File

<u>Performer</u>	<u>Action</u>
File Administrator	(1) Assigns file numbers to documents which are to be filed in accordance with Attachment A.
	(2) Ensures files are maintained in accordance with the HLW Office File Instruction (Attachment B) and the guidelines in DOE Order 1324.3.
	(3) Maintains a list of any alterations, additions, or deletions to Attachment A until this instruction can be revised to reflect the changes.

Note: Changes to Attachment A should be incorporated as soon as possible. Changes which affect the DOE Standard Classification Code should be submitted in accordance with DOE Order 0000.1A.

6. ATTACHMENTS:

- a. Attachment A - HLW Office File Guide
- d. Attachment B - HLW Office File Instruction

Attachment A

HLW Office File Guide

- 0000 CLASSIFICATION CODES, CHECKLISTS, AND INDEXES**
- 1000 MANAGEMENT AND ADMINISTRATION - General**
 - 1010 Determination and Transfer Orders**
- 1100 ORGANIZATION, AUTHORITIES, FUNCTIONS, AND INTERNAL RELATIONSHIPS**
 - 1110 Appointments and Designations**
 - 1120 Field Facilities**
 - 1130 Committees, Conferences, Boards, Panels, Groups**
- 1200 EXTERNAL RELATIONSHIPS**
 - 1210 Public Relations**
 - 1220 Congressional Relations**
 - 1230 Intergovernmental Affairs**
 - 1240 International Relations**
 - 1250 Energy Education Programs**
 - 1260 Business/Labor Relations**
 - 1270 Interagency Relations/Agreements**
 - 1280 Memorandums of Understanding**
 - 1290 Consumer Affairs**
- 1300 MANAGEMENT SYSTEMS AND STANDARDS**
 - 1310 Management Studies, Analyses, and Surveys**
 - 1320 Paperwork Management**
 - 1321 Directives Management**
 - 1322 Forms Management**
 - 1323 Reports Management**
 - 1324 Records Management**
 - 1325 Correspondence Management**
 - 1330 Management Information Systems**
 - 1331 Integrated Management Information Systems**
 - 1332 Uniform Reporting System**
 - 1340 Publishing Management**
 - 1350 Audio-Visuals Management**

Attachment A (Cont'd)

- 1360 Data Processing Management
- 1370 Computer-Aided Technology Management

- 1400 ADMINISTRATIVE SUPPORT AND SERVICES
 - 1410 Mail Services
 - 1420 Publishing, Photography, and Graphic Services
 - 1430 Library Services
 - 1440 Office Services
 - 1450 Communications

- 1500 TRAVEL AND TRANSPORTATION
 - 1510 Personnel
 - 1511 Domestic
 - 1512 International
 - 1520 Personal Effects
 - 1521 Domestic
 - 1522 International
 - 1530 Equipment
 - 1540 Materials (Materials)

- 1600 EQUAL OPPORTUNITY
 - 1610 Contractor Industrial Relations

- 1700 FREEDOM OF INFORMATION

- 1800 PRIVACY ACT

- 1900 FEDERAL REGISTER

- 2000 LEGAL
 - 2010 Opinions
 - 2020 Legislation
 - 2030 Rules and Regulations
 - 2040 Claims and Litigation
 - 2050 Patents
 - 2060 Hearings
 - 2070 Appeals

Attachment A (Cont'd)

- 2100 FINANCIAL MANAGEMENT - GENERAL
 - 2110 Pricing
- 2200 ACCOUNTING
 - 2210 General Financial Reports
 - 2200 Payroll, Leave, and Allowances
 - 2230 Voucher Examination and Certification
 - 2240 Collection, Safekeeping, Deposit, and Disbursement of Funds
 - 2250 Contracts/Contractor
 - 2260 Obligations
 - 2270 Cost Accounting Standards
- 2300 AUDITING
 - 2310 Audit Reporting
 - 2320 Internal Audit and Investigation
 - 2321 Internal Audit
 - 2322 Internal Investigation
 - 2330 External Auditing
 - 2340 General Accounting Office Audits
- 2400 - 2900 (RESERVED)
- 3000 PERSONNEL MANAGEMENT - GENERAL (Numbering system compatible with the Federal Personnel Manual numbers.)
- 3100 (RESERVED)
- 3200 PERSONNEL PROVISIONS - GENERAL
 - 3210 Basic Concepts and Definitions
 - 3211 Veteran Preference
 - 3212 Competitive Service and Status
 - 3213 Excepted Service
 - 3220 Contractor Personnel
 - 3230 (Reserved)
 - 3240 Military Personnel
 - 3250 Personnel Management

Attachment A (Cont'd)

- 3251 (Reserved)
- 3252 Professional or Other Associations
- 3240 - 3280 (Reserved)
- 3290 Personnel Information (Records and Document Processing)
- 3291 Personnel Reports
- 3292 (Reserved)
- 3293 Personnel Records and Files
- 3294 - 3295 (Reserved)
- 3296 Processing Personnel Actions

3300 EMPLOYMENT

- 3301 (Reserved)
- 3302 Excepted Service
- 3303 (Reserved)
- 3304 Experts and Consultants
- 3305 Executive Assignment System
- 3306 (Reserved)
- 3307 Veterans
- 3308 Students
- 3309 Contractor Personnel
- 3310 - 3320 (Reserved)
- 3330 Recruitment, Selection, and Placement
- 3331 International Recruitment, Selection, and Placement
- 3332 Contractor Recruitment, Selection, and Placement
- 3333 (Reserved)
- 3334 Temporary Assignment
- 3335 Promotion and Internal Placement
- 3340 Part-time Career Employment
- 3350 Job Retention
- 3351 Reduction in Force
- 3352 Reemployment Rights
- 3353 Restoration After Military duty
- 3360 Career Intern Program

3400 EMPLOYEE PERFORMANCE AND UTILIZATION

- 3410 Employee Training and Development
- 3420 Management Training and Development

Attachment A (Cont'd)

- 3430 Performance Evaluation
- 3440 (Reserved)
- 3450 Incentive Awards and Employee Recognition

3500 POSITION CLASSIFICATION, PAY, AND ALLOWANCES

- 3510 Position Classification and Job Evaluation
- 3520 (Reserved)
- 3530 Pay Rates and Systems
- 3540 Merit Pay
- 3550 Pay Administration
- 3560 - 3580 (Reserved)
- 3590 Allowances and Differentials

3600 ATTENDANCE AND LEAVE

- 3610 Hours of Duty
- 3620 (Reserved)
- 3630 Absence and Leave

3700 PERSONNEL RELATIONS AND SERVICES

- 3710 Labor-Management Relations
- 3720 Contractor Relations
- 3730 Suitability
- 3731 - 3732 (Reserved)
- 3733 Political Activity
- 3734 (Reserved)
- 3735 Employee Responsibilities and Conduct
- 3740 (Reserved)
- 3750 Employee Discipline
- 3751 (Reserved)
- 3752 Adverse Actions
- 3760 (Reserved)
- 3770 Grievances, Appeals, and Hearings
- 3780 Services to Employees
- 3781 Employee Recreation and Welfare Activities
- 3790 Occupational Safety and Health Program for Federal Employees
- 3791 Safety
- 3792 Health

Attachment A (Cont'd)

3800 INSURANCE AND ANNUITIES

- 3810 Injury**
- 3820 (Reserved)**
- 3830 Retirement**
- 3840 - 3860 (Reserved)**
- 3870 Life Insurance**
- 3880 (Reserved)**
- 3890 Health Benefits**

3900 GENERAL AND MISCELLANEOUS

- 3910 Fund-Raising Campaigns**
- 3920 Savings Bond Campaigns**

4000 LOGISTICS MANAGEMENT - GENERAL

- 4010 Value Engineering**

4100 (RESERVED)

4200 PROCUREMENT

- 4210 Authorities, Responsibilities, and Regulations**
- 4220 Contracting**
- 4230 Small Purchasing**
- 4240 Major Systems Acquisition**
- 4250 Requisitioning and Ordering**
- 4260 Personal Services**

4300 REAL PROPERTY MANAGEMENT

- 4310 Authorities, Responsibilities, and Regulations**
- 4320 Facilities Planning**
- 4330 Facilities Management (Including Space)**
- 4340 Services**

4400 PERSONAL PROPERTY MANAGEMENT

- 4410 Authorities, Responsibilities, and Regulations**
- 4420 Equipment, Supply, and Inventory Management**

Attachment A (Cont'd)

- 4430 **Property in Use Management**
 - 4431 **Excess**
 - 4432 **Surplus**
 - 4433 **Disposal**
- 4440 **Vehicle Management**
- 4450 **Aircraft Management**
- 4460 **Reports**

- 4500 **COMMERCIAL AND INDUSTRIAL ACTIVITIES**
 - 4510 **Authorities, Responsibilities, and Regulations**
 - 4520 **Commercial (Including Commissary, Messing, Laundry, Housekeeping)**
 - 4530 **Industrial**
 - 4540 **Public Services**

- 4600 **GRANT MANAGEMENT**
 - 4610 **Authorities, Responsibilities, and Regulations**
 - 4620 **Grants**
 - 4630 **Grants-in-Aid**
 - 4640 **Cooperative Agreements**
 - 4650 **Loans/Loan Guarantees**

- 4700 **PROJECT MANAGEMENT**

- 4800 - 4900 **(RESERVED)**

- 5000 **PROGRAM PLANNING AND MANAGEMENT**
 - 5010 **Economic Affairs (Including Economic Analysis and Forecasting)**
 - 5020 **Program Coordination and Evaluation (Including Federal, State, Local, Industry, Intermodel)**
 - 5030 **Policy Development and Coordination**
 - 5031 **Domestic**
 - 5032 **International**
 - 5040 **Program Financing Methods (Including Loan Guarantees, Taxes, User Charges - See 4600 for Grants Management)**

Attachment A (Cont'd)

5100 PLANNING, PROGRAMMING, AND BUDGETING

- 5110 Special Studies**
- 5120 Program Proposals**
- 5130 Departmental Review**
 - 5130 Secretarial Review**
 - 5132 Internal DOE Appeals**
- 5140 Program Memorandums**
 - 5141 Program and Financial Plan**
- 5150 Budget Submissions**
 - 5151 DOE Review**
 - 5152 OMB Review**
 - 5153 Congressional Review**
- 5160 Budget Execution**
- 5170 Budget Reports**

5200 MANPOWER MANAGEMENT

5300 TELECOMMUNICATIONS

- 5310 Data/Computer**
- 5320 Radio Frequency Management**
- 5330 Landline (Telephone, Telegraph)**
- 5340 Space/Satellites**
- 5350 Command and Control Systems**

5400 ENVIRONMENTAL QUALITY AND IMPACT

- 5410 Environmental Analyses**
- 5420 Environmental Development Plans**
- 5430 Environmental Assessments**
- 5440 Environmental Impact Statements**
- 5450 Physical Sciences**
 - 5451 Seismicity**
 - 5452 Geology**
 - 5453 Oceanography**
 - 5454 Meteorology**
- 5460 Bioenvironmental Sciences**
 - 5461 Wildlife**
 - 5462 Vegetation**

Attachment A (Cont'd)

- 5470 Protection and Enhancement**
 - 5471 Noise Control**
 - 5472 Pollution Control**
 - 5473 Community Impact**
 - 5474 Parks**
 - 5475 Recreation Areas**
 - 5476 Wildlife and Waterfowl Refuge**
 - 5477 Historical Sites**
- 5480 Environmental Safety and Health**
 - 5481 Analysis**
 - 5482 Appraisal**
 - 5483 Contractor Programs**
 - 5484 Reporting**

5500 EMERGENCY PREPAREDNESS

- 5510 Operational Plans**
 - 5511 Domestic**
 - 5512 International**
- 5520 Chemical, Biological, and Radiological Defense**
- 5530 Emergency Resources Management**
- 5540 Reports, Tests, and Exercises**
 - 5541 Domestic**
 - 5542 International**
- 5550 Industrial Mobilization**
- 5560 Priorities and Allocations**

