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7. Abstract

This Quality Assurance Program Plan is being revised as a supporting document for Project W-236A.

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**MULTI-FUNCTION WASTE
TANK FACILITY
QUALITY ASSURANCE
PROGRAM PLAN
PROJECT W236A**

Issued by:

WESTINGHOUSE HANFORD COMPANY

APRIL 1995

Prepared for the U.S. DEPARTMENT OF ENERGY
RICHLAND FIELD OFFICE
RICHLAND, WASHINGTON

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**MULTI-FUNCTION WASTE TANK FACILITY
QUALITY ASSURANCE PROGRAM PLAN**

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MULTI-FUNCTION WASTE TANK FACILITY PROGRAM DESCRIPTION

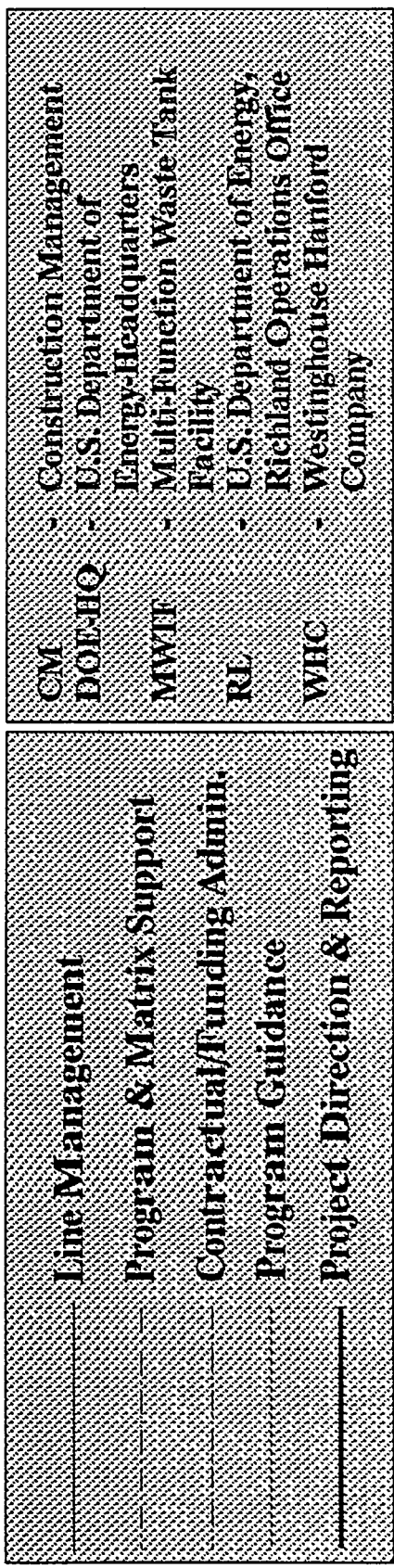
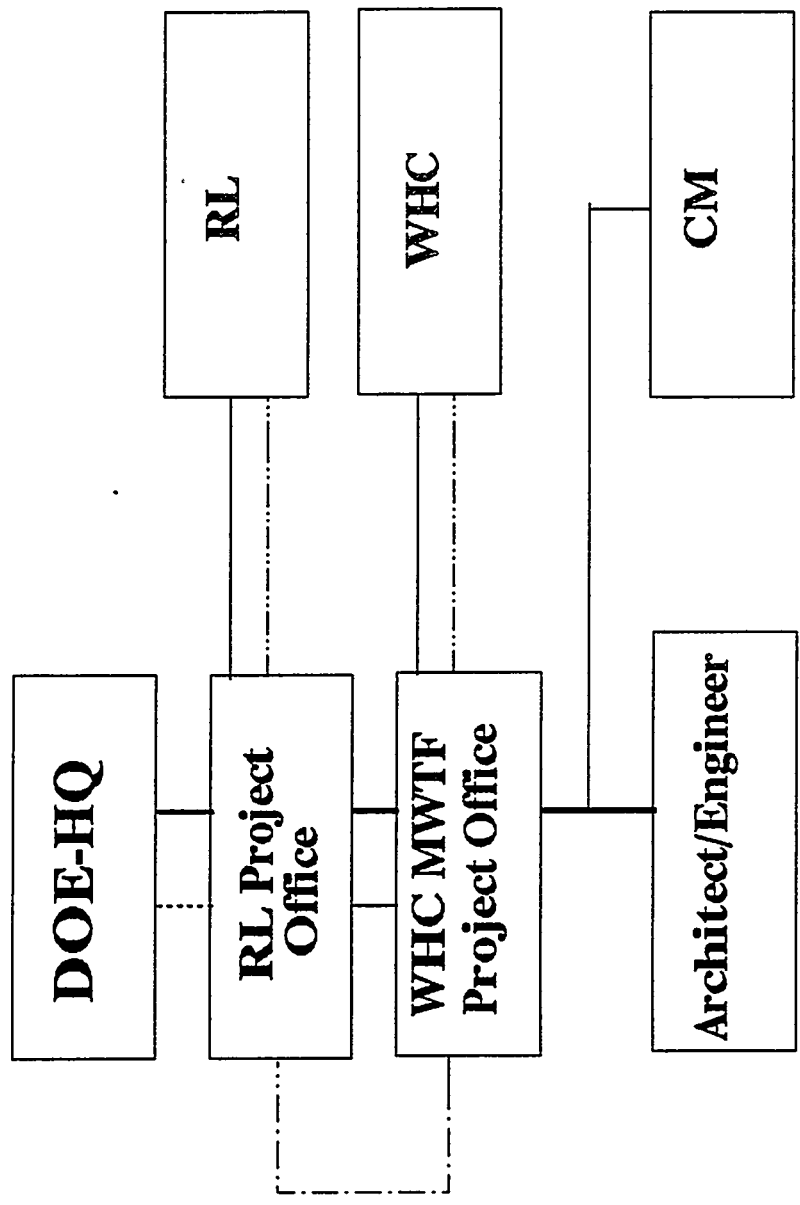
This document describes the Quality Assurance (QA) program for the Multi-Function Waste Tank Facility (MWTF) Project. The purpose of this QA program is to control project activities in such a manner as to achieve the mission of the MWTF Project in a safe and reliable manner. The QA program for the MWTF Project is founded on DOE Order 5700.6C, *Quality Assurance*, and implemented through the use of ASME NQA-1, *Quality Assurance Program Requirements for Nuclear Facilities* (ASME 1989 with addenda 1a-1989, 1b-1991 and 1c-1992).

This document describes the program and planned actions which the Westinghouse Hanford Company (WHC) will implement to demonstrate and ensure that the project meets the requirements of DOE Order 5700.6C through the interpretive guidance of ASME NQA-1.

The Project Participants (participants) are responsible for a QA program covering the quality requirements applicable to their assigned tasks and for work performed by others in support of those tasks. The W236A Project QA program, which controls all participant QA programs, is described in this Multi-Function Waste Tank Facility Quality Assurance Program Plan (QAPP) and is passed on selectively through the design documents. The MWTF QAPP and the participant QA plans and implementing procedures collectively control the total W236A Project QA program.

The MWTF Project organizational relationships are defined in Figure 1-1. Each of the participating organizations shown in Figure 1-1 has an assigned individual responsible for the quality activities described by the Statement of Work (SOW), contract, Letter of Instruction (LOI), or work order for that participant. The cognizant quality engineer(s) report to management within their respective organizations, ensuring independence from cost and schedule considerations and provide direct communications channels with appropriate levels of project management.

Figure 1-1
Multi-Function Waste Tank Facility Project Organization



1.0 ORGANIZATION

1.1 GENERAL

This section describes the organizational responsibilities and authorities for the project and identifies organizational interfaces among the participants. The assignment of responsibilities is based on the project policy to establish quality assurance requirements and ensure that the risks and environmental impacts are minimized. Safety, reliability, and performance are maximized through the application of effective management systems commensurate with the risks posed by the facility and its work. Senior management provides planning, organization, direction, control, and support to achieve the organizations objectives; the line organization achieves quality; and the overall performance is reviewed and evaluated using a rigorous assessment process.