5600 DEFENSE PROGRAMS

- 5610 Military Application**
- 5620 Laser Fusion**
- 5630 Safeguards and Security**
 - 5631 Personnel Security**
 - 5632 Physical Security**
 - 5633 Materials Control and Accountability**
 - 5634 Reviews**
 - 5635 Document Control**
 - 5636 Technical Security**
 - 5637 Computer Security**
 - 5638 Travel to Communist Controlled Countries**
- 5640 International Security Affairs**
- 5650 Classification**

Attachment A (Cont'd)

- 5660 Nuclear Materials Production
- 5670 Foreign Intelligence

- 5700 ENERGY PROGRAMS AND POLICIES - GENERAL

- 5800 ENERGY RESEARCH AND TECHNOLOGY
 - 5810 Health and Safety
 - 5820 Radioactive Material
 - 5821 Radioactive Waste
 - 5822 Radioactive Materials/Waste Transportation
 - 5823 Containerization
 - 5830 Process Development
 - 5840 Reactor Development
 - 5850 Medical
 - 5860 Biological
 - 5870 Chemical

- 5900 ENERGY INFORMATION

- 6000 ENERGY POLICY AND EVALUATION

- 6100 RESOURCE APPLICATIONS
 - 6110 Petroleum
 - 6111 Natural Gas
 - 6112 Coal
 - 6113 Uranium
 - 6114 Shale
 - 6120 Power Marketing
 - 6130 Geothermal

- 6200 ENERGY CONSERVATION

- 6300 SOLAR APPLICATIONS

- 6400 CONSTRUCTION AND ENGINEERING
 - 6410 Construction
 - 6420 Engineering
 - 6430 Design Criteria

Attachment B

DWTM-HLW Office File Instructions

1. In preparation for filing, documents to be filed should be gathered in a designated place within the program office. The orderly collection of documents and the placing of these documents in an established holding file are important for both the security of the records and their accessibility for use during the interim. The holding file may be a special file box or tray, a specially marked folder, or a special drawer in a desk or file cabinet.
2. Documents in the holding file should then be checked to make sure they have been released for filing. Papers attached together by clamps, paper clips, etc. should be checked to ensure they belong together. If possible, paper clips or clamps should be removed and the papers stapled to avoid separation of documents.
3. Documents now should be sorted in accordance with the file classification code assigned by the file administrator from Attachment A or as appropriate. These documents should then be placed in a file folder labeled with the file classification code in chronological order with the most recently dated documents to the front.

Note: Reference documents should merely be placed on their designated shelves.

4. File folders then should be placed in a file drawer which is accurately labeled. Hanging folders are recommended to facilitate storage and retrieval. File drawer capacity should be limited to approximately 80 percent to ease retrieval and storage within the file drawer.
5. Once filed, "out guides" should be used to mark files removed for reference purposes. These "out guides" should identify the user and date taken out. Documents removed for more than a month should be followed up on to verify their location.
6. Files should be periodically reviewed (a minimum of once a year) and disposed of when no longer needed for working purposes. Files, which upon completion become quality records, are identified and handled in accordance with SPP 7.01.

Note: Care should be taken when disposing of documents to ensure no potential quality records are discarded. If any doubt exists, the Quality Assurance Specialist should be consulted.

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PREPARATION OF CORRESPONDENCE

1. PURPOSE:

To provide instructions for the preparation and handling of correspondence.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 6.01, Official HLW Office Files
- b. SPP 6.04, Commitment Control
- c. DOE Order 1325.1A, Department of Energy Correspondence Manual

4. GENERAL:

This instruction reflects the basic premise that correspondence and communication channels will be established at the lowest organizational level with responsibility and authority for the work addressed without violating DOE protocol as discussed in Attachment A.

Verbal communications are encouraged in order to maintain a free exchange of information at all working levels. However, quality-related activities that are verbally communicated will be promptly documented in writing and distributed to affected parties when necessary to record commitments or action items in accordance with SPP 6.04.

a. Definitions

- (1) Outgoing Correspondence - Any correspondence issued by an organization to any other organization (external) or division of the same organization (internal).
- (2) Originator of Correspondence - A generic term used to identify singularly or as a composite the author, preparer, reviewer, approver, and/or secretary.

- (3) Reading File - A file within each organization that contains one copy of each piece of correspondence issued. Copies of attachments to correspondence are to be included unless: 1) the attachments are identified uniquely in the correspondence; and, 2) the attachments are available from another file.

5. PROCEDURE:

a. Preparation and Processing Outgoing Correspondence

<u>Performer</u>	<u>Action</u>
Originator of Correspondence	<ul style="list-style-type: none"> (1) Prepares outgoing correspondence in accordance with DOE Order 1325.1A and Attachment A. (2) Identifies needed concurrences, references, attachments, and distribution on the draft correspondence. (3) Forwards the draft correspondence to the secretary.
Originating Secretary	<ul style="list-style-type: none"> (4) Types in final form in accordance with DOE Order 1325.1A, assigns a file number (from SPP 6.01), and obtains the originator's review. (5) Makes any necessary changes and copies the original correspondence (file copy) with a concurrence block and another copy for the reading file. (6) Forwards the original and file copy back to the originator. (7) Obtains any concurrence initials indicated on the file copy.

<u>Performer</u>	<u>Action</u>
Originating Secretary	Note: Prior to transmittal, correspondence should receive sufficient internal management review to ensure it represents the organization's position for internal or external correspondence. Supporting information should be attached to the file copy when obtaining concurrence initials.
Originator	(8) Forwards the original correspondence and file copy with concurrence initials to the authorized manager or person for signature.
Approver	(9) Signs the correspondence and returns it and the file copy to their secretary for transmittal and filing.
	Note: For any significant changes mandated by the concurrence or approval cycle return to step 5.a.(5).

b. Transmittal of Correspondence

<u>Performer</u>	<u>Action</u>
Secretary of the Approver	(1) If other than the originating secretary, makes another reading copy for the reading file and routes the file copy with signature date stamped on it to the Correspondence Control Clerk.
	(2) Transmits the original correspondence in accordance with DOE Order 1325.1A.

<u>Performer</u>	<u>Action</u>
Correspondence Control Clerk	(3) Ensures applicable correspondence is logged into the Commitment Control System per SPP 6.04.
	(4) Sends the file copy back to the originating secretary.
Originating Secretary	(5) Notes the signature date on the reading file copy and files the file copy in the indicated file.

6. ATTACHMENTS:

- a. Attachment A - Outgoing Correspondence Guidelines**

Attachment A

Outgoing Correspondence Guidelines

- **"Subject" line should accurately describe the content of the correspondence; e.g., DEVIATION REPORT TRANSMITTAL.**
- **The purpose of the correspondence should be stated in the first line as a "lead-in" to the remainder of the correspondence.**
- **Directives, commitments assigned, and responses requested should be clearly identified in the text.**
- **Titles or designations for which acronyms or abbreviations are used should be written out in full the first time they are used, with the acronym or abbreviation following in parentheses only when it will be used again. Exceptions to this are when the acronym or abbreviation are in such common use that recipients of the correspondence are certain to be familiar with them.**
- **Memo Route Slips may be used for correspondence within the organization; however, they should not be used for official correspondence to outside organizations.**
- **Outgoing correspondence should always follow DOE protocol as outlined in the policy section of DOE Order 1325.1A. Although most outgoing correspondence is sent out under the DWTM Director's signature, it is permissible for those individuals designated as points of contacts for Operations Offices and contractors to correspond directly with the Operations Offices and contractors involved.**

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INCOMING MAIL

1. PURPOSE:

To provide instructions for receipt and control of non-classified incoming mail .

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 6.01, Official HLW Office Files
- b. SPP 6.04, Commitment Control
- c. SPP 6.05, Controlled Documents

4. GENERAL:

None

5. PROCEDURE:

a. Incoming Mail Routing and Handling Matrix

<u>Performer</u>	<u>Action</u>
Correspondence Control Clerk	(1) Develops a matrix similar to Attachment A for routing and handling incoming mail, indicating type of mail, who is to receive the original, who is to receive copies, and who makes the decision to file. (See SPP 6.01.)
	(2) Coordinates the Incoming Mail Matrix with potential recipients, and the Quality Assurance Specialist (QAS), and obtains their concurrence.

<u>Performer</u>	<u>Action</u>
Recipients	(3) Provides input to the Correspondence Control Clerk regarding any necessary revisions to the matrix.
Correspondence Control Clerk	(4) Updates the matrix as to responsibilities, personnel, and the organization change. (5) Coordinates changes to the incoming mail matrix with affected recipients, and obtains concurrence.

b. Processing Incoming Mail

<u>Performer</u>	<u>Action</u>
Correspondence Control Clerk	(1) Receives and sorts incoming mail each day. Note: Mail for individuals not listed in the matrix should be readdressed and dispatched for proper delivery. (2) Opens mail addressed to management personnel except for "personal" or "confidential" mail. Note: Anyone receiving mail through private means or personal routing which should be part of office records has the responsibility to provide the Correspondence Control Clerk with a copy.

<u>Performer</u>	<u>Action</u>
Correspondence Control Clerk	<p>(3) Using the incoming mail matrix for guidance, copies the mail as needed and handles as follows:</p> <p>(a) For controlled documents, processes in accordance with SPP 6.05.</p> <p>(b) For "personal" or "confidential" mail, distributes unopened to the appropriate recipient.</p> <p>(c) For all other mail, logs in on Incoming Mail Log similar to Attachment B and distributes using a routing slip which indicates responsibilities for filing.</p> <p><u>Note:</u> Logging mail in on an incoming mail log is the first step in the commitment control process per SPP 6.04.</p> <p>(4) Files a copy of each days incoming mail log.</p>
Recipient	<p>(5) For mail in which filing responsibility is indicated, determines the need to file.</p> <p>(6) Makes a file copy and files in accordance with SPP 6.01, if appropriate.</p>

c. Records

<u>Performer</u>	<u>Action</u>
Correspondence Control Clerk	<p>(1) Maintains copies of each revision of the Incoming Mail Routing and Handling Matrix for working and historical purposes.</p>

6. ATTACHMENTS:

- a. Attachment A - Incoming Mail Routing and Handling Matrix (Example)
- b. Attachment B - Incoming Mail Log (Example)

Attachment A

Incoming Mail Routing and Handling Matrix (Example)

INCOMING MAIL ROUTING AND HANDLING MATRIX				
Document	Organization Issued By	Route Original To	Route Copies To	Decision to File

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COMMITMENT CONTROL

1. PURPOSE:

To provide instructions for the identification and control of action items or commitments that are identified in correspondence, and includes instructions for maintaining information on the status of the action items or commitments.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 5.02, Management Action Request
- b. SPPW 6.03, Incoming Mail

4. GENERAL:

This SPP primarily addresses the handling of action items or commitments requested in correspondence received from external organizations. Although certain types of action items may not necessarily be "commitments" in the strict sense of the word, the word commitment as used in this SPP is intended to refer to such actions as commitments. (See the definition below.)

a. Definitions

- (1) Commitment - An agreement by one organization to accept the responsibility to perform a function or activity which has been assigned or requested by another outside organization. The commitment normally has a defined scope and due date.

5. PROCEDURE:

All actions performed by the Correspondence Control Clerk or the Quality Assurance Specialist may be performed by the correspondence reviewer (hereafter "Reviewer") when necessary.

a. Identification and Logging of Commitments

<u>Performer</u>	<u>Action</u>
Reviewer	<p>(1) Identifies commitments contained in incoming correspondence (or in outgoing correspondence initiated by internal personnel).</p> <p><u>Note:</u> Commitments from incoming correspondence may be identified in and "lifted" from the Incoming Mail Log (see SPP 6.03).</p> <p>(2) Identifies the responsible manager who accepts or assigns action for the commitment; and obtains his/her signature on Commitment Data Sheet (see Attachment A).</p> <p>(3) Completes the Commitment Data Sheet and provides the data associated with any identified commitment to the Correspondence Control Clerk for processing.</p>
Correspondence Control Clerk	<p>(4) Assigns a unique commitment tracking number to each new identified commitment received.</p> <p>(5) Records the information on the commitments in a Commitment Log similar to Attachment B.</p>

<u>Performer</u>	<u>Action</u>
Correspondence Control Clerk	<p>Note: It is advisable to record the commitment information within a computer data base. Each day's new entries should be indicated with an asterisk. All asterisks from previous entries would be dropped.</p> <p>(6) Sorts the commitments by due date with the most recent ones first within the Commitment Log.</p> <p>(7) Removes those commitments shown as completed after they have been distributed in hard copy form.</p> <p>(8) Distributes the Commitment Log weekly to the Reviewer and Quality Assurance Specialist (QAS).</p>

b. Control of Commitments

<u>Performer</u>	<u>Action</u>
Reviewer, (with support from the Quality Assurance Specialist)	<p>(1) Reviews the Commitment Log to identify new commitments and to monitor progress of previously established commitments.</p> <p>(2) Ensures that responsibilities for performing of new actions have been properly assigned to meet the commitments and their due dates.</p> <p>(3) For commitments that cannot be met, reschedules a new due date with the requesting organization.</p>

Performer

Action

Reviewer, (with support from the Quality Assurance Specialist)

- (4) For commitments assigned to others (both internal and external to the organization) which are past due, follows up and reschedules if necessary.

Note: When necessary, follow-up action may include the use of Management Action Requests per SPP 5.02.

c. Maintaining Status of Commitments

Performer

Action

Reviewer, (with support from the Quality Assurance Specialist)

- (1) Indicates the latest status (including completion) of commitments by appropriately marking the Commitment Log (Attachment B) and returning it to the Correspondence Control Clerk.

Correspondence Control Clerk

- (2) Updates the Commitment Log using the latest status information.
- (3) Advises the Reviewer and reminds the appropriate individual and his/her supervisor of commitments that are more than 10 days past due.

d. Records

Performer

Action

Correspondence Control Clerk

- (1) Maintains a hard copy of the Commitment Log and all updates to the log for working and historical purposes.

6. ATTACHMENTS:

- a. Attachment A - Commitment Data Sheet (Example)**
- b. Attachment B - Commitment Log (Example)**

Attachment A

Commitment Data Sheet (Example)

COMMITMENT DATA SHEET	
JOB NUMBER: _____	DATA SHEET NO: _____
REQUESTING ORGANIZATION/INDIVIDUAL: _____	
RESPONSIBLE MANAGER: _____	
ACTION ASSIGNED TO: _____	
DESCRIPTION OF COMMITMENT _____	

DATE OF CORRESPONDENCE REQUESTING ACTION _____	
IDENTIFICATION OF CORRESPONDENCE _____	
REQUESTED COMPLETION DATE _____	
PROMISED COMPLETION DATE _____	
EXPECTED COMPLETION DATE _____	
DELIVERED COMPLETION DATE _____	
RESPONSIBLE MANAGER'S SIGNATURE _____	DATE _____

Attachment B
Commitment Log (Example)

COMMITMENT LOG							
LOG FOR _____				DATE _____			
Commitment Item Tracking Number	Date of Correspondence	From (Person, Org., and any Ref. No. or File No.)	To (Person and Org.)	Commitment	Assignment	Due Date	Completion Date

* Indicate new entries for the day with asterisks prior to the date.

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CONTROLLED DOCUMENTS

1. PURPOSE:

To describe the procedure for handling of controlled documents.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

None

4. GENERAL:

This SPP addresses the handling of controlled documents.

a. Definitions

- (1) Controlled Document - Any document for which distribution and status are to be kept current in order to assure that authorized holders or users of the document have available the up-to-date version of the document for accomplishment of work activities.
- (2) Receipt Control - A system of control where the recipient of a controlled document confirms, by documented evidence to the document distributor, that the document has been received, filed, or inserted; and earlier copies removed and either destroyed or stamped superseded, or returned as directed by the distributor of the document.

Note: A controlled document generated internal to the organization is controlled in accordance with instructions specific to the document.

5. PROCEDURE:

a. Receipt and Filing of Controlled Documents

<u>Performer</u>	<u>Action</u>
Document Control Coordinator	(1) Routes the controlled document or revision to a controlled document to the person to whom the document has been assigned (i.e., "Assignee").
Assignee	(2) Maintains the controlled document assigned to him/her in a current state. (3) Routes the controlled document or its revision to the Document Control Coordinator if the document is received directly from the issuing organization. (4) Files any revisions to controlled document according to the specific instructions provided by the issuing organization.
	Note: If no instructions are provided by the issuing organization, follow step 5.a.(6) below.
	(5) Returns the controlled document acknowledgement receipt in the timeframe requested.
	(6) Files the new controlled document or its revision and destroys or stamps "superseded" on the front page of the former version of, or previous revision to, the document.

b. Copying Controlled Documents

<u>Performer</u>	<u>Action</u>
Assignee	<ol style="list-style-type: none">(1) Stamps or writes "Uncontrolled" on each copied page or as a minimum on the front page of one section (e.g., for a controlled procedure manual; the front page of each procedure.)(2) Uses an uncontrolled document for information purposes only and <u>not</u> for accomplishing quality related work activities.

c. Notifying the Originating Organization of Distribution Changes

<u>Performer</u>	<u>Action</u>
Assignee	<ol style="list-style-type: none">(1) Notifies the Document Control Coordinator in writing of any needed distribution changes. <u>Note:</u> Changes may be required by changes in address, job function, change of employment, or simply that the controlled document is no longer needed.(2) Forwards the controlled document no longer needed to the Document Control Coordinator.
Document Control Coordinator	<ol style="list-style-type: none">(3) In accordance with direction from the organization that originated the document, disposes of any unneeded document by either:<ol style="list-style-type: none">(a) Returning the document to the originating organization, or(b) Marking the document "Uncontrolled" per step 5 b.(1), or

Performer

Action

Document Control
Coordinator

(c) Destroying the document.

d. Development and Maintenance of a Controlled Document Master List

Performer

Action

Document Control
Coordinator

(1) Develops a Controlled Document Master List similar to Attachment A which lists all controlled documents.

(2) Annually submits the Controlled Document Master List to the issuing or originating organization for review.

Reviewer

(3) Annually reviews the Controlled Document Master List for continuing need for, and assignments of, the controlled documents.

(4) Initiates any needed distribution changes and returns the Controlled Document Master List to the Document Control Coordinator with changes marked.

Document Control
Coordinator

(5) Updates the Controlled Document Master List as necessary and assures by a periodic survey that the controlled documents that are in existence are in accordance with the latest issued Master List.

e. Records

Performer

Action

Document Control
Coordinator

(1) Maintains the latest revision of the Controlled Document Master List for working and historical purposes.

6. ATTACHMENTS:

- a. Attachment A - Controlled Document Master List Form (Example)

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PREPARATION, TRANSFER, AND RECEIPT OF QUALITY RECORDS

1. PURPOSE:

To define the responsibilities and actions to be executed in the preparation, transfer, and receipt of quality records.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. DOE Order 1324.3, Files Management
- b. SPP 6.01, Official HLW Office Files
- c. SPP 7.02, Quality Records Management

4. GENERAL:

Most SPPs address quality records by requiring some performer to prepare specified documents as quality records. These performers who are authorized to prepare documents as quality records are referred to generically as the "preparer" in this instruction.

Sometimes retrievability of quality records is best served by combining several related documents into a single quality record. For example, a report and the correspondence resolving concerns about that report should be combined into a single quality record. Documents are not considered quality records until they are prepared in accordance with this instruction. Where a document or file is used extensively, a working copy should be retained to minimize the retrieval of quality records.

Management of records as defined in DOE Order 1324.3 is addressed in SPP 7.02. Quality records are also managed (stored and dispositioned) in accordance with SPP 7.02 and are considered a subset of "records" as defined in DOE Order 1324.3.

a. Definitions

- (1) Document - Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a quality assurance record until it satisfies the definition of a quality assurance record--NQA-1.
- (2) Quality Record - A completed document that furnishes evidence of quality in items and/or activities affecting quality--DOE/RW-0214.
- (3) Lifetime Quality Records - Lifetime quality records are those which meet one or more of the following criteria:
 - (a) Those which would be of significant value in demonstrating capability for safe operation.
 - (b) Those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item.
 - (c) Those which would be of significant value in determining the cause of an accident or malfunction of an item.
 - (d) Those which provide required baseline data for in-service inspections--NQA-1.

Lifetime quality records related to waste form production are those quality records that are to be turned over to the repository operator for preservation as required for the canistered waste form to which they relate--DOE/RW-0214.

Note: For the purposes of this instruction, their preservation and lifetime are limited to the time that they are in the waste form producer's possession prior to turnover to the repository.

- (4) Nonpermanent Quality Records - Nonpermanent quality records are those required to show evidence that an activity was performed in accordance with the applicable requirements, but need not be retained for the life of the item because they do not meet the criteria for lifetime records.

5. PROCEDURE:

a. Identification and Classification of Quality Records

<u>Performer</u>	<u>Action</u>
Quality Assurance Specialist (QAS)	<p>(1) Establishes a Quality Records Index consistent with the numbering in SPP 6.01 and similar to Attachment A listing the types of categories of quality records that will be generated.</p> <p>(2) Classifies each type of quality record as permanent or nonpermanent in accordance with Attachment B.</p> <p>(3) Forwards the Quality Records Index to the DOE interface for approval.</p> <p>(4) Incorporates the Quality Records Index after approval within the file guides listed in SPP 6.01.</p> <p>(5) Keeps the Quality Records Index current and obtains review and approval as in steps 5.a.(3) and 5.a.(4) for each revision.</p> <p><u>Note:</u> Once the Quality Records Index is established, categories should not be deleted unless either every quality record in that subject has exceeded its retention time and has been dispositioned, or no quality records have been generated in the category being deleted.</p> <p>(6) Distributes the Quality Records Index for information to document preparers.</p>

b. Preparation of Documents as Quality Records

<u>Performer</u>	<u>Action</u>
Preparer	<p>(1) Collects and assembles the document(s) that are quality record(s).</p> <p>(2) Ensures quality records are legible, current, complete, and are clearly identifiable to the associated item or activity.</p> <p><u>Note:</u> The original should normally be used. When the original is not used, the record must be a reproducible copy of the original.</p> <p>(3) Ensures any corrections are made by drawing a single line through the incorrect information, entering the correct information adjacent, and signing and dating beside the new entry.</p> <p><u>Note:</u> Use of correction fluid and erasure of information is not acceptable.</p> <p>(4) Ensures duplicate documents are not included unless the duplicate(s) contains pertinent comments and/or significant notations or corrections.</p> <p>(5) Authenticates each quality record or any document in the quality record that is not authenticated by signing and dating in black ink.</p> <p>(6) Prints or letters the name or initials immediately adjacent using black ink, in the event signatures or initials are illegible.</p>

<u>Performer</u>	<u>Action</u>
Preparer	<p>(7) Arranges the documents which will comprise each quality record chronologically or logically according to the subject matter or as determined by the document originator.</p> <p>(8) Initiates a Quality Record Verification Sheet by completing the top portion and attach to the front of each quality record (see Attachment C).</p> <p><u>Note:</u> The bottom portion of the Quality Record Verification Sheet is completed by the Quality Records Coordinator at receipt of the record.</p> <p>(9) Secures each quality record or group of records in a binder, folder, or in an envelope.</p>

c. Transfer and Receipt of Quality Records

<u>Performer</u>	<u>Action</u>
Preparer	<p>(1) Prepares a Quality Records Inventory List and Receipt (see Attachment D) form showing the identification of each quality record being transferred.</p> <p>(2) Transfers quality records to the Quality Records Coordinator.</p>
Quality Records Coordinator	<p>(3) Receives quality records which have been transferred.</p> <p>(4) Verifies that each quality record received is complete and as represented on the originator's Quality Records Inventory List and Receipt, and the Quality Verification Record Sheet.</p>

Performer

Action

Quality Records
Coordinator

Note: Unacceptable records are returned to the Preparer with an explanation of the deficiencies. The Preparer corrects the deficiencies and resubmits.

- (5) Completes bottom portion of the Quality Verification Sheet.
- (6) Returns a receipt copy of each Quality Records Inventory List and Receipt to the preparer, and proceeds to store quality records in accordance with SPP 7.02.

d. Corrections and Supplements to and Invalidation of Quality Records

Performer

Action

QAS

- (1) Obtains copy of a quality record to be corrected from the Quality Records Coordinator.
- (2) Routes quality records to be corrected to the Document Preparer.