Several organizations are involved in the MWTF Project. The design and construction of the project represent an integrated effort by the DOE; the Integrating Contractor (Operations and Engineering Contractor; O&EC); the Architect/Engineer (A-E); the Construction Management (CM); and the Construction Contractor (CC). The involvement of numerous participants underscores the need to effectively integrate activities to reduce or eliminate redundancies. The potential problem of overlap in responsibilities among participants has been addressed by adopting an integrated management team approach for the project. An organization chart documenting the interfaces of the participants in this approach is shown in Figure 1-1. Additional charts depicting the organization of the project appear in this section (see Figures 1-2 and 1-3). The development of the QA requirements for the project is primarily the responsibility of WHC, with assistance from the A-E and CM.

Each affected organization is required to identify the position within its organization responsible for the establishment and implementation of its QA program. The following characteristics are required of this position:

- An organizational position at the same or higher organization level as the highest line manager responsible for performing activities affecting quality
- Knowledge and experience in the areas of quality assurance and management
- The authority and responsibility to verify the adequacy and implementation effectiveness of the QA programs of organizations and subtier organizations
- No other duties or responsibilities unrelated to QA that could prevent full attention to QA program matters
- Sufficient freedom from cost and schedule considerations when such considerations could impact quality considerations

- Access to senior management and management at the next higher program organizational level to identify, and obtain resolution of, unresolved quality concerns
- Review and approval recommendation authority for QA programs and for revising and interpreting those programs.

The specific responsibilities and authorities for interface among the participants are described in the remainder of this section.

1.2 U. S. DEPARTMENT OF ENERGY-HEADQUARTERS

The DOE-Headquarters (DOE-HQ) is responsible for establishing major program direction for the MWTF Project. Directives issued by the DOE-HQ are channeled through the DOE-Richland Operations Office (RL).

1.2.1 U. S. Department of Energy, Richland Operations Office

The RL Multi-Function Waste Remediation Facility (MRF) office is responsible for providing overall management for the MWTF Project. The project objectives are to design and construct the facility. As such, the RL has total responsibility for the project QA program; the Tank Waste Projects Division Project Office (TWP PO) of RL supports in implementing this responsibility. The RL Division provides program direction and coordination of project activities through WHC.

The RL is responsible for accomplishing the management, administration, and performance of the project in accordance with established technical, cost, and schedule baselines. The RL interfaces include other RL divisions, the DOE-HQ, and the MWTF Project Office (PO).

1.2.2 Westinghouse Hanford Company Organization

1.2.2.1 Operations and Engineering Contractor - Westinghouse Hanford Company

The RL has delegated responsibility for QA and project management of the MWTF Project to WHC, which is responsible for establishing a project-level management structure and reporting system for the project.

1.2.2.2 Tank Waste Remediation System - Westinghouse Hanford Company

The WHC Tank Waste Remediation System (TWRS) Projects Organization is responsible for managing the project in accordance with established policies and procedures for projects at the Hanford Site. The TWRS Projects Department is responsible for coordinating the efforts of projects related to the MWTF Project to effectively integrate the MWTF into the overall waste handling system.

Figure 1-2
Multi-Function Waste Tank Facility Project Office Organization

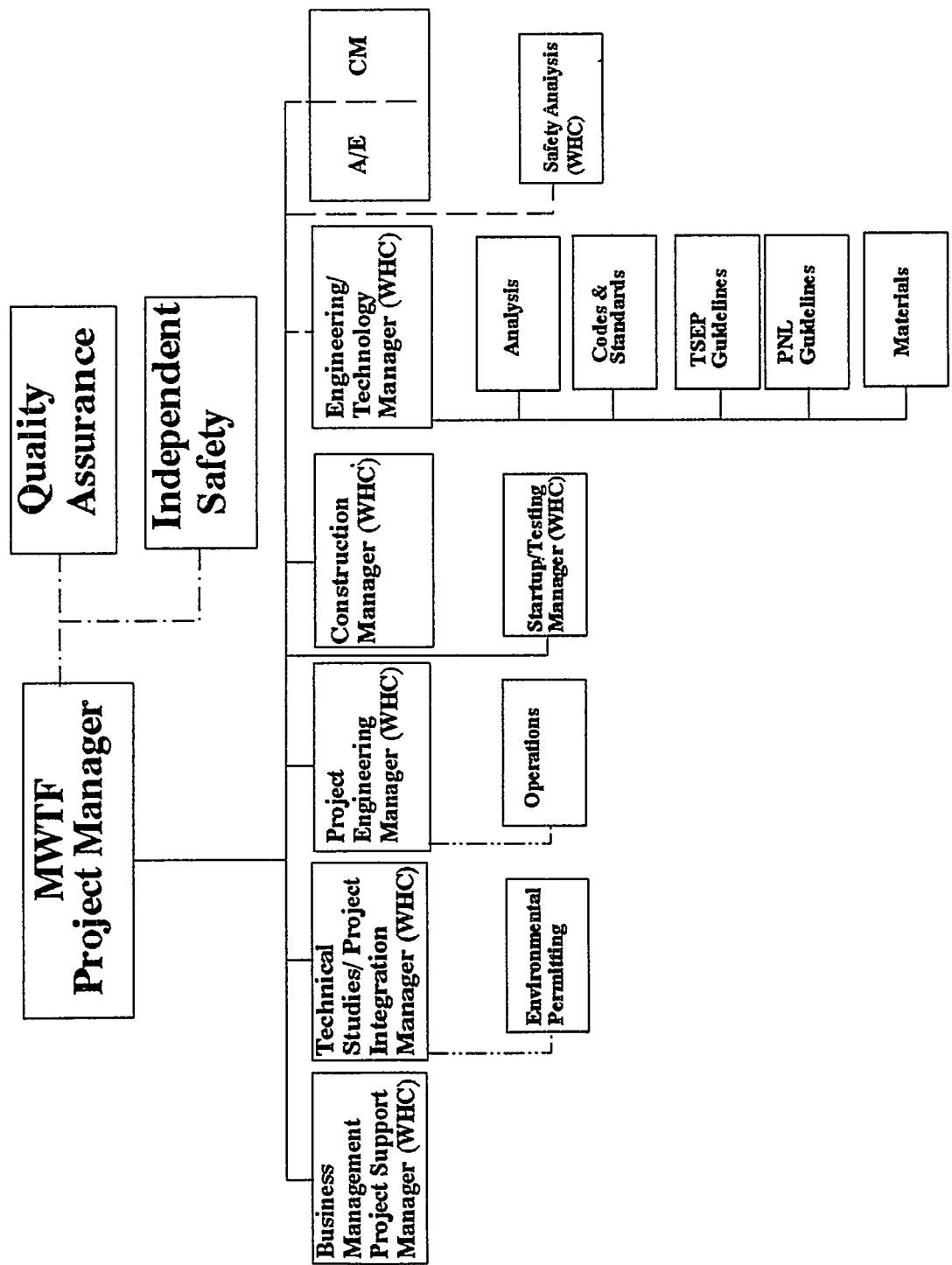
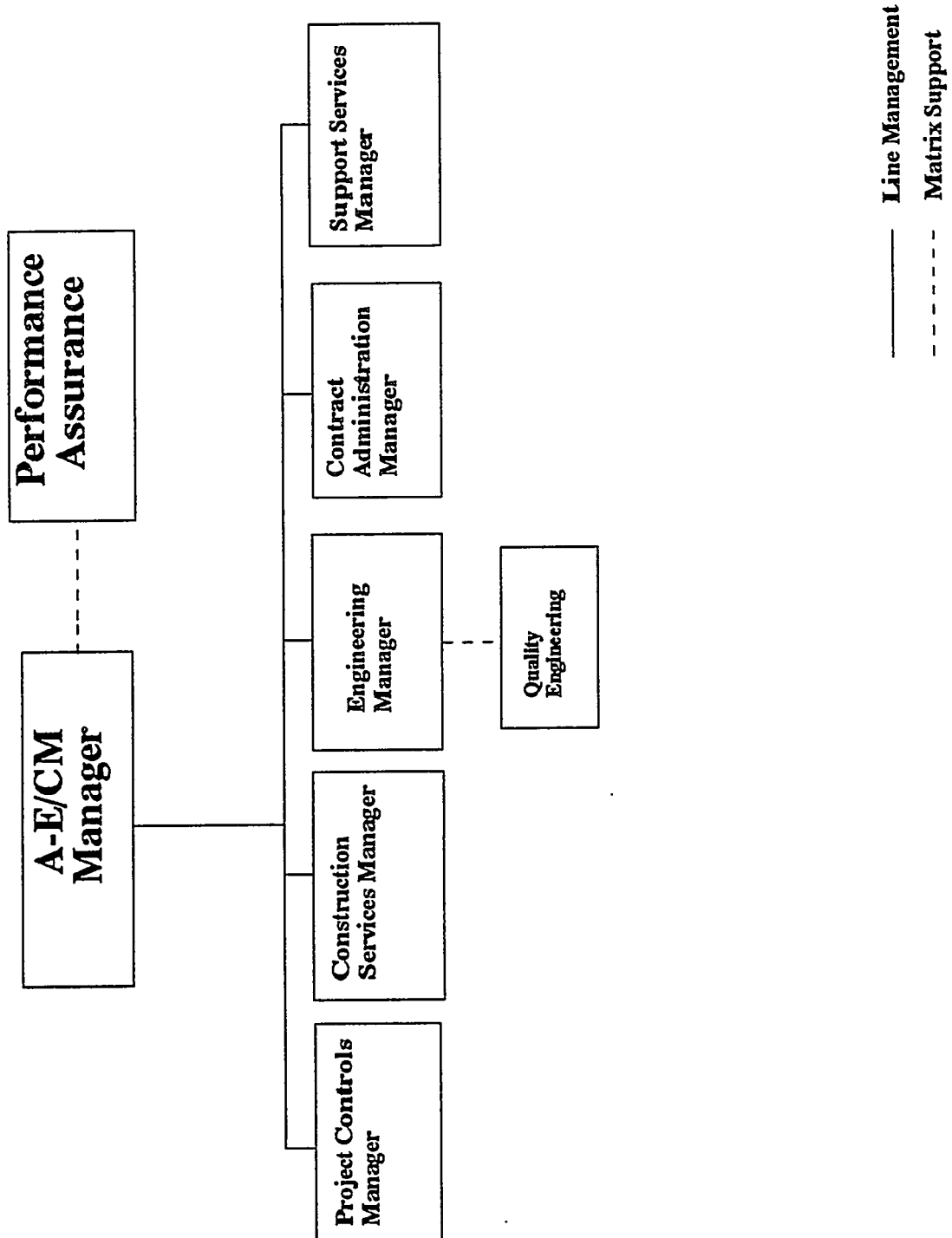