Note: When the preparing individual or organization is no longer available, efforts should be made to route the change to an equivalent individual or organization. If this cannot be done, the QAS will perform steps 5.d.(3) through 5.d.(5) and will attach a Memorandum to File explaining the reason why the preparer was unable to make the correction.

<u>Performer</u>	<u>Action</u>
Preparer	<p>(3) Corrects the quality record by drawing a single line through the incorrect information, enter the correct information immediately adjacent to the incorrect information, and sign and date the new entry.</p> <p>(4) Adds appropriate supplemental material to the quality record, clearly identifying the supplementary material and sign and date each supplement.</p>
QAS	<p>(5) Forwards corrected copy to the QAS.</p> <p>(6) Obtains review and approval of the revision.</p> <p>(7) Prepares the revised record as a quality record in accordance with section 5.a, clearly noting it is a revised record.</p>
Quality Records Coordinator	<p>(8) Annotates the original Quality Record Verification Sheet (Attachment C) and the Quality Records Inventory List and Receipt (Attachment D) by assigning a revision number to the quality record and signs and dates the annotations.</p>

Note: The original quality record should remain in storage for the retention period.

e. Records

<u>Performer</u>	<u>Action</u>
QAS	<p>(1) Prepares the Quality Records Index as a quality record in accordance with section 5.b.</p>

6. ATTACHMENTS:

- a. Attachment A - Quality Record Index (Example)**
- b. Attachment B - Classification and Retention Criteria for Quality Records**
- c. Attachment C - Qualification Record Verification Sheet (Example)**
- d. Attachment D - Quality Records Inventory List and Receipt**

Attachment A

Quality Record Index (Example)

File Number**	Type of Quality Record	Applicable Standard Practice Procedures	Classification	
			Lifetime	Non Permanent*
	HLW Instructions	2.01	X	
	HLW Quality Assurance Program Description	2.03	X	
	Qualification, Training and Certification Records	3.03 through 3.05		X (3 years)
	Evaluation Plans	4.01	X	
	Audit Report Packages	4.02 and 4.03	X	
	Surveillance Reports	4.04	X	
	Operational Readiness Reviews	4.07	X	
	Peer Review Reports	4.08 and 4.09	X	
	Document Review Files	4.10 and 4.11	X	
	Deviation and Corrective Action Report Files	5.01		X (3 years)
	Immediate Action Directives	5.03	X	
	External Deviation Report File	5.04	X	
	Unusual Occurrence Reports	5.05	X	
	Quality Record Indexes & Logs	7.01	X	
	Quality Assurance Program Evaluation and Progress Reports	8.02 and 8.03	X	
	Quality Trend Files	10.01	X	
	Quality Problem File	10.01	X	

* Non permanent quality records must be retained until the High Level Waste Form Product is accepted for disposal in a Federal Repository.

** File numbers should be consistent with the numbers in SPP 6.01.

Attachment B

Classification and Retention Criteria for Quality Records

Quality Records

Documentation sufficient to demonstrate canistered waste form compliance with the WAS and implementation of this specification is to be prepared and maintained as quality records. These records are to be collected and maintained as follows.

- A. Documentation sufficient to demonstrate satisfactory implementation of the WCP shall be collected and maintained as lifetime quality records by the major participant that generated the documentation or caused it to be generated. Copies of these records shall 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. 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 shall be collected and maintained as nonpermanent quality records.**
- B. Documentation sufficient to support preparation of the WQR shall be collected and maintained as lifetime quality records by the major participant that generated the documentation or caused it to be generated. Copies of these records shall 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. Such records will be maintained by the Federal Repository Operator to satisfy any repository requirements. Other documentation generated during preparation and maintenance of the WQR shall be collected and maintained as nonpermanent quality records.**
- C. Production documentation shall be identified in a manner that facilitates positive-direct correlation between documents and canistered waste forms to which they relate.**

Attachment B (Cont'd)

- D. Production documentation shall be declared lifetime quality records and transferred to the Federal Repository Operator with the canistered waste forms to which they relate.**

- E. Copies of production documentation shall be kept and maintained by the waste form producer as non-permanent quality records. These records shall 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.**

Note: The above information is referenced in DOE/RW-0214.

Attachment C

Quality Record Verification Sheet (Example)

QUALITY RECORD VERIFICATION SHEET	
<small>Type or letter in black or blue ink</small>	
Document Type	_____
Document Subject/Title	_____
Document Date	_____
Document Author(s)	_____
Author(s) Organization:	_____
Other	_____
Total number of pages excluding this page	_____
Recorded by	_____ Date _____
Quality Record Number	_____
Index Subject	_____
Retention Date	_____ (or if lifetime, enter lifetime)
Verification of Receipt of Complete Document	_____ Date _____ <small>Quality Records Coordinator</small>

QUALITY RECORDS MANAGEMENT

1. PURPOSE:

To define the actions and responsibilities for managing, storing and dispositioning HLW records, including quality records.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. ANSI/ASME NQA-1-1986, Quality Assurance Program Requirements for Nuclear Facilities
- b. DOE Order 1324.2A, Records Disposition
- c. DOE Order 1324.3, Files Management
- d. DOE Order 5700.6, Quality Assurance
- e. SPP 6.01, Official HLW Office Files
- f. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records

4. GENERAL:

DOE records management practices are driven from two different directions. DOE Order 1324.2 establishes requirements for inventorying, managing, and dispositioning both record and nonrecord material. From DOE Order 5700.6 and DOE-RW-0214 come requirements for quality records. The DOE definition of records is sufficiently broad that quality records fall within it. This instruction implements the DOE "records" requirements which are all inclusive and also implements additional requirements imposed on "quality records." When and if any conflicts exist between "records" requirements and "quality record" requirements, the more stringent requirement applies.

Cutting off or breaking a filing series periodically helps control the volume of material in active office space and in filing equipment. It makes possible the

transfer or disposal of subject files in uniform chronological blocks. Cutoff periods are established for all subject files. The interval between cutoffs is not necessarily the same for all filing series. The interval in each instance is determined by factors such as use, volume, and retention period.

DOE HLW meets quality records storage requirements by a combination of temporary storage and dual storage. Quality records are accumulated within the HLW Program in a way which meets the requirements of temporary storage. During temporary storage, a dual record system is established by requiring the originator to keep a copy and also forward a copy as directed by DOE-HLW Program. Quality records in temporary storage are copied and indexed. The copies and index are then transferred to a Federal Records Center or a facility that meets the dual facility requirements within two years of the start of temporary storage. Thus, the quality records storage will be temporary until the records are copied and transferred. After transfer of the copies, storage will be considered dual.

It is suggested that personnel involved in Quality Records Management be familiar with DOE 1324.2A and 1324.3.

a. Definitions

In the definitions that follow, quality records, lifetime quality records, and non permanent quality records are quality assurance terms associated with ANSI/ASME NQA-1 and DOE/RW-0214. Records, non records, permanent records, filing series, and file stations are terms associated with management and disposition of documents that fall under DOE Order 1324.2 and DOE Order 1324.3.

- (1) **Filing Series** - A series of identical or equivalent file items characterized by a consistent method of assembly and handling, a common arrangement of the component items, and uniform as to subject, type of information recorded, or kinds of transactions reflected. A filing series may also include related elements physically separated from it, such as finding aids or bulky material.
- (2) **File Station** - A location where records are maintained for current use.
- (3) **Lifetime Quality Records** - Lifetime quality records are those quality records that meet one or more of the following criteria:
 - (a) Those which would be of significant value in demonstrating capability for safe operation.

- (b) Those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item.
- (c) Those which would be of significant value in determining the cause of an accident or malfunction of an item.
- (d) Those which provide required baseline data for in-service inspections.

Note: Lifetime quality records related to waste form production are those that are to be turned over to the repository operator for preservation.

- (4) **Nonpermanent Quality Records** - Nonpermanent quality records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records.
- (5) **Nonrecords** - Nonrecords are those classes of documentary or other material that may be disposed of without archival authority such as the following:
 - (a) Library or museum material made or acquired for reference or exhibition purposes.
 - (b) Extra copies of documents preserved only for convenience of reference on which no action is recorded or taken.
 - (c) Stocks of publications or other processed documents that require no action and are not part of a case on which action is taken.
 - (d) Routing slips and transmittal sheets adding no information to that contained in the transmitted material; i.e., concurrences, direction on how to proceed or implement.
 - (e) Papers of a private or nonofficial character that pertain to an individual's private affairs. (See Disposition of Federal records, Records Management Handbook, FSN 7610-01-055-8704.)

- (6) Permanent Records - Records that have been determined, by National Archives and Records Administration (NARA), to have historical or other value warranting permanent preservation. Such determinations are reflected in the AUTHORIZED DISPOSITION columns of NARA's General Record Schedules and DOE Records Schedules, as appropriate. Normally, permanent records are offered to NARA when they are 25 years old.
- (7) Quality Record - Completed document(s) that furnish evidence of the quality of items and/or activities affecting quality.
- (8) Records - Books, papers, maps, photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business and preserved, or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of the data in them.

5. PROCEDURE:

a. Preparation of Record Inventory and Disposition Schedule (RIDS)

Note: RIDS is a DOE form (DOE F 1324.10) that may be either hard copy or electronic media. (A copy is included as Attachment A.)

<u>Performer</u>	<u>Action</u>
File Administrator(s)	<ul style="list-style-type: none"> (1) Initiates a preliminary draft RIDS form for each file station. (2) Establishes the filing series for each file station. <p><u>Note:</u> Filing series should be congruous with the DOE Record Schedules (DOERS) listed in Attachment V to DOE 1324.2A.</p> <ul style="list-style-type: none"> (3) Records the filing series information in column 6 on RIDS.

<u>Performer</u>	<u>Action</u>
File Administrator(s)	<p>(4) Categorizes each filing series as covered by DOERS, not covered by DOERS, or nonrecord material.</p> <p>(5) For filing series covered by DOERS, completes column 7, Disposition Authority and column 8, Authorized Disposition Instructions on RIDS.</p> <p>(6) Establishes disposition instructions for nonrecord material.</p> <p>(7) Obtains DOE concurrence as appropriate on the disposition instructions.</p> <p>(8) Enters, for nonrecord filing series, "nonrecord" in column 7 of RIDS and the disposition instructions in column 8 of RIDS.</p> <p>(9) Enters, for filing series not covered in DOERS, "to be obtained" in column 7 and "to be developed" in column 8 of RIDS, then obtains approval of disposition instruction as per Chapter I of DOE Order 1324.2A.</p> <p>(10) Establishes cutoff period(s) for the files.</p> <p>(11) Obtains DOE concurrence on the cutoff period(s).</p> <p>(12) Develops instructions for file cutoff, retirement, transfer and disposition of inactive files.</p> <p>(13) Enters the instructions in column 9 of the RIDS form for each file series.</p>

b. Coordination of RIDS For Approval

<u>Performer</u>	<u>Action</u>
File Administrator(s)	(1) Rearranges the sequence of the filing series if the rearrangement enhances the understanding of the RIDS. (2) Finishes the draft RIDS by placing any discontinued filing series on separate continuation sheets. (3) Forwards the draft RIDS for review and approval to the Quality Assurance Specialist (QAS), DOE interface, or HLW Program Manager.

c. Annual Review of RIDS

<u>Performer</u>	<u>Action</u>
File Administrator(s)	(1) Reviews the RIDS annually and updates. (2) Obtains the same review and approval as in section 5.b of this instruction.

d. Management of Quality Records

<u>Performer</u>	<u>Action</u>
Quality Records Coordinator	(1) Assigns a quality record number to each quality record and records that number on the Quality Record Verification Sheet (Attachment B to SPP 7.01). (2) Assigns each quality record to a subject in the Quality Record Index (Attachment A, SPP 7.01) and records the assignment on the Quality Record Verification Sheet. (3) Determines the disposition date from the retention time for the subject in the Quality Record Index.