Figure 1-3

Multi-Function Waste Tank Facility Project Architect-Engineer/Construction Manager



1.2.2.3 Multi-Function Waste Tank Facility Project Office- Westinghouse Hanford Company

The MWTF Project Office (PO), in its capacity as the Integrating Contractor, is responsible for and supports the DOE, RL MRF Project Office, by supporting technical direction, cost and schedule management, control, integration, QA, applied technology, safety/regulatory compliance support, and startup and operations interface activities. Line personnel within the project are responsible for participating with QA to determine the extent of assessment controls applied to items and activities.

The Project Office manages and integrates the A-E, Technology, CM, and WHC support organizations. The work performed by each participant will be coordinated, guided, technically monitored, and reviewed for compliance to requirements by the Project Office as the Integrating Contractor. The Project Office is responsible for preparing LOI's, and transmitting other appropriate documentation required for the A-E, CM, and other participants.

1.2.2.4 Quality Assurance

The President of WHC is responsible for establishing controls to ensure that RL requirements for quality are satisfactorily implemented. As a department within WHC, QA is independent of line functions and is responsible for providing oversight and support to the project.

1.2.2.5 Multi-Function Waste Tank Facility Quality Assurance

The MWTF QA Engineer(s), reports to the WHC Manager of ~~Project/Site Support QA~~. Functionally, the cognizant QA engineer(s) provides support to the MWTF Project Manager. The cognizant QA Engineer(s) maintains independence by reporting to the WHC Manager of ~~Project/Site Support QA~~. This organizational structure ensures that the cognizant QA engineer(s) has the authority, functional independence and freedom to access work to verify that activities affecting quality have been properly implemented. In addition the cognizant QA engineer(s) may identify quality problems, initiate, recommend, or provide solutions to quality problems, verify implementation of solutions, and assure that further processing, delivery, installation, or use is controlled until the problem is corrected.

The cognizant QA engineer(s) is responsible for developing this MWTF QAPP description document. The MWTF Project QA program shall meet DOE Order 5700.6C and the applicable requirements of ASME NQA-1. Implementing procedures are used to support each of the applicable quality requirements functions.

The cognizant QA engineer(s) is responsible for:

- Developing the project specific QAPP
- Interpreting QA program requirements for the project
- Reviewing and concurring with WHC procedures and instructions that affect the MWTF Project QA program

- Integrating and coordinating QA activities for the project
- Reporting to upper management and the RL on the status and adequacy of Project QA activities
- Reviewing the QA programs/plans of the participating contractors and providing approval recommendations to line management
- Ensuring that quality control (QC) activities are planned and executed
- Identifying, reporting, and providing solutions for quality problems and recognizing and acting on quality trends to avert quality problems
- Monitoring the PO activities related to quality (including RL delegated activities) at WHC, and verifying compliance and effectiveness of WHC and participants' QA programs through assessment activities, which include surveillances, and reviews
- Ensuring that effective corrective action is taken before continuing affected work where serious quality problems have been identified
- Providing "stop work" authority including criteria and methodology for stopping work and lifting stop work, definition of work being stopped, and authorities and responsibilities.

1.3 DELEGATION OF WORK

RL is responsible for the overall execution of the MWTF Project but has delegated, through the WHC MWTF Project Office, the responsibility for design to the A-E, procurement to the O&EC, and construction activities to the CM. Direct responsibility for regulatory compliance and project integration has been delegated by RL to WHC, who is accountable for work that is delegated. Specification of work will be provided by contract, SOW, or LOI as applicable to the participants. The participants are responsible for the quality of their work. The WHC MWTF Project Office will assess the quality-related activities to ensure adequacy and acceptability and to verify compliance with project requirements.

1.4 STOP WORK AUTHORITY

It is the responsibility of all participant line managers to ensure that project activities are performed in a safe, environmentally sound manner, and in compliance with quality, safety and environmental requirements. The performing organization is responsible for and shall have the authority to stop and/or correct their work whenever work continuation could result in unsafe acts, danger to the environment, or a violation of approved work requirements. When unsafe or incorrect work is observed by MWTF PO (WHC) representatives during monitoring, or assessment of participant work activities, the cognizant WHC representative shall have authority to initiate stop work action by the participant manager in direct charge of the observed

work activity. Stop work actions shall be reported first to the cognizant project management and to the WHC Project Manager.

Before work can resume, the stop work action must be dispositioned. The disposition must identify the conditions/occurrences that caused the stop work, the corrective action(s) that must be implemented, and which actions must be taken to release or "lift" the stop work. Verification of the actions taken to release the stop work must be documented and approval to resume work issued by the cognizant project management, with concurrence from the WHC Project/Support QA Manager.

Each of the participants shall have procedures that define and implement the requirements for stop work.

2.0 QUALITY ASSURANCE PROGRAM

2.1 GENERAL

The MWTF Project QA program for WHC, as defined herein, covers those activities necessary to design and construct the MWTF. This project QAPP does not address plant operation.

The project QA program shall be reviewed annually to ensure continued compatibility to project direction and schedule. Changes affecting QA requirements will be revised as necessary.

This MWTF QAPP describes the QA requirements that must be implemented for the MWTF Project. The narrative in each section is aimed primarily at the participant with the prime responsibility for a particular activity.

2.2 QUALITY ASSURANCE PROGRAM

WHC has an established quality assurance program that is based on ASME NQA-1. The WHC QA program for this project is derived from the applicable sections of ASME NQA-1 and its supplements. ASME NQA-1 controlled activities are defined as those safety class 1 and selected safety class 2 activities governed by the requirements stated in ASME NQA-1 basic and supplement criteria called out in this QAPP. Quality assurance requirements are judiciously applied by graded approach to QA as referenced in section 2.6.

The Minimum QA requirements for Contractors shall be selectively established within the design documents. Contractors shall have a Quality Assurance Program (QAP) which addresses the quality assurance requirements applicable to their assigned tasks and for work performed by others in support of those tasks.

2.3 REPORTING INDEPENDENCE OF PERSONNEL

This section identifies how accountability for the achievement of quality is distinguished from accountability for assurance of quality. The line organization is accountable for achieving quality, while the QA organization is accountable for assuring that quality has been achieved. Because of this distinction in functional accountability between QA and the line organization, and because cost and/or schedule pressures may tempt the line organization to influence the QA organization to accept unsatisfactory work, the QA organization does report (in an organizational sense) independent of the line organization. The requirements for QA reporting independence are described below.

The WHC Project/Site Support QA manager reports independent of the MWTF line organization. The Project/Site Support QA group is part of the WHC ESQ Division, and the flow down of directives occurs as follows:

- WHC division vice-president, ESQ
- WHC department manager, QA
- WHC group manager, Project/Site Support QA.

The Project/Site Support QA group is matrixed to the MWTF Project Office line organization to provide QA support for the project. Thus, QA personnel have the independence, authority, and access to the work area to perform the following.

- Identify problems.
- Initiate, recommend, or provide solutions to conditions adverse to quality.
- Verify implementation of solutions.
- Ensure that further processing, delivery, installation, or use is controlled until proper disposition of the problem is complete.

When project participant organizations other than WHC Project/Site Support QA provide verification, the QA group overviews the activities by periodic assessment.

2.3.1 Participant Reporting Independence

The reporting independence of WHC Project/Site Support QA personnel is addressed above. For other participants, their respective QAP shall describe the reporting independence of QA personnel.

2.4 PLANNING

The participants' QA programs shall include provisions for QA program planning to be coordinated among participating organizations, including the QA organization, to provide consistency and completeness and to avoid duplication of effort.

Participant QA organizations review implementing procedures to verify that quality requirements have been adequately defined and can be effectively implemented. Implementation of the QA program shall be verified by assessments conducted in accordance with approved procedures using approved plans and/or checklists, documented, and reported to appropriate management. Any deficiencies identified will be processed in accordance with the requirements of Sections 15.0 and 16.0 of this QAPP, as appropriate.

The project activities are planned so that activities affecting quality are accomplished under suitably controlled conditions. The project QA program describes controlled conditions as (1) the use of appropriate equipment, (2) suitable environmental conditions for accomplishing activities, and (3) assurance that prerequisites for activities have been satisfied. The QA program also states the provisions for any special controls, processes, test equipment, tools, and needed skills that are required to attain or verify quality.

Quality Assurance program planning includes the integration and coordination of the individual participants' QA programs by the WHC Project/Site Support QA group. The integration and coordination effort is performed to provide consistency and completeness and to avoid duplication of

effort. The following elements shall be considered when planning the QA program for the MWTF project:

- Definition of activities
- Selective application of appropriate QA program requirements and procedural controls to items and activities
- Assignment of responsibilities for QA program control and verification activities
- Identification of applicable technical and QA program management control and verification activities
- Provisions for the identification of required QA records.

Environmental interfaces relative to DOE Order 5700.6C shall be included in the participants QA planning efforts.

2.5 READINESS REVIEW

An Operational Readiness Review will be performed as part of the pre-operational and start-up phase of the MWTF project in accordance with WHC-CM-1-5, Section 1.2, to support facility readiness and turnover to operations.

Readiness to proceed to various sub-phases of the project (i.e. procurement, construction, testing, etc.) shall be in compliance with project procedures. Specific review/approvals of project media are documented in accordance with this QAPP (i.e. design packages, procurement documentation, test plans, QA procedures, etc.).

2.6 GRADED QUALITY ASSURANCE

The graded approach to QA is founded on the concept of judicious application of specific QA requirements to particular activities, items, components, systems, or structures in accordance with the importance of the activity, item, or structure. The MWTF Project QA program describes the QA requirements that are active during the design and construction phases of the project. In addition, the program provides for those active requirements to be applied selectively to achieve a graded approach. The methodology used to determine the QA requirements and procedural controls selected for specific items, components, systems, structures, and activities is described below.

- Identify items, components, systems, and structures that are candidates for procedural control by the Project QA program. These are listed in the Preliminary Safety Equipment List and the Functional Design Criteria.
- Select the QA requirements (and their degree of application) that are appropriate for each candidate item, component, system, structure, and activity based on the following considerations:
 - Consequence of failure

- Importance of data
- Complexity of function
- Reliability of process
- Reproducibility of results
- Uniqueness of product
- Degree of functional product demonstration
- Degree of standardization
- Impact on schedule or cost to replace in the event of failure
- Environmental impacts due to failure
- Necessity of special controls or processes
- Significance to licensing process.

2.7 QUALITY ASSURANCE PROGRAM INDEX

In addition to the policies and procedures within the WHC quality program, a WHC MWTF Quality Assurance Program Index (QAPI) is supplied in appendix A of this QAPP. The QAPI is a listing, in table format, of manuals which contain general procedures, and specific QA implementing procedures to be utilized by WHC on this project. It must be noted that use of each and every procedure identified is not required for the complete project, rather, the use shall be determined by the Line Manager and the activity involved.

The QAPI demonstrates how the MWTF QAPP meets DOE Order 5700.6C criteria using ASME NQA-1 requirements as implemented by the WHC QA Program.

Project Participants shall develop a "Quality Assurance Program Index" of implementing procedures or instructions covering the quality requirements applicable to their assigned tasks. This QAPI shall be included as part of their QA Plan and updated yearly with the QA Plan.

2.8 PERSONNEL SELECTION, INDOCTRINATION, TRAINING, AND QUALIFICATION

Personnel assigned to the project who will perform activities affecting quality will receive appropriate indoctrination and training in accordance with DOE Order 5700.6C; and ASME NQA-1, Supplements 2S-1 through 2S-4, and Appendix 2A-1 and 2A-3, prior to performing work. This training includes personnel who conduct inspections and test activities to verify conformance of items to specified requirements for the purpose of acceptance, and to demonstrate that items will perform satisfactorily in service. This indoctrination and training ensures that personnel achieve and maintain suitable proficiency. Indoctrination and training shall be verified by the participant's assessment program. Non-inspection or test personnel are not required to comply with paragraphs 2.7 and 2.8 of Supplement 2S-1 of ASME NQA-1.

A systematic approach to the determination of applicable indoctrination and training of personnel who perform activities affecting quality is implemented with consideration of the following.

Job Evaluation

- Management analyzes every job position to determine the quality affecting task responsibilities of the position. Position descriptions identify job duties that include the quality affecting responsibilities of the position. Minimum personnel qualification standards (including minimum education and experience requirements) are established as a recognized standard for each position. Supervisors evaluate and assess the need for additional indoctrination and training as assignments, positions, and procedures change. If capabilities of an individual are not in accordance with the qualification requirements specified, that person shall be removed from that activity.

Personnel Selection

- Personnel assigned to perform quality affecting activities are required to have education, experience, and training commensurate with the functions associated with the work. A documented evaluation of the candidate's qualification against the requirements is made. Relevant education and experience must be verified.

Determination of Indoctrination and Training

- Management of each participant will identify the qualification requirements, training needs, and proficiency maintenance requirements of personnel who perform quality affecting activities. Documented on-the-job training shall be included in the participants program.

Documentation for training and qualification programs includes the objective, content of the program, attendees, and date of attendance. Records of personnel qualification shall be maintained by the employer.

2.9 INDEPENDENT ASSESSMENT

Surveillance of work in progress is a means to verify the correct performance of quality affecting activities or the correct use of items. Surveillance is a type of independent assessment. The term 'surveillance' usually pertains to an oversight activity performed by an oversight group, such as QA. Other types of monitoring activity (i.e. technical surveillance) may be performed by other WHC MWTF Project personnel as needed. Other means of verification, such as audit, ~~assessment~~ inspection, and review, are discussed elsewhere in this document. The remainder of this section is devoted to describing the requirements that pertain to surveillance performed by oversight groups.

Surveillance of activities affecting quality are planned, performed, documented, and reported to the management of the organization responsible for

the performance of the activity under surveillance. Surveillances are conducted to accomplish the following objectives.