<u>Performer</u>	<u>Action</u>
Quality Records Coordinator	<p>(4) Enters the disposition date on the Quality Record Verification sheet. If a lifetime record enter lifetime.</p> <p>(5) Enters the quality record in the Quality Records Logs. (See Attachment B.)</p> <p>(6) Duplicates the quality record and Quality Verification Sheet and files separately for eventual transmittal to a dual records storage facility.</p> <p>(7) Files the original quality record according to the indexing system and temporarily maintains it in an environment which minimizes deterioration, damage, or loss.</p> <p>(8) Controls access to the temporary quality record files by:</p> <ul style="list-style-type: none">(a) Physically securing the files when they are not staffed.(b) Establishing and ensuring the use of a records checkout process such as Attachment C. <p>Note: Persons authorized access to the temporary quality records file shall be designated in writing.</p> <p>(9) Packages, indexes, and transfers duplicate quality records that have accumulated in logical blocks, to a Federal Records Center or other suitable dual storage facility, using a Quality Records Inventory List (Attachment C, SPP 7.01).</p> <p>(10) Logs the quality records transferred on the Quality Records Log (date transferred and storage location).</p>

e. Dispositioning Quality Records

<u>Preparer</u>	<u>Action</u>
Quality Records Coordinator	<ol style="list-style-type: none">(1) Periodically reviews the quality records indices.(2) Identifies those non-permanent quality records that have exceeded their retention times.(3) Removes the non-permanent quality records that have exceeded their retention time and treats them as records in accordance with section 5.a.

f. Dispositioning of Records

<u>Performer</u>	<u>Action</u>
Files Administrator(s)	<ol style="list-style-type: none">(1) Break files at cutoff time.(2) Separates and retains any filing series for which there is:<ol style="list-style-type: none">(a) Current or pending litigation and investigation.(b) Pending Freedom of Information matters.(c) Exceptions taken by General Accounting Offices.(3) Arranges for transfer of permanent and lifetime retention records to Federal Records Center.(4) Disposes file material scheduled to be destroyed by shredding, landfill burial, or sales waste paper.

<u>Performer</u>	<u>Action</u>
File Administrator(s)	<p><u>Note:</u> (a) Records are to be disposed of no later than 1 year after their authorized disposal dates (i.e., record material disposal dates are minimum periods of retention).</p> <p>(b) Nonrecord material is to be disposed of prior to but no later than the scheduled disposal date, (i.e., nonrecord disposal dates should be construed as maximum period of retention).</p>

6. ATTACHMENTS:

Attachment A - Records Inventory and Disposition Schedule (Example)

Attachment B - Quality Records Log (Example)

Attachment C - Quality Records Checkout Log (Example)

Attachment A

Records Inventory and Disposition Schedule (Example)

<small>DOE FORM 10 6-87</small>		RECORDS INVENTORY AND DISPOSITION SCHEDULE	<small>OMB Control No. 1010-7700</small>	<input type="checkbox"/> DOE <input type="checkbox"/> Contractor	1. Page of
2a. Organizational Unit (Creating or Custodial Unit)				2b. Routing Symbol	3. Date
4. Signatures (of appropriate personnel)					
Prepared by _____		Records Liaison Officer _____		Date _____	
Approved by _____		Records Officer Approval _____		Date _____	
5. Item No.	6. Filing Series Title, Description, and Location of File, and Inclusive Dates	7. Disposition Authority	8. Authorized Disposition Instructions	9. Transfer Instructions	

Attachment C

Quality Records Checkout Log (Example)

QUALITY RECORDS CHECKOUT LOG						
DATE CHECKED OUT	RECORD NUMBER	CHECKED OUT TO	DATE RETURNED	DATE REFILED	SIGNATURE OF FILER	REMARKS

STANDARD PRACTICE PROCEDURE

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COORDINATION OF REVIEWS AND EVALUATIONS BY OUTSIDE ORGANIZATIONS

1. PURPOSE:

To provide required instructions for coordinated reviews and evaluations by external organizations.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 4.01, Planning and Scheduling of Evaluation Activities
- b. SPP 5.06, Control and Disposition of Deviations and Recommendations for Improvement by Outside Organizations

4. GENERAL:

Various DOE and Regulatory organizations will perform reviews and evaluations of program operations as a part of their own evaluation efforts. Organizations likely to perform reviews and evaluations include: Office of Civilian Radioactive Waste Management (OCRWM); Office of the Assistant Secretary of Environmental, Safety and Health (ES&H) Organization; and the Nuclear Regulatory Commission (NRC).

It is the policy therefore to encourage joint reviews and evaluations where practical and where timing permits. Use of these joint reviews and evaluations could minimize the adverse impacts of multiple overview actions and make the best possible use of government resources.

Joint reviews and evaluations may have the program sponsor or owner as the lead organization with external organizations participating. In such a case the review or evaluation activity would be conducted in accordance with the lead organization's procedures. A Memorandum of Understanding (MOU) is currently being developed to further define joint overview practices between DOE and NRC. When this MOU is finalized, its guidance will be incorporated into this SPP.

5. PROCEDURE:

All actions may be performed by the Program Coordinator when necessary.

a. Cooperation with Reviews or Evaluations by External Organizations

<u>Performer</u>	<u>Action</u>
Program Coordinator	(1) Receives notification of scheduled reviews or evaluations by external organizations. (2) Notifies the Quality Assurance Specialist (QAS) as to the review or evaluation schedule and scope.
QAS	(3) Acts as the Coordinator for the owner/sponsor of the program and serves as primary contact for the external review and evaluation team. (4) As requested by the external review or evaluation team: (a) Arranges for meeting facilities, notification and attendance of key owner/sponsor personnel at meetings. (b) Arranges for work space for the external review or evaluation team. (c) Coordinates activities to provide assistance and arranges for access to owner/sponsor personnel activities, files, and records. (5) Prepares notes on the review or evaluation teams concerns and assists in clarifying issues.

<u>Performer</u>	<u>Action</u>
QAS	(6) Routinely apprises the Program Coordinator and affected owner/sponsor Directors of external organizations concerns. (7) Responds promptly to review and evaluation findings in accordance with SPP 5.05.

b. Records

<u>Performer</u>	<u>Action</u>
QAS	(1) Maintains external evaluation notes for working and historical purposes. <u>Note:</u> Notes and correspondence should be maintained in the external evaluation report file generated in SPP 5.05.

6. ATTACHMENTS:

None

**QUALITY ASSURANCE PROGRAM EVALUATION AND
ASSESSMENT OF ADEQUACY AND EFFECTIVENESS**

1. PURPOSE:

To provide instructions required to annually evaluate and assess the Quality Assurance Program for adequacy and effectiveness.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records

4. GENERAL:

This instruction describes the ongoing program overview practice to assess the scope, implementation, adequacy, and effectiveness of the overall Quality Assurance Program. This instruction describes how to perform this review and assessment; however, management may choose to select an outside independent organization to perform the assessment. In this case, the organization chosen will still perform the assessment in accordance with this instruction.

5. PROCEDURE:

All actions delegated by the Program Coordinator may also be performed by that office when necessary.

a. Collecting, Reviewing, and Evaluating Information

<u>Performer</u>	<u>Action</u>
Quality Assurance Specialist (QAS)	<p>(1) Routinely collects information in order to assess the effectiveness of the quality assurance program during the year including:</p> <ul style="list-style-type: none">(a) Results of Organizational Evaluation Activities.(b) Organizational Quality Progress and Review Reports.(c) Quality Trend Reports.(d) Quality Problem Reports.(e) Results of any special reviews conducted during the year.(f) Field Office Evaluation and Assessment of Contractors. <p>(2) Each year in January, reviews the collected information and determines if any additional data is necessary to adequately assess the Quality Assurance Program.</p> <p>(3) If additional information is necessary, obtains it through appropriate means.</p>

Note: This may include planning and performing additional evaluation activities.

Performer

Action

Quality Assurance Specialist (QAS)

- (4) Using the collected information, identifies accomplishments, problem areas, quality trends, and evaluation results. Then assesses the adequacy and effectiveness of program practices and instructions.

b. Preparation, Review, and Approval of the Annual Quality Assurance Program Evaluation and Assessment Report

Performer

Action

QAS

- (1) Prepares the annual evaluation and assessment report using the guidance in Attachment A.
- (2) Submits the annual evaluation and assessment report to the Program Coordinator.

Program Coordinator

- (3) Reviews the annual evaluation and assessment report and provides comments to the QAS.

QAS

- (4) Incorporates the Program Coordinator's comments, finalizes the annual evaluation and assessment report, and forwards to the Program Coordinator for final distribution.

Program Coordinator

- (5) Approves the annual evaluation and assessment report and distributes to the Sponsor(s) and Owner(s) of the Program.

c. Records

Performer

Action

QAS

- (1) Prepares the Quality Assurance Program Annual Evaluation and Assessment Report as a quality record in accordance with SPP 7.01.

6. ATTACHMENTS:

- a. **Attachment A - Guidance for the Quality Assurance Program Annual Evaluation and Assessment Report**

Attachment A

Guidance for the Quality Assurance Program Annual Evaluation and Assessment Report

TO: Organization Director

FROM: Program Coordinator

SUBJECT: Quality Assurance Program Annual Evaluation and Assessment Report

This report provides the results of my annual evaluation and assessment of the Quality Assurance Program.

- 1. Introduction - Provide a narrative summary addressing the following points:**
 - Purpose, objective, and scope of the assessment.**
 - Arrangement, form, and method of presenting results of assessment.**
 - Interpretations, limitations, cautions, or special instructions to facilitate understanding of the report.**

- 2. Overall Program Assessment - Describe in summary form those factors and conditions indicative of the current state of the Quality Assurance Program and identify the more important events and activities that have combined to produce that state. As a minimum, specific statements and/or conclusions should be made regarding the following areas related to the program:**
 - Significant events and activities taking place within the program (including Operations Offices and operating contractors) during the reporting period.**

Attachment A (Cont'd)

- **Principal efforts of the Operations Offices and the operating contractors relative to satisfactory implementation of their quality assurance programs.**
 - **Key initiatives related to development, maintenance, improvement, and management of the Operations Offices and operating contractors programs.**
 - **Current status of program defining/describing documents, including management controls at the Organizational, Operations Office, and operating contractor levels.**
 - **Overall status and effectiveness of quality problem identification and reporting systems (e.g., audits, reviews, surveillance, trends, inspections, deviation control, and other such systems).**
 - **Overall status and effectiveness of corrective action systems in terms of both preventing and controlling quality problems.**
 - **Overall status of operating contractor effectiveness in terms of qualification/training, staffing adequacy, disciplined and correct performance, team spirit and effective organizational relationships, management involvement and support.**
- Note: Contractor evaluations are based on written Operations Office evaluations and assessments and on joint evaluations and assessments.**
- **Overall status of "product quality" as reflected by the data, results, and reports referred to in section 5.a.**
- 3. Supporting Data - This section should present additional data to support the conclusions reached in the Overall Program Assessment section.**

REVIEW AND REPORTING OF QUALITY ASSURANCE PROGRAM PROGRESS AND STATUS

1. PURPOSE:

To provide instructions for the review of the HLW Quality Assurance Program on a monthly basis as well as the preparation of comprehensive program status reports for the Director, Division of Waste Management Projects.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records
- b. SPP 9.02, HLW Monthly Progress Reporting

4. GENERAL:

This report is input to the HLW Monthly Progress Report per SPP 9.02 paragraph 5.a.(1)(e).

5. PROCEDURE:

- a. **Monthly Review of Quality Assurance Program Progress and Status**

<u>Performer</u>	<u>Action</u>
Quality Assurance Specialist (QAS)	(1) Reviews Quality Assurance Program activities at the end of each month such as:

<u>Performer</u>	<u>Action</u>
QAS	<ul style="list-style-type: none">(a) Operations Offices Quality Status Reports.(b) Results of Evaluation Activities.(c) Quality Problem Reports.(d) Quality Trend Reports. <p>(2) Identifies accomplishments, problem areas, quality trends, evaluation results and assesses the adequacy of program practices and instructions.</p>

b. Preparation and Distribution of the Monthly Quality Assurance Program Progress and Status Report

<u>Performer</u>	<u>Action</u>
QAS	<ul style="list-style-type: none">(1) Organizes the material from 5.a. into a status report using the guidance in Attachment A.(2) Presents the Monthly Program Progress and Status Report to the HLW Program Manager (PM).(3) Obtains PM review and comment on the Monthly Program Progress and Status Report.(4) Incorporates PM comments and forwards the Monthly Program Progress and Status Report to the PM for approval.(5) Distributes to PM selected individuals after approval.

c. Records

<u>Performer</u>	<u>Action</u>
QAS	(1) Prepares the approved Monthly Quality Assurance Program Progress and Status Report as a quality record in accordance with SPP 7.01.