- Verify the quality of work in progress.
- Identify and document actual and potential deficiencies and deviations and promote prompt corrective action by cognizant management responsible for performing the work.
- Verify timely implementation of corrective action associated with surveillances.

Personnel selected to perform surveillances are required to be knowledgeable in the topic of the surveillance and independent of direct responsibility for performance of the activity to be surveilled. Selected project activities are surveilled in accordance with prescribed procedures. Surveillance personnel shall be trained for their assignments, but formal qualification is not required. Surveillance results are documented in a report to affected management, and the report is required to address, at a minimum, the following:

- A discrete surveillance tracking number
- Date of surveillance
- Description of the activity or item under surveillance
- Persons conducting the surveillance
- Persons contacted during the surveillance
- Requirements for the item or activity upon which the surveillance is based
- Results of the surveillance
- Deficiencies identified during the surveillance
- Identification of measuring and test equipment (M&TE) used to perform the surveillance
- Summary of actions taken during the surveillance to correct deficiencies on the spot.

Deficiencies noted during the surveillance are tracked to ensure the timely completion of corrective action as well as closure. Data relating to deficiencies are input into the quality tracking and trending system to aid in identifying recurrent or common problems.

The WHC ~~Project/Site Support~~ QA group is responsible for overseeing the activities of the MWTF Project participants through the surveillance process. The results of these surveillances will be documented and reported to the organization overviewed and to project management. Any deficiencies noted

will be corrected by the responsible organization and the deficiency tracked to verify the adequacy of the corrective action and its implementation.

2.10 MANAGEMENT ASSESSMENTS

A management assessment is an evaluation conducted by management of its own performance in implementing the integrated QA program. This evaluation is performed in a planned and controlled manner to provide management with insight about the accomplishment of their responsibilities for achieving quality.

Management assessment of the participants' portion of the MWTF Project QA Program will be conducted at least annually by each participant's management or by designees who are independent of the participant's QA organization.

Assessments are conducted to evaluate the following:

- Adequacy of organizational structure and staffing to implement the QA program
- Effectiveness of QA program implementation
- Adequacy of the indoctrination and training program
- Adequacy of planning and procedural controls
- Effectiveness of the nonconformance and corrective action system
- Adequacy of the QA management information tracking, evaluation, and reporting system
- Opportunities for improvement in quality

Results of the management assessment will be documented, and identified deficiencies will be processed in accordance with the requirements of this QAPP, Section 16.0. Opportunities for improving quality also shall be transmitted to respective participant's management for consideration.

2.11 QUALITY ASSURANCE PROGRAM MANAGEMENT-INFORMATION REPORTING AND TRACKING

Multi-Function Waste Tank Facility Project participant organizations are required to report, disseminate, and track quality-related management information. A monthly report is prepared by each participant to submit to the participant's management and to the management of the next higher organizational level. The types of quality-related management information that is reported and tracked is as follows:

- A summary of deficiencies in the QA program that require immediate corrective action, and a discussion of corrective actions that are being implemented
- Other significant events such as the issuance of stop work orders, solutions to vendor problems, changes in key personnel, etc.

- Assessments performed and results
- NCR status and corrective action status
- Trending information.

A description of the quality reporting and trending program is provided in Section 16.0 of this QAPP.

2.12 QUALITY ASSURANCE PROCEDURES

Part of the QA program addresses the QA/QC activities that comprise policy, procedures, and instructions implemented by each of the participants. The administrative procedures usually are developed, implemented, and maintained by the QA organization within each of the participating companies and contained in their QA manuals.

The other part of the QA program directs specific activities to control the quality of the work for which each participant is responsible. The technical procedures normally are developed, implemented, and maintained by those responsible for the specific activities assigned to a participant and delivered as a product (e.g., design, documents, development data, a facility, etc.).

2.13 PROJECT PROCEDURES

Procedures addressing controls specific to the MWTF project are documented in project-specific procedures, as required (reference section 5.3). The WHC MWTF Project Office develops, assigns implementation, and maintains these procedures, which are in addition to those of the participants, and which govern activities that are unique to the Project.

2.14 QUALITY ASSURANCE CONTROLS

The QA program is implemented by management, QA staff, and line organization personnel at each of the participating organizations. The functional line organizations are responsible for the accomplishment of quality, and line managers supervising the work will ensure that specified quality is achieved. Responsible managers will review the status and line performance of their QA programs to determine acceptability of product quality, programmatic compliance, and implementation effectiveness and to resolve quality problems.

3.0 DESIGN CONTROL

3.1 GENERAL

The design of the MWTF is controlled as defined in Basic Requirement 3 and Supplement 3S-1 of ASME NQA-1 and criterion 6 of DOE Order 5700.6C. The design is defined, controlled, and verified. Applicable design inputs are appropriately specified on a timely basis and correctly translated into design documents. Design interfaces are identified and controlled. Design adequacy is verified by persons other than those who designed the item. Design changes, including field changes, are governed by control measures commensurate with those applied to the original design.

3.2 DESIGN INPUT

Design inputs consist of applicable DOE orders; the MWTF functional design criteria (FDC); national standards; and Hanford Site Standards. These are controlled by WHC through the MWTF FDC, MWTF SDRD, and MWTF SDD. The input is accepted or developed by the WHC MWTF Project Office and transmitted to the A-E, which has responsibility for the design. Changes to the design input are formally controlled by a change control process.

The A-E is responsible to maintain the design current with the FDC and SDRD. Design inputs are specified and approved by the WHC MWTF Project Office in a timely manner to permit the design to be carried out correctly by the A-E and to provide a consistent basis for making design decisions, verifying the design, and evaluating design changes.

3.3 DESIGN PROCESS

The design is carried out in accordance with A-E plans and procedures. Adequacy of the documents is ensured by the A-E and the WHC MWTF Project Office reviews. The applicable technical standards are specified as design input, and their adequate application verified through reviews. If changes are made from the quality standards, they are reviewed and approved by the A-E prior to affecting the change. Documentation and control of the changes is accomplished through the change control system. The suitability of application of materials and components is ensured during A-E and WHC MWTF Project Office reviews. Information derived from experience, as set forth in reports or other documentation, is available to cognizant design personnel. The final design is related to design input to allow documentation of verification and to ensure identification of the assemblies or components that are part of the design.

Commercially available items should be used whenever practical. Commercial grade items used in safety class systems (Safety Class 1) require identification and additional documented inspection, testing, or verification to ensure they are suitable for their intended use. The A-E design verifications shall consider the applicability of commercial grade items and verify that the commercial grade items will perform their intended function and meet design requirements. The design is sufficiently documented such that design verification can be accomplished by a technically qualified person without recourse to the originator.

3.3.1 Design Analyses

Design analyses is performed by the A-E in accordance with written procedures and instructions. Design analysis documents are prepared by the A-E in such a manner as to be legible, reproducible, and controlled to ensure retrievability. The format, identification, content, and documentation of the analyses are controlled by written instructions and procedures. The analyses are verified by supervisory personnel and independent verifiers to ensure methods, assumptions, results and references are correct and that both analysis and verification are performed by qualified personnel. The use of computer programs is controlled to ensure that only validated and verified codes are used, and then only when approved for use on the project. Engineers must use approved software for design. Changes to codes shall be controlled to prevent unauthorized modification and to ensure that the effect on previously performed analyses are verified when approved changes are accomplished. Computer programs must be verified to indicate they produce valid results for the limits of each variable used. The programs must produce valid solutions for the physical problem associated with specific applications. Computer program testing shall comply with the requirements of section 11.6 of this QAPP.

Design calculations shall be identified by subject (including structure, system, or component to which the calculation applies), originator, reviewer and date, or by other means whereby the calculations are retrievable.

Design analysis documentation shall meet the requirements of ASME NQA-1, Supplement 3S-1, paragraph 3.1.

3.3.2 Design Verification

Safety class designs shall be verified in accordance with A-E written instructions and procedures by independent qualified personnel. The adequacy of the design is verified by means of design reviews, alternate calculations, or qualification tests. These verifications are to be performed in a timely manner and before release for procurement, manufacture, construction, fabrication, or use in other design activities. In those cases where unverified design information is to be used in other design activities, the unverified portion of the design is identified and controlled. Results of the applied verifications and methods shall be documented.