6. ATTACHMENTS:

- a. Attachment A - Example Monthly Quality Assurance Program Progress and Status Report**

Attachment A

Example Monthly Quality Assurance Program Progress and Status Report

TO: Division Director

SUBJECT: HLW QUALITY ASSURANCE PROGRAM PROGRESS AND STATUS REPORT FOR _____

(Month and Year)

This report provides the results of the monthly quality assurance program progress and status reviews and assessment of program adequacy for the month of _____

1. Progress and Accomplishments - Provide a narrative summary of specific accomplishments pertinent to quality assurance activities. Indicate previously identified problems, deviations and/or corrective actions which have been completed/closed out during the current reporting period.
2. Problems and Deviations - Identify and describe the significance of quality problems and deviations identified, including status of corrective action.
3. Quality Trends - Describe any recurring situation which could have a significant impact, either positive or negative, on quality.
4. Results of Evaluation Activities - Findings of audits, reviews, surveillance, etc. should be summarized in enough detail to give the reader a clear indication of the overall status of the organization or system involved.
5. Summary - Provide an assessment as to the adequacy of program practices and procedures.

PM

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**PREPARATION AND MAINTENANCE OF THE
PROGRAM SCHEDULES**

1. PURPOSE:

To provide instructions for the development, review, approval, and maintenance of the HLW Program Schedules.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 4.01, Planning and Scheduling of Evaluation Activities

4. GENERAL:

This instruction is formulated to provide guidance for the development and maintenance of an overall Program Schedule. This schedule is based on milestone dates from Supporting Schedules such as the Operations Office Schedules. Control of the Supporting Schedules will be by the responsible organization's implementing procedures. After initial issue of the Program Schedule in accordance with section 5.a, the schedule will be revised, updated, and reissued no less than quarterly.

The objective of this overall Program Schedule is to provide a complete picture of the program by pulling together all of the individual schedules related to the different portions of the operation at a summary level to provide an overall picture of the Program. This schedule can then provide a credible basis for evaluation planning in accordance with SPP 4.01.

a. Definitions

- (1) **Milestone** - An important or critical event and/or activity that must occur in the project cycle in order to achieve the project objective(s) (e.g., facility cold start - Operating Contractor's design and construction schedule), or Operations Office assignment (e.g., report completion of an audit of the Savannah River Operations).
- (2) **Assignment** - A work or task assignment to develop or perform an effort which may or may not relate to a major system or Program.
- (3) **Completion Due Date** - The date a scheduled milestone is required to be completed to meet the supporting schedule (e.g., late-date of a Critical Path Method [CPM] schedule).
- (4) **Forecast Due Date** - The date a schedule milestone can be finished based on available information, resources, priorities, and ability to perform (e.g., early-date of a CPM Schedule).
- (5) **Data Date** - The calendar date that provides information that a milestone is current (e.g., data is effective through the last day of the previous month).
- (6) **Schedule Approval** - The Program Schedule will be considered approved when the transmittal document is signed and issued by the DOE Program Manager or designee and dated.
- (7) **Segment Schedule** - A schedule of a work assignment or area of responsibility that is a subset of the higher level schedule and is identified on the higher schedule (e.g., Time-line Schedule, Building Schedule, or Quality Assurance Program Development and Implementation).

5. PROCEDURE:

a. Development of the Program Schedule

<u>Performer</u>	<u>Action</u>
Schedule Coordinator	<p>(1) Initiates the Program Schedule development by requesting information from operations which are responsible for individual segment schedules.</p> <p>(2) Requests, as a minimum, the following schedule information for selected milestones within the segment schedules:</p> <ul style="list-style-type: none">(a) Segment Identification.(b) Milestone description.(c) Status or progress remarks.(d) Completion due date.(e) Forecast Completion date.(f) Responsible Manager.(g) Person responsible for next action.(h) Date of the data. <p>(3) Reviews each submittal for completeness and obtains any needed additional information.</p> <p>(4) Assembles data into a draft program schedule.</p> <p>(5) Incorporates comments into a Program Schedule.</p>

<u>Performer</u>	<u>Action</u>
Schedule Coordinator	(6) Establishes a supporting data base as a basis for schedule information.
Program Coordinator	(7) Reviews Program Schedule for items of responsibility and verifies listing of all needed activities.
	(8) Concurs with the Program Schedule and forwards to the DOE designate for review and approval.
Schedule Coordinator	(9) Distributes the Program Schedule to the DOE selected personnel, QAS, Operations Offices, and Operating Contractors which provided input, with notice of the monthly update cycle and due date of required status/progress input.
	(10) Finalizes the supporting schedule data base.

b. Maintenance of the Program Schedule

<u>Performer</u>	<u>Action</u>
Schedule Coordinator	(1) Reviews data submitted by contributors in response to step 5.a.
	<u>Note:</u> Makes any needed corrections and provides requested data to Schedule Coordinator in the time frame requested.
	(2) Requests and provides information as listed in step 5.a.(2) for new milestones developed during job performance.
	(3) Assembles and reviews the submitted data and contacts appropriate personnel for needed additional information.

<u>Performer</u>	<u>Action</u>
Schedule Coordinator	(4) Revises the Program Schedule and the supporting data base using the submitted information as a basis. (5) Obtains Program Schedule review and approval as in steps 5.a.(7) through 5.a.(9). (6) Distributes the Program Schedule as in step 5.a.(10).

6. ATTACHMENTS:

None

STANDARD PRACTICE PROCEDURE

SPP 9.02
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Effective
Date 02/02/90

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HLW MONTHLY PROGRESS REPORTING

1. PURPOSE:

To provide instructions for the preparation, assembly, review, and distribution of the Monthly Progress Report as well as the summary of these reports in the Program Quarterly Progress Report.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. DOE Order 4700.1, Project Management System
- b. DOE Order 1332.1A, Uniform Reporting System
- c. SPP 9.01, Preparation and Maintenance of the Program Schedules
- d. SPP 8.03, Review and Reporting of Quality Assurance Program Progress and Status

4. GENERAL:

DOE Order 4700.1 only requires a Quarterly Project Progress Report; however, the HLW Program prepares a monthly progress report because of its size and complexity. The requirement is a Monthly Progress Report for the first two months of a quarter, then a quarterly report is prepared during the third month which sums the progress for the previous two months with the current months progress. A separate monthly report is not prepared for the last month of the quarter.

5. PROCEDURE:

a. Preparation of Project Monthly Progress Report

<u>Performer</u>	<u>Action</u>
Program Control Assistant	(1) Collects input for HLW Monthly Progress Report.
	<u>Note:</u> Input includes but is not limited to: <ul style="list-style-type: none">(a) Work change orders approved and in process.(b) Changes in principal agreements.(c) Significant program accomplishments including events, milestones met, and major alterations.(d) Contractor reports (uniform reporting system - DOE 1332.1A) as per contractual agreements and/or working agreements.(e) Monthly Quality Assurance Program Progress and Status Report (see SPP 8.03).(f) Latest Project Schedule (see SPP 9.01).
	(2) Drafts the HLW Monthly Progress Report in accordance with the guidance in DOE Order 4700.1 Chapter IV, Part B and includes a section to reflect quality assurance program progress and status.

<u>Performer</u>	<u>Action</u>
Program Control Assistant	(3) At the end of each calendar quarter, prepares the HLW Monthly Progress Report as a Project Quarterly Progress Report and includes progress and status for the entire quarter.
	<u>Note:</u> When appropriate, some of the input may be used in total, such as the Project Schedule and the Monthly Quality Assurance Program Progress and Status Report.
	(4) Forwards to the Program Coordinator for review.
Program Coordinator	(5) Reviews and forwards to the DOE Designate for review and approval.

b. Records

<u>Performer</u>	<u>Action</u>
Program Control Assistant	(1) Retains HLW Monthly and Quarterly Progress Reports and backup material for working and historical purposes.

6. ATTACHMENTS:

None

**PREPARATION AND MAINTENANCE OF THE WORK
BREAKDOWN STRUCTURES (WBS)**

1. PURPOSE:

To provide instructions for developing and maintaining the HLW Summary Work Breakdown Structure (SWBS).

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. DOE Order 4700.1, Project Management System
- b. DOE/MA-0295, Work Breakdown Structure Guide
- c. DOE Order 1332.1A, Uniform Reporting System

4. GENERAL:

This instruction is formulated to provide guidance for the development and maintenance of the HLW SWBS. The HLW SWBS is the summation of the program effort and is based on major elements of the HLW program responsibilities. As new major divisions are identified or revised, the SWBS will be revised to incorporate these changes.

a. Definitions

- (1) Contract WBS (CWBS) - The complete WBS for a specific contract developed by the contractor in accordance with DOE 4700.1 and DOE/MA-0295 and the contract statement of work.
- (2) Operations Office (OO) or Project Office (PO) WBS - A WBS which identifies and documents the functions and responsibilities of the OO or PO Organization.
- (3) HLW WBS - A WBS which identifies and documents the functions and responsibilities of the HLW Program Organization.

- (4) **ELEMENT (WBS)** - An individual product specified in the WBS. Each element below the end product is an item of real estate, hardware, software, data, or service. Each element name is, thus, a noun. The total of all the elements within a WBS defines the entire system or end product being developed or produced.
- (5) **Level (WBS)** - Each sub-breakdown of the WBS.
- (6) **Program Plan** - A document developed in accordance with DOE Order 4700.1 which describes the program and establishes how it will be accomplished plus approved program baselines by which overall progress of the program and effectiveness of its management is measured.
- (7) **Program Management Plan** - A document developed in accordance with DOE Order 4700.1 which sets forth the plans, organization, and systems needed to implement the program plan.
- (8) **Summary WBS (SWBS)** - The structure that encompasses the entire program at a summary level. The SWBS normally identifies program elements through the third level; however, lower level elements may be included when necessary to clearly define the program.
- (9) **Work Breakdown Structure (WBS)** - A product (something that costs money and takes time) oriented family tree composed of real estate, hardware, software, data, and/or services. The WBS completely defines the program and relates elements of work to each other and to the total product.

5. PROCEDURE:

a. Development of the SWBS

<u>Performer</u>	<u>Action</u>
Program Control Assistant	<ul style="list-style-type: none"> (1) Obtains Work Breakdown Structure from each support contributor for HLW work and forwards to the Program Coordinator. (2) Reviews each WBS to assure each meets requirements of DOE 4700.1 and DOE/MA-0295 and coordinates as required with contributors.

<u>Performer</u>	<u>Action</u>
Program Control Assistant	(3) Integrates the first 3 levels of each WBS and the WBS into the SWBS in a flow diagram format (see Attachment A for sample). (4) Develops and documents the SWBS Dictionary in accordance with DOE/MA-0295 on forms DOE F1332.10 and DOE F1332-11. (See Attachment B for samples.)
Program Coordinator	(5) Reviews the SWBS and SWBS Dictionary and secures DOE approval. (6) Reviews and returns the approved document to the Program Control Assistant.
Program Control Assistant	(7) Coordinates or performs the incorporation of the SWBS into the HLW Program Plan and incorporation of the SWBS Flow Diagram and Dictionary into the DWPF Program Management Plan in accordance with DOE 4700.1. (8) Assembles the SWBS, HLW WBS, CWBS and DWPF-PO WBS data and information into a database for background of WBS development for reviews and later revisions.

b. Updating and Revising the SWBS

<u>Performer</u>	<u>Action</u>
Program Control Assistant	(1) Receives information requiring SWBS revision (e.g., WBS revision, addition of new project-related contract, project function re-assignment).

<u>Performer</u>	<u>Action</u>
Program Control Assistant	(2) Notifies coordinator for Program Plan and Program Management Plan that the SWBS is being revised. (3) Revises the affected portions of the WBS and prepares for review. (4) Forwards the revised SWBS Flow Diagram and Dictionary with reason for revision to Project Coordinator for concurrence and approval.
Program Coordinator	(5) Reviews and secures DOE approval of the revised SWBS Flow Diagram and Dictionary, and returns to the Program Control Assistant.
Program Control Assistant	(6) Coordinates or performs the incorporation of the revised SWBS into the Program Plan, and incorporation of the revised SWBS and SWBS Dictionary into the overall Program Management Plan. (7) Revises the data base developed in step 5.a.(12) to include background data and information for revision.

c. Records

<u>Performer</u>	<u>Action</u>
Program Control Assistant	(1) Maintains a file with WBS background information for working and historical purposes.

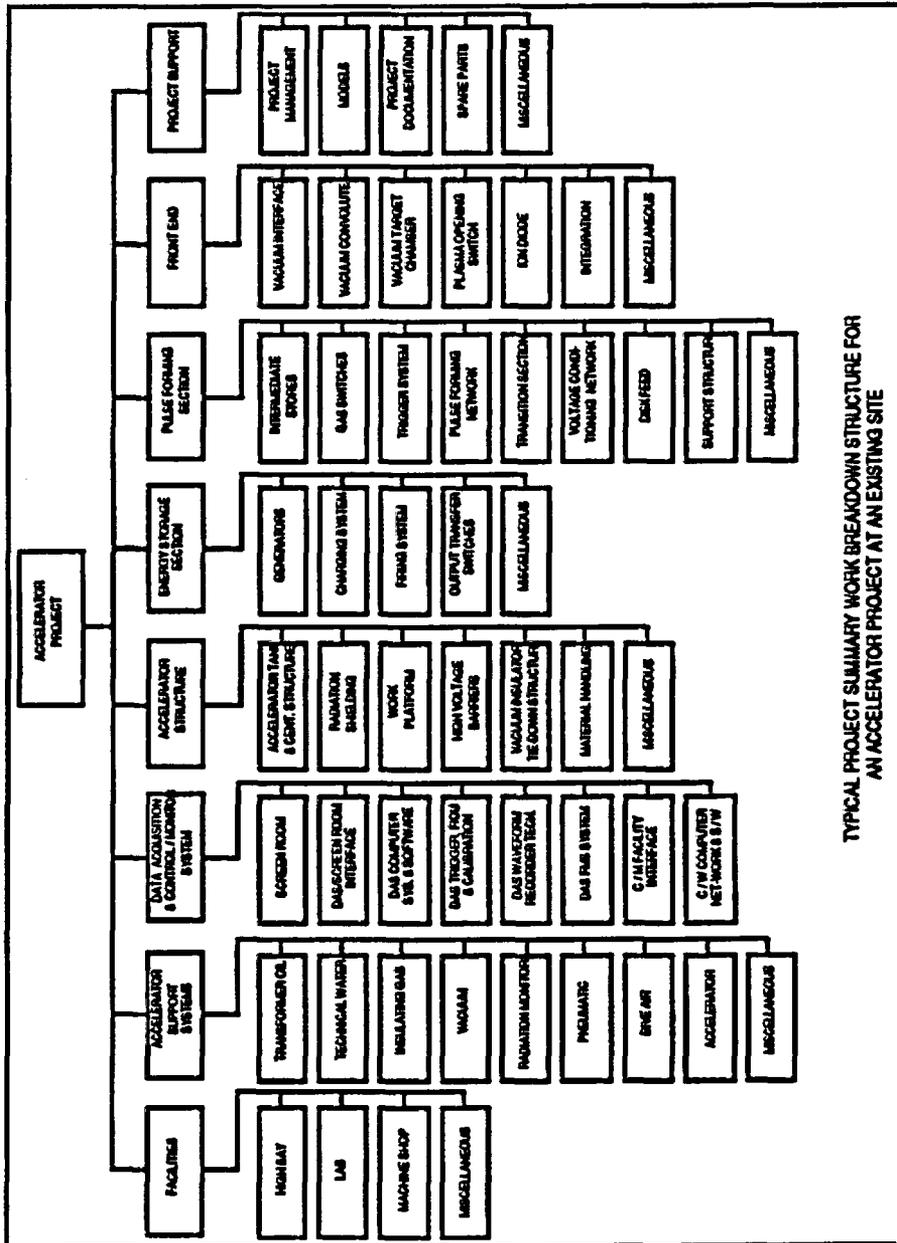
Note: The official SWBS resides in the program plan and the SWBS and SWBS Dictionary in the program management plan.

6. ATTACHMENTS:

- a. Attachment A - Sample Work Breakdown Structure**
- b. Attachment B. - Sample WBS Dictionary**

Attachment A

Work Breakdown Structure (WBS) (Sample)



TYPICAL PROJECT SUMMARY WORK BREAKDOWN STRUCTURE FOR AN ACCELERATOR PROJECT AT AN EXISTING SITE

Attachment B

Sample WBS Dictionary
Page 1

WORK BREAKDOWN STRUCTURE DICTIONARY

- 1. Work Breakdown Structure Dictionary
Part I - Index (DOE Form 1332.10)**
- 2. Work Breakdown Structure Dictionary
Part II - Element Definition
(DOE Form 1332.11)**

Attachment B (Cont'd)

Sample WBS Dictionary
 Page 2 - Part I - Index

U.S. DEPARTMENT OF ENERGY												
WORK BREAKDOWN STRUCTURE DICTIONARY												
PART I - Index												
DOE F1332.10 (11/84)								FORM APPROVED OMB NO. 1901-1400				
1. PROJECT TITLE/PARTICIPANT				2. DATE			3. IDENTIFICATION NUMBER					
Energistic Corporation				10-1-86			DE-AC01-86HQ21347					
LINE NO.	4. WBS ELEMENTS							5. PARTICIPANT WBS ELEMENT CODE	7. BUDGET AND REPORTING NO.	6. PHASE	8. OTHER	
	INDENTURE LEVEL										COA ¹	SOW ²
	1	2	3	4	5	6	-					
1	X							*Energistic Unit	1.0		3C	
2		X						*Site	1.1	39EC0304		3.0
3			X					*Improved Land	1.1.1		460	3.1
4				X				Graded Land	1.1.1.1			
5				X				Roads and Walks	1.1.1.2			
6				X				Fences	1.1.1.3			
7				X				Parking Lots	1.1.1.4			
8				X				Landscaping	1.1.1.5			
9			X					*Buildings	1.1.2		501	3.2
10			X					Building #1	1.1.2.1			
11				X				*Foundation and Substructure	1.1.2.1.1			
12					X			Excavation	1.1.2.1.1.1			
13					X			Pillings	1.1.2.1.2.1			
14					X			Sub Level Slabs	1.1.2.1.3.1			
15					X			Ground Level Slabs	1.1.2.1.4.1			
16				X				*Superstructure	1.1.2.1.2			
17					X			Framing	1.1.2.1.2.1			
18					X			Upper Levels	1.1.2.1.2.2			
19					X			Shell	1.1.2.1.2.3			
20					X			Exterior Finishing	1.1.2.1.2.4			
21					X			Interior Finishing	1.1.2.1.2.5			
22		X						*Structures (S/C)	1.1.3	39EC0508	550	3.3

¹ COA = Code of Accounts
² SOW = Statement of Work

Attachment B (Cont'd)

Sample WBS Dictionary
Page 3 - Part II - Element Definition

U.S. DEPARTMENT OF ENERGY

WORK BREAKDOWN STRUCTURE DICTIONARY
PART II - ELEMENT DEFINITION

DOE F1332.11
(11/84)

FORM APPROVED
OMB NO.1901-1400

1. PROJECT TITLE/PARTICIPANT Energistic Corporation		2. DATE 10-1-86	3. IDENTIFICATION NUMBER DE-AC01-86HQ21347
4. WBS ELEMENT CODE 1.1.1		5. WBS ELEMENT TITLE Improved Land	
6. INDEX LINE NO. 3	7. REVISION NO. AND AUTHORIZATION N/A		8. DATE N/A
9. APPROVED CHANGES N/A			
10. SYSTEM DESIGN DESCRIPTION Number: 48E32 (1.1.1) Title: Improved Land		11. BUDGET AND REPORTING NUMBER N/A	
12. ELEMENT TASK DESCRIPTION			
<p>a. Cost Constant</p> <p>Civil Engineering Labor Construction Labor Purchased Material Subcontracted Efforts:</p> <p>Overhead Cost of Money G&A</p> <p>Transportation Warehousing Equipment Rental</p>			
<p>b. Technical Content</p> <p>74.2 acre triangular graded, cleared and landscaped plot at N.E. junction of Ronald Reagan Blvd and Jimmy Carter Avenue, and adjoining the Mohawk River on the remaining side. Includes 18.1 miles chain link perimeter fence for industrial grade security, with 2 electrically powered gates to give vehicle and pedestrian access to both adjoining roads. Includes 5.8 acre rectangular asphalt lot to park 20 passenger vehicles. 2.3 miles asphalt roadway to link parking lot with both adjoining roads, roadway curbs with drains to channel runoff to river, and 3.2 miles concrete sidewalk to connect gates and buildings.</p>			
<p>c. Work Statement</p> <p>Note: Most major work is performed at lower WBS levels.</p> <p>Engineering: Prepare integrating design documents; Monitor and evaluate integration of lower level element construction; Provide integrating design changes as required; Prepare integrated as-built drawings.</p> <p>Construction: Integrate lower level elements.</p>			

STANDARD PRACTICE PROCEDURE

SPP 10.01
Page 1 of 5
Rev. 0
Effective
Date 02/02/90

IDENTIFICATION AND ANALYSIS OF ADVERSE QUALITY TRENDS AND PROBLEMS

1. PURPOSE:

To provide instructions for monitoring product and programmatic data to identify and analyze adverse quality trends and problems.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 10.02, Planning and Conduct of Quality Improvement
- b. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records

4. GENERAL:

The DOE HLW Program routinely monitors the results of evaluation activities (audits, surveillance, reviews, etc.) progress and status reports, and other informational records to identify adverse quality trends and/or previously unidentified quality problems. Adverse trends and problems are then studied to identify the causes and contributors. Actions are then planned and conducted in accordance with SPP 10.02 to improve quality and to improve efficiency and effectiveness.

5. PROCEDURE:

a. Identification of Adverse Quality Trends and Problems

<u>Performer</u>	<u>Action</u>
Quality Assurance Specialist (QAS)	(1) Monitors program feedback information quarterly (see Attachment A for typical sources of program feedback).
	(2) Identifies adverse trends or quality problems using the feedback information.

<u>Performer</u>	<u>Action</u>
QAS	<p>Note: Where sufficient quantity and kinds of data are available, statistical analysis should be used where meaningful to identify adverse quality trends. When these kinds of data are not available, identification will depend on the judgment of the QAS.</p> <p>(3) Documents each adverse quality trend or problem in Sections 1 and 2 of a Adverse Quality Trend/Problem Report (Attachment B).</p> <p>(4) Signs the Adverse Quality Trend/Problem Report and forwards to the DOE Program Manager (PM) for concurrence and approval.</p>

b. Analysis of Adverse Quality Trends and Problems

<u>Performer</u>	<u>Action</u>
QAS	<p>(1) Analyzes the adverse quality trend/problem.</p> <p>(2) Determines the root cause(s) and contributors to the adverse quality trend/problem (indicate causes and contributors that were identified on earlier Adverse Quality Trend/Problem Reports).</p> <p>Note: Affected managers should be utilized in determining the root causes.</p> <p>(3) Documents the analysis, causes, and contributors in Section 3 of the Adverse Quality Trend/Problem Report, and signs.</p> <p>(4) Forwards the Adverse Quality Trend/Problem Report to the PM for concurrence and approval.</p>

<u>Performer</u>	<u>Action</u>
QAS	(5) Distributes the Adverse Quality Trend/Problem Report to PM selected individuals.
	(6) Initiates quality improvement in accordance with SPP 10.02.

c. Records

<u>Performer</u>	<u>Action</u>
QAS	(1) Prepares the Adverse Quality Trend/Problem Report as a quality record in accordance with SPP 7.01.