Computer programs shall be verified by appropriate documented testing. In all cases, verification including operability tests, shall be completed prior to placing the system, facility, or item into service. Comments requiring resolution as well as the resolutions shall be documented and maintained as QA records.

The verification process is controlled by procedures developed and implemented by the A-E. These procedures require the following to be addressed:

- Identification of the reviewers
- Specification of the area or features to be reviewed and verified

- Documentation of the methods used for resolving comments
- Establishment of the criteria for determining the appropriate method for verification
- Definition of the extent of documentation required to perform the verification or validation
- Definition of the responsibilities of persons performing verification or validation.

The results of design verification shall be documented with the identification of the verifier indicated and the method used. Design verification is performed by an individual or group within, or external to, the A-E's organization other than those who performed the original design. This verification may be performed by the supervisor of the person who originated the design, provided the supervisor: 1) did not specify a singular design approach or rule out certain design considerations, 2) did not establish the design input used in the design, or 3) is the only individual in the organization competent to perform the verification.

3.3.2.1 Extent of Design Verification.

The extent of design verification shall be established as required based on a graded QA approach, related to safety class. The verification considers degree of standardization, complexity of design, state of the art, and similar proven designs. The change management system requires an evaluation of design verification of all proposed design changes such that the effect on overall design is considered before incorporation of any changes.

The applicability of standard or previously proven designs is verified for each application to ensure it meets design inputs. Known problems affecting these designs and their effects on other features shall be considered. The original design and associated verification shall be documented and referenced in the files of subsequent application of the design. Where changes to previously verified design are made, verification includes evaluation of the effects on any design analysis (upon which the design is based) that are affected by the change to the previously verified design.

3.3.2.2 Methods.

The acceptable design verification methods are design review, alternate calculations, or qualification tests. A combination of one or more of the three methods will be applied to the MWTF design.

Design Reviews: Design reviews are conducted by the A-E. These reviews include an interdisciplinary check along with independent verification of selection of design inputs, incorporation of the inputs into the design, reasonableness of design outputs, interfacing organization verification requirements, and evaluation of assumptions and design methodology. These reviews assure that design inputs were correctly selected, and that assumptions are adequate and reasonable. Assumptions shall be documented such that subsequent reverifications may be made when the detailed design is

completed. Necessary verification requirements for interfacing organizations shall be specified in supporting procedures.

WHC evaluates the design for safety, operability, adequacy of QA requirements, compliance with the FDC and SDRD, and compatibility with Hanford Site practices and standards.

Alternate Calculations: Alternate calculations may be used to verify portions of the design when appropriate and when the design review method of design verification is not appropriate. Verification shall involve examining the appropriateness of the methods used, proper coverage of the analysis, validity of the assumptions and input data, any computer program used, and the reasonableness of the results.

Qualification Tests: Qualification tests are performed to demonstrate the adequacy of the design. Test results will be documented and evaluated by the A-E. Qualification testing includes the following as applicable:

- The test configuration is clearly defined and documented
- Testing demonstrates adequacy of performance under design conditions
- Operating modes and environmental conditions considered in determining the most adverse conditions
- Only those features specified are verified
- Results shall be documented and evaluated to assure that test requirements have been met
- Modifications shall be documented and modified items retested to verify satisfactory performance
- Scaling boundaries shall be established and verified for model or mockup testing; results are subject to error analysis prior to use in final design.

3.4 CHANGE CONTROL

Changes to final designs, changes resulting from disposition of nonconformance reports (NCRs), and field changes shall be controlled and subject to verification measures commensurate with the original design (see Section 15). These change control measures also apply to nonconformance dispositions of "use-as-is" and "repair". These dispositions shall be approved by the A-E and are controlled through the review and approval process. "As-built" drawings and specifications are prepared by the responsible A-E to incorporate all the approved changes to the baseline design to accurately represent the constructed facility. The control measures ensure that the design analysis for the structure, system, or component are still valid. Changes shall be approved by the same affected organizations that reviewed and approved the original design documents. The individuals who review and approve the changes are required to have demonstrated competence in

the specific design area of interest and to have an adequate understanding of the requirements and intent of the original design.

3.4.1 Impact of Design Changes

Design changes are evaluated as required by the baseline change control procedure. The changes shall be communicated to affected groups so necessary actions can be taken.

3.4.2 Design Deficiency Control

For incorrect design that results in a significant design change, the A-E is required to review and modify the design process and verification procedure to preclude further instances of significantly incorrect designs. Instances of deficiencies in approved design, and design information documents, shall be documented and corrective action is to be taken as described in Section 16 of this document.

3.5 INTERFACE CONTROL

Design interfaces within the project will be limited. The A-E is responsible for performing and/or managing all direct project plant designs and reviews. Internal (interdisciplinary) controls are accomplished in accordance with A-E approved procedures. Designs provided by suppliers will be evaluated by the A-E in the submittal review process. This single point control by the A-E provides assurance that interfaces are controlled within one organizational management system.

Transmittal of information across organizational interfaces is documented and controlled. Transmittals identify status of information, action required, or approval. Informal transmittal of design information is followed by a controlled document.

3.6 DOCUMENTATION AND RECORDS

Design documentation and records, which provide evidence that the design and verification processes were accomplished in accordance with the requirements of ASME NQA-1 and DOE Order 5700.6C, are collected, maintained, and stored in accordance with the A-E approved procedures. The A-E is responsible for maintaining control of design records until the project is completed and records are formally dispositioned and transferred to the document processing center (DPC), which is operated by WHC. The records include the final drawings and specifications as well as supporting documents identifying important steps in the design, verification data, and sources (if inputs to the final design).

3.7 TECHNICAL REVIEWS

Technical reviews are performed by the A-E when the information or document under review is within the state of the art and is based on accepted standards, criteria, principles, and practices. These reviews are used when documents, activities, material, or data require technical evaluation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied. Such reviews are performed by

individuals with sufficient technical knowledge of the area being reviewed, and results shall be documented. The questions identified above by a design review are answered by performing a technical review.

Technical reviews of major activities such as seismic design reviews, are based on predetermined requirements, industry standards, or common scientific, engineering, and industry practice. Reviews are performed by a qualified, independent organization to ensure that the design approach complies with the DOE orders and applicable code requirements.

3.8 PEER REVIEWS

Peer reviews will be conducted for designs based on unproven assumptions or new technologies developed for the processes and products that have not been previously demonstrated as effective.

3.9 COMPUTER SOFTWARE CONTROL

Computer software use for ASME NQA-1 controlled activities shall comply with Section 11.6 of this document. Computer systems that have an overall affect on the quality of MWTF, other than those affecting safety class 1 or selected safety class 2 items, shall also be controlled. Controls should be based on the selective application of good business practices such as those identified in section 19 of this document.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 GENERAL

The provisions by which the WHC Project/Site Support QA group will provide overview of participant procurement activities are discussed in this section. The WHC MWTF Project Office and each participant will have a system in place for procurement document control that meets the requirements of ASME NQA-1, Basic Requirement 4 its Supplement 4S-1, and DOE Order 5700.6C. Procurement document control procedures contained in the MWTF Project QA Program at WHC and procurement control documents comply with these requirements.

4.2 PROCUREMENT DOCUMENT PROCESS

The project QA program controls the process of developing and using procurement documents to ensure that requirements for quality are formally communicated to vendors of items and services. The A-E is responsible for procurement of services in accordance with this section. The CM has been given responsibility for management and administration of construction subcontracts and procurement of materials and equipment. Specific procurement document control implementation requirements are addressed in the QA Plan generated by the CM. The A-E will provide the applicable technical requirements to the CM for inclusion into the procurement document. Review of the procurement document is accomplished by the CM to ensure that all appropriate requirements are addressed. The procurement document is then controlled so that subsequent changes to the document are subjected to the same level of review as the original. After review, the procurement document is approved and released to the vendors. Any changes to the procurement documents after release shall be approved in the same manner as the original design approval. The WHC MWTF Project Office will provide overview and monitoring of procurement activities to ensure procedural document adequacy and control implementation.

Suppliers shall have QA programs consistent with the requirements contained in the procurement documents. Suppliers of materials shall meet the quality requirements of the specified codes and this QAPP, as appropriate to their assigned tasks.