6. ATTACHMENTS:

- a. Attachment A - Typical Sources of Program Feedback Information
- b. Attachment B - Adverse Quality Trend/Problem Report (Example)

Attachment A

Typical Sources of Program Feedback Information

Adverse Quality Trend/Problem Reports
Audit Reports
Change Orders and changes in Basic Data
Contractor Progress and Status Reports
Contractor reported non-conformances and deviations
Design Review Reports
Deviation and Corrective Action Reports
Inspector, Examination, and Test Results
Operational Readiness Review Reports
Peer Review Reports
Procurement Document Review Reports
Quality Assurance Program Progress and Status Reports
Reviews and evaluations by outside organizations
Reviews and Evaluations by internal organizations
Surveillance Reports
Technical Documents Review Reports
Unusual Occurrence Reports

Attachment B

Adverse Quality Trend/Problem Report (Example)

ADVERSE QUALITY TREND / PROBLEM REPORT	
_____ ADVERSE QUALITY TREND / PROBLEM REPORT NUMBER	_____ DATE
PAGE 1 OF _____ <small>(Show pagination on all attachments)</small>	
1) IDENTIFICATION OF ADVERSE QUALITY TREND / PROBLEM 	
2) DATA SOURCES USED FOR IDENTIFICATION 	
LEQA _____	DATE _____
PM CONCURRENCE _____	DATE _____
3) ANALYSIS OF TREND / PROBLEM 	
LEQA _____	DATE _____
PM CONCURRENCE _____	DATE _____

STANDARD PRACTICE PROCEDURE

SPP 10.02
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Rev. 0
Effective
Date 02/02/90

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PLANNING AND CONDUCT OF QUALITY IMPROVEMENT

1. PURPOSE:

To define responsibilities for planning and conducting quality improvement activities which are not addressed within deviation and corrective action control systems.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

- a. SPP 10.01, Identification and Analysis of Adverse Quality Trends and Problems.
- b. SPP 4.01, Planning and Scheduling of Evaluation Activities.
- c. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records.

4. GENERAL:

This instruction addresses the planning and conduct of quality improvement for those adverse quality trends and/or problems identified and analyzed in accordance with SPP 10.01.

5. PROCEDURE:

<u>Performer</u>	<u>Action</u>
Quality Assurance Specialist (QAS)	(1) Initiates quality improvement planning by logging the adverse quality trend/problem on a Quality Improvement Log (Attachment A). Documents each adverse quality trend/problem in accordance with SPP 10.01 on a Quality Trend/Problem Report.

<u>Performer</u>	<u>Action</u>
QAS	<ul style="list-style-type: none">(2) Monitors improvements developed to address the root causes and contributors to the adverse quality trend/problem identified.(3) Documents proposed improvement actions in a plan similar to Attachment B, with a plan and schedule for implementation.(4) Forwards the Quality Improvement Plan to the HLW Program Manager (PM) for review and approval.(5) Distributes to PM selected individuals.(6) Prepares the original as a quality record.(7) Logs the approval of quality improvement actions on the Quality Improvement Log.

b. Conduct of Quality Improvement Activities

<u>Performer</u>	<u>Action</u>
QAS	<ul style="list-style-type: none">(1) Follows actions necessary to implement the plan for quality improvement. Supports the PM by drafting memorandums or letters as appropriate.(2) Informs the PM of progress.(3) Verifies accomplishment of quality improvement action and logs the completion date on the Quality Improvement Log.

<u>Performer</u>	<u>Action</u>
QAS	<u>Note:</u> Verify accomplishment of quality improvement actions using SPP 4.01 when warranted by complex or important actions.

c. Records

<u>Performer</u>	<u>Action</u>
QAS	(1) Prepares Quality Improvement Logs and Plans as quality records in accordance with SPP 7.01.

6. ATTACHMENTS:

- a. Attachment A - Quality Improvement Log (Example)
- b. Attachment B - Quality Improvement Plan (Example)

Attachment A

Quality Improvement Log (Example)

QUALITY IMPROVEMENT LOG				
ADVERSE QUALITY TREND/PROBLEM	DATE DOCUMENTED	DATE QUALITY IMPROVEMENT PLAN COMPLETED	QUALITY IMPROVEMENT ACTIONS COMPLETED	
			DATE	VERIFIED BY

* Date Documented by the PM

Attachment B

Quality Improvement Plan

Quality Improvement Plan

(Date)

Quality Improvement Plan for _____

In response to the adverse quality trend/problem documented on
(date) _____ in regard to _____ this quality
improvement plan has been developed.

Quality Improvement Actions:

Describe those actions necessary to address the root causes and contributors to the adverse quality trends/problem.

Plan and Schedule:

Detail a plan and schedule for accomplishment of the quality improvement actions.

(PM)

cc: QAS (Original)
PM Selected Individuals

STANDARD PRACTICE PROCEDURE

SPP 10.03
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Rev. 0
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DIFFERING STAFF OPINIONS AND ALLEGATIONS

1. PURPOSE:

To provide guidelines, assign responsibilities and actions which will document, evaluate, and respond to differing staff opinions or allegations that relate to issues of inadequate quality or safety.

2. SCOPE:

The provisions of this Standard Practice Procedure (SPP) apply only to the organization(s) that has adopted this SPP for its own use or that has had it invoked by contractual or other means.

3. REFERENCES:

None

4. GENERAL:

It is organizational policy that differing staff opinions including employee concerns, are valued and can be brought to management's attention without fear of reprisal. It is also policy to evaluate and respond to allegations of inadequate quality or safety made to or against management or its personnel.

Employees are encouraged to resolve or attempt to resolve differing staff opinions or employee concerns informally with direct communication with their immediate supervisors or managers. When such resolution attempts are unsatisfactory, the person(s) involved may formally process his/her differing opinion or concern in accordance with this instruction.

a. Definitions

- (1) Allegation - An assertion made to or against management which cites existing or potential conditions of inadequate quality or safety without, at the same time, furnishing complete and positive proof of the allegation.
- (2) Differing Staff Opinion - An employee view or concern which differs from that of the employee's management or DOE decisions or policies; and in the opinion of that employee, relates to: (a) the project's Quality Assurance Program; or (b) the quality of a product

or service covered by the project's Quality Assurance Program; or
 (c) issues of health and safety of employees and the general public.

- (3) **Investigator** - The person(s) assigned by management to determine the validity of the allegation and to make recommendations for corrective action (if required).

5. PROCEDURE:

All actions not involving the Concerned Individual may be performed by the affected Manager.

a. Documenting Differing Opinions or Concerns

<u>Performer</u>	<u>Action</u>
<p>Concerned Individual</p>	<ul style="list-style-type: none"> (1) Informally expresses differing opinions or concerns regarding organizational or DOE decisions or policies, or their execution, to his/her immediate supervisor/manager. (2) If resolution of the differing opinion is not obtained informally, may elect to document his/her concern or opinion on the Employee Differing Staff Opinion Form (Attachment A). <p>Note: Confidentiality will be maintained if the employee so desires. The employee need not sign the originator portion of the Differing Staff Opinion Form. The employee may anonymously submit the form to the affected manager, who shall respond and post for 30 days the response on the organization's Bulletin Board where other legal notices are posted.</p> <ul style="list-style-type: none"> (3) If anonymity is not desired, presents the Differing Staff Opinion Form to his/her manager.

b. Processing of Documented Differing Opinions or Concerns

<u>Performer</u>	<u>Action</u>
Affected Manager	(1) Receives the Differing Staff Opinion Form and discusses it with the concerned individual (if not anonymously submitted). (2) Assigns an identification number and enters in the Allegations and Differing Staff Opinion Log, Attachment B. (3) Proposes a resolution to the issue to the concerned individual as soon as practicable. (4) If the resolution is acceptable to the concerned individual, documents the proposed resolution on the Differing Staff Opinion Form.
	<p>Note: If resolution is not acceptable proceeds to step 7.</p>
Concerned Individual	(5) Indicates his/her concurrence with the proposed resolution on the Differing Staff Opinion Form and signs and dates the form.
Affected Manager	(6) Provides a copy of the completed Differing Staff Opinion Form to the originator and files the original. (7) When resolution is not obtained, documents the discussion(s) with the originator on a memorandum and forwards the memorandum and Differing Staff Opinion Form to his/her immediate higher-level manager.
Higher-Level Manager	(8) Reviews the memorandum and all related data and, if the concern is not anonymous, discusses the issue with the originator and the affected manager.

<u>Performer</u>	<u>Action</u>
Higher-Level Manager	<p>(9) Proposes resolution to the issue as soon as practicable.</p> <p>(10) Proceeds as in steps 3 through 6, unless the proposed resolution remains unacceptable to the initiator, in which case the stated concern will be further escalated up through the management chain until a final decision is rendered.</p>

Note: At any time the concerned individual feels that proceeding up through the management chain will be ineffective, the individual may choose to forward the Differing Staff Opinion Form to the DOE Headquarters Site Environmental, Safety, and Health Representative.

Affected Manager	(11) Upon closure, completes the entry in the Allegations and Differing Staff Opinions Log.
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c. Documenting and Processing Allegations

<u>Performer</u>	<u>Action</u>
Concerned Individual	(1) Expresses allegation(s) of inadequate quality, safe operation of a facility, the health and safety of personnel or at the public or the protection of the environment to any member of management.

<u>Performer</u>	<u>Action</u>
Concerned Individual	<p>Note: This concerned individual may be a member of the general public. Allegations may also be received from other outside organizations. In those cases the processing follows the same procedure as if the allegation was received internally by management, except the contact is channeled back to the organization that forwarded the allegation.</p>
Employee Receiving Allegation	<p>(2) If verbally received, requests the concerned person to put his/her concern in writing.</p> <p>Note: If the concerned individual does not, or cannot, put the allegation in writing, then the writeup should be done by the person receiving the allegation, using care to be specific and to "boundary" the allegation. The employee shall then attempt to ensure, with the allegator, that the statement of allegation is correct and complete.</p> <p>If the allegator desires to remain anonymous, the anonymity must be maintained.</p>
Affected Manager	<p>(3) Forwards the documented allegation to the affected manager.</p> <p>(4) Assigns an identification number and enters it in the Allegation and Differing Staff Opinions Log.</p> <p>(5) Arranges for an investigation of the allegation (generally someone removed from the line organization or the area being investigated).</p>

<u>Performer</u>	<u>Action</u>
Investigator	<p>(6) Investigates the allegation, and documents the findings.</p> <p>(7) Forwards the findings to the affected manager.</p>
Affected Manager	<p>(8) Initiates any corrective action, further investigation, or other action.</p> <p>(9) Documents any initiation of action.</p> <p>(10) Forwards the documentation of the proposed or initiated corrective action, and, when appropriate, a copy of the investigation report is provided to the person who received the allegation.</p> <p>(11) Keeps appropriate members of management informed.</p>
Person Receiving Allegation (or affected Manger)	<p>(12) Informs the concerned persons of actions taken. If he/she is anonymous, proceeds according to initial instructions to the extent possible.</p> <p>(13) Documents that the person was informed.</p> <p>(14) Forwards the closure documentation to the affected manager.</p> <p>(15) Informs the affected manager if the allegation is not resolved by the corrective action.</p>
Affected Manager	<p>(16) Initiates further action as appropriate and pursues resolution until satisfactory disposition is achieved.</p>

<u>Performer</u>	<u>Action</u>
Affected Manager	(17) Closes entry in the Allegations and Differing Staff Opinions Log.

d. Records

<u>Performer</u>	<u>Action</u>
Affected Manager	(1) Maintain files of allegations, employee concerns, and differing opinions for historical purposes.

6. ATTACHMENTS:

- a. Attachment A - Employee Differing Staff Opinions Form
- b. Attachment B - Allegations and Differing Staff Opinions Log

Attachment A

Employee Differing Staff Opinions Form

EMPLOYEE DIFFERING STAFF OPINIONS	
STATEMENT OF DIFFERING OPINION:	

Name of Employee _____	Date _____
Received By _____	Date _____
RESOLUTION:	
Evaluator _____	Date Evaluation Complete _____
Resolution _____	

Prepared By _____	Date _____
Review By _____	Date _____
CLOSURE:	
Employee Notified On _____	(Date)
Employee Comments _____	

Employee Notified By _____	Employee Signature _____ Date _____
(Signature)	Date _____