4.3 DOCUMENT CONTENTS

Procurement documents contain the following requirements necessary to ensure quality of procured items and services (as appropriate):

- A Statement of Work, which details the scope of activities to be performed.
- Technical requirements with necessary references to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions. Appropriate test, inspection, and acceptance requirements are provided for evaluation of the supplier's performance

- The supplier is required to have a documented QA program that implements the applicable requirements for its activity, as described in the procurement document. In addition, the supplier is required to invoke the appropriate requirements on any sub-tier suppliers that support this project. When deemed appropriate, the supplier may work under the umbrella of the purchaser's QA program provided the scope of the activity is sufficiently addressed. When this condition exists, the procurement documents will specify which portions of the purchaser's QA program apply
- Suppliers are required to provide access to their facilities and records for inspections or assessments by the purchaser or purchaser's authorized representative
- Documentation of submittal requirements including time of submittal and approval requirements; and retention time and disposition requirements for any quality records the supplier must retain
- A system to identify, report, and control nonconformances, and assessment findings
- Identification of spares and replacement parts, and necessary supporting documentation, as required by the procurement document.

Procurement documents require that departure from specified requirements be documented and submitted to the procuring organization for evaluation and disposition.

4.4 PROCUREMENT DOCUMENT REVIEWS

Procurement documents are reviewed by the CM representatives, QA organization representatives, and the A-E, as applicable, to ensure that all applicable technical and QA program requirements are incorporated. These reviews are documented to provide objective evidence of satisfactory reviews prior to award of a contract, purchase order, or other work-authorizing document. Changes recommended as a result of bid evaluation or precontract negotiation are reviewed and approved in the same manner as the original procurement document and incorporated before award. The review of changes includes criteria listed in Section 4.2 as well as any additional or modified design criteria, and analysis of exceptions by the vendor. Reviews are performed by personnel who have access to relevant information and who adequately understand the intent and requirements of the procurement document.

4.5 PROCUREMENT DOCUMENT CHANGE CONTROL

The project QA program provides for the control of procurement documents by procedures written specifically for procurement document control. The procedure identifies the responsibilities of individuals and addresses the controls applied through the various phases of the life of a procurement document. A procurement document comes under control when it is initially released for review. Every change to the procurement document subsequent to initial release for review is subjected to the review and approval process commensurate with the original document. The performance of the review and

approval process is documented for each change. These changes shall be reviewed by QA and technical personnel.

4.6 QUALITY ASSURANCE OVERVIEW OF PROCUREMENT/CONTRACT ACTIVITIES

The WHC Project/Site Support QA group will verify by assessments that participants' procurement document control is performed in accordance with approved procedures. Participants are responsible for appropriate procurement control of their subcontractors, however, WHC Project/Site Support QA retains an overview function.

The WHC Project/Site Support QA group will perform periodic assessments of the CM and other participants involved in programmatic procurement activities to determine that the following criteria have been met.

- A system has been established that provides for the establishment of procedures, which delineate the preparation, review, approval, and control of procurement documents.
- Procedures have been established for the review of procurement documents to determine that QA requirements are identified where appropriate.
- Organizational responsibilities, including involvement of QA, are described for the following:
 - Procurement planning
 - Preparation, review, and approval
 - Bid evaluation
 - Review and acceptance of supplier's QA programs.

The WHC Project/Site Support QA group will perform assessments of selected procurement documents to ensure the following.

- Procuring documents specify QA program requirements for contractors, subcontractors, and consultants commensurate with their scope of work.
- Documented reviews of procurement documents have been accomplished.
- The procurement document specifies the right of access at each procurement stage.
- Technical requirements, design bases, codes, standards, and regulatory specifications have been addressed.
- Procurement documents adequately address the appropriate documentation submittals for approval by the purchaser.

- Procurement document changes have been subjected to the same review requirements as required of the originals.
- Procurement for hazardous materials shall include all applicable clauses for handling, storage and disposal of same, including the Material Safety Data Sheet.

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 GENERAL

The project activities affecting quality are prescribed by, and performed in accordance with, plans, procedures, drawings, and instructions. The need for instructions, drawings, and procedures defining work performed in support of the project are identified and selected from existing documents, or prepared, approved, and issued. The MWTF Project QA Program and associated procedures shall meet the requirements of ASME NQA-1, Basic Requirement 5 and DOE Order 5700.6C.

5.2 RESPONSIBILITIES

Participant activities that affect quality are prescribed by, and performed in accordance with, documented instructions, procedures, plans or drawings. Controlled procedures delineate documents to be generated as a result of implementation. These documents are to be designated as QA records. These procedures and instructions contain quantitative and qualitative acceptance criteria, as appropriate.

The WHC MWTF Project Office is responsible for ensuring that each organization has sufficient procedures to properly implement its respective QA program. In addition, TWRS Project Administration and Technical Support will develop TWRS projects implementing procedures (project procedures), as necessary, to describe how the efforts of the MWTF Project participant organizations are integrated for procedural functions involving multiple participants. The MWTF Project participants are required to adhere to the project procedures as directed by the WHC MWTF Project Office.

The WHC MWTF Project Office is also responsible for review and acceptance of selected project procedures including QA/QC procedures: reviews of these selected QA/QC procedures occur during oversight activity (surveillance, inspection, assessment, etc.), and acceptance is indicated in documentation for the oversight activity.

5.3 PROCEDURE SYSTEM

Procedures used by MWTF Project participants can be categorized by their origin and extent of application.

- Company-level procedures are those that apply to the parent organization of the MWTF Project participant organization as well as potentially to the participant's MWTF organization. Further, company-level procedures for one MWTF Project participant do not apply to any other MWTF Project participant. For instance, the parent organization of the WHC MWTF Project Office is WHC. The procedures the WHC MWTF Project Office uses from WHC to govern project-specific activities are regarded as company-level procedures: the A-E cannot directly implement a WHC company-level procedure because WHC's procedure has been written to apply only to WHC performance.

- Project-specific procedures are those that apply only to the MWTF project because either (1) the requirement(s) that spawn the project-specific procedure are not common to the participant's parent organization, or (2) the need for careful interfacing among MWTF Project participants necessitates an integrated approach to the procedural task. For instance there may be instances where company-level procedures are not adequate for MWTF project use. Also, some procedural topics require partial accomplishment by several participants in order to effectively perform the entire task, so company-level procedures (which are not scoped to apply to more than one participant) are not appropriate.

Project-specific procedures are developed and used when company-level procedures are too limited in application, when they do not fully address project-specific requirements, or when there is significant interfacing among multiple participant organizations to effectively accomplish the procedural task. Unlike company-level procedures, project-specific procedures are not applicable outside the MWTF project.

Project-specific procedures can be further subdivided into internal procedures and integrating procedures.

- Internal procedures are used when the activity addressed by the procedure is either (1) implemented only by one of the participants, or (2) implemented commonly among the participants.

An example of a topic of an internal procedure that is implemented only by one participant is design verification: The A-E has sole responsibility for accomplishment of design verification and its requirements are project-specific because the ASME Code adds unique requirements for design verification.

An example of a topic of an internal procedure that is implemented commonly among participants is document control: all MWTF Project participant organizations are required to establish systems for control of documents they generate. In this instance, each of the MWTF Project participants internally implement the same project-specific requirements.

- Integrating procedures are used when the activity addressed by the procedure requires significant interfacing among two or more participants in order to effectively accomplish the procedural task.

An example of a topic of an integrating procedure is change control: potentially, all of the MWTF Project participants have a role in initiating, processing, and approving an MWTF Change Request.

Participant organizations develop, implement, and maintain procedures commensurate with their scope for the MWTF. In general, participants utilize

company-level procedures whenever possible. Project-specific procedures are developed and used to supplement the company-level procedures of a participant. There is no order of precedence among these procedures. Also, an internal, project-specific procedure does not supersede an integrating procedure; however, an integrating procedure may require a participant to develop and/or use an internal procedure (or even a company-level procedure) within specific limitations as defined in the integrating procedure. The procedures that MWTF Project participants use to implement the requirements of their respective programs are delineated in their individual QAPI (refer to section 2.7 of this QAPP). The effective date for each procedure is indicated on the procedure itself.

5.4 REVIEWS

Independent reviews of instructions, procedures, and drawings are performed by the originating organization to ensure technical adequacy, regulatory compliance, inclusion of quality requirements, and to verify correct translation of design requirements. The preparation, issuance, and change of these documents is reviewed and controlled by the originating organization to ensure that correct and approved documents are being used in the work place.

5.5 QUALITY ASSURANCE VERIFICATION

Verification that current issues of documents are available in the work place will be made through periodic assessments. Verification also shall consist of independent reviews by the originating participants to ensure documents are technically adequate and include the appropriate quality requirements.

6.0 DOCUMENT CONTROL

6.1 GENERAL

The MWTF Project participants will develop and implement procedures that ensure the program documents affecting quality are prepared, revised, reviewed, approved, and issued in a prescribed and controlled manner.

6.2 DOCUMENT CONTROL SYSTEM

An integrated document control system for the design and construction phases of the project is in place. This system provides a single focus (i.e., MWTF Project management) for document control practices for all participants. The document control system provides for the following activities:

- Documentation of the control system
- Identification of documents to be controlled
- Identification of the distribution for specific documents
- Identification of the assignment of responsibility for preparing, reviewing, approving, and issuing documents
- Review of documents for adequacy, completeness, and correctness prior to their approval and issuance
- Resolution of mandatory comments prior to approval and issuance of the document
- Documentation and maintenance of review comments and resolutions
- Timely replacement of obsolete or superseded documents at work areas
- Consistent means for identifying the revision status of controlled documents
- Special approval and issuance requirements for minor changes to documents (i.e., editorial changes, which do not change how work is done or the results of work), including who can approve the changes.

Participant documents, which specify quality requirements or prescribe activities affecting quality shall be controlled. This control applies during preparation, distribution, and modification to ensure that correct documents are available for use when and where needed.

6.3 ISSUANCE, DISTRIBUTION, AND STORAGE

Document issuance and distribution will be controlled to ensure that correct, applicable, and current documents are available to the personnel performing work activities. Approved procedures delineate the responsibility and authority for such releases.

Procedures for issuance and distribution address the following:

- Identification and marking of documents
- Provisions for use of documents prior to verification or approval.
- Use of receipt acknowledgment document transmittal forms
- Maintenance of controlled document distribution lists
- Marking, removal, or destruction of obsolete or superseded controlled documents
- Maintenance of an index that provides revision status for controlled documents.

Controlled document recipients are responsible for acknowledging document receipt; ensuring that the latest authorized documents are in use; and marking, destroying, or returning obsolete or superseded documents.

The WHC Project/Site Support QA group will ensure adequate control of documents by periodic assessment of participants' document control practices.

6.4 REVIEW AND APPROVAL

Documents requiring control will be reviewed for adequacy and approved by authorized personnel for release and use. Each participant who prepares controlled documents will have a procedure that establishes the measures for review and approval of documents within their document control system. These measures include identification of personnel authorized to review and approve documents. These personnel include QA personnel when the controlled document contains or implements QA requirements. The organization that prepares the document will determine the appropriate level of review and approval for the document. Evidence of approval (i.e., signatures) is required on the controlled documents. Changes to documents that affect how the work is done or results of the work, will require review and approval by the originating organization in the same manner as the original documents. This will include access to background data or information upon which to base the review.

6.5 DOCUMENT RETIREMENT, RECALL, OR TRANSFER

The project QA program shall provide for the retirement, recall, or transfer of controlled documents. After a quality affecting activity has been satisfactorily completed, the requirements document for that activity may be retired or canceled to reduce the quantity of documents that are tracked for control. Documents that describe activities that are temporarily suspended may be recalled to prevent inadvertent accomplishment of activities. When individuals change job functions or leave the project, the controlled documents issued to them are retired if appropriate, or transferred to other individuals. In the case of document retirement, recall, or transfer, the project QA program requires sufficient notice in writing to be given to controlled copy holders, and records are maintained for the change in distribution status. Specific requirements for document retirement, recall, or transfer shall be addressed in procedures.

6.6 MAJOR AND MINOR CHANGES

The project QA program shall provide for an expedited means to release changes or revisions to documents when those changes are minor in character. Changes that are editorial in nature, (i.e., those that do not alter work results or affect how work is accomplished) do not require the same level of review and approval as major changes. The definitions for major and minor changes shall be provided in the project participant internal procedures; authorized personnel are designated to determine whether changes are minor. The procedure that governs issuance of controlled documents shall also describe the measures implemented to release minor changes.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 GENERAL

This section describes the controls applied to the purchase of items and services that affect quality. Implementation of these controls ensures conformance with specified requirements. As appropriate, these controls provide for source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, ~~assessment~~, and examination of items or services upon delivery or completion.

7.2 RESPONSIBILITIES AND INTERFACES

The responsibility for procurement of items and services for plant construction and equipment/systems will be delegated to the CM. Each participant will implement a QA system that meets the requirements of ASME NQA-1, Basic Requirement 7 and its Supplement 7S-1, and procurement criteria of DOE Order 5700.6C.

7.3 CONTROL OF PURCHASED ITEMS AND SERVICES

Procurement activities are performed by participants in accordance with documented procedures to ensure a systematic approach is used in procurement processes. Procurement of computer software that supports project activities shall be in accordance with Section 19.0 of this QAPP. Procedures shall take into consideration, as a minimum, the following activities.

7.3.1 Procurement Planning

The project QA Program requires that procurement activities be planned and documented at the earliest practical time to provide appropriate interfaces ensuring compatibility and uniformity to the procurement process. Planning should include, as a minimum, what is to be accomplished, how it will be accomplished, who will accomplish it, and when it is to be accomplished. Procedures that control the procurement process shall address the following:

- Procurement documents and their preparation, review, and release
- Selection of procurement sources
- Bid evaluation and award
- Supplier performance evaluation
- Control of supplier generated documents
- Inspections, source and/or receiving; verification activities by purchaser, including notification for hold and witness points
- Control of changes to procurement documents for items and services
- Material identification and control
- Acceptance of items and services

- Control of nonconformances
- Corrective action
- Quality assurance records.

7.3.2 Procurement Source Selection

The selection of suppliers is based on evaluation of their capability to provide items and services in accordance with the requirements of the procurement documents prior to contract award. These evaluations will be documented and include one or more of the following:

- The supplier's history on past contracts for providing identical or like items that perform satisfactorily in service; the supplier's history must also reflect current capability
- Assessment of the supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated
- Assessment of the supplier's technical and quality capabilities by direct evaluation of the facilities, personnel, and implementation of the QA program.

7.3.3 Proposal Evaluation

Proposal evaluations shall be performed by individuals or organizations that have the necessary expertise to make decisions for technical considerations, QA requirements, personnel, and supplier past performance. Evaluation shall include a determination of the extent of conformance to procurement documents. All contract negotiations shall be complete and documented, including resolution of unacceptable quality conditions prior to award of contract. Proposal evaluation considers the following:

- Technical considerations
- Quality assurance requirements
- Supplier's personnel
- Supplier's production capability
- Supplier's past performance
- Supplier's QA program
- Alternates
- Exceptions.

7.3.4 Supplier Performance Evaluation

Evaluation of supplier's performance throughout the life of the contract is planned and documented. These verifications shall be initiated as early as practical to establish compliance to program requirements.

Evaluation methods include review of supplier's plans and procedures, source surveillance inspections, assessments, receipt inspections, nonconformances, dispositions, waivers, and corrective actions. This documentation will be utilized to determine the effectiveness of the supplier's QA program.

Evaluation activities include the following:

- Establishing an understanding of the provisions and specifications of the procurement documents
- Requiring the supplier to identify methods used to meet procurement document requirements
- Reviewing supplier documentation generated or processed during activities, fulfilling procurement requirements
- Providing necessary change information
- Controlling information exchange between the purchaser and the supplier
- Establishing the extent of source surveillance and inspection activities.

Procurement documents require the supplier to accomplish the requirements stated and to verify that requirements have been met. Verification conducted by the purchaser does not relieve the supplier of responsibility for verification of quality achievement.

The extent of verification activities, including planning, is a function of the relative importance, complexity, and quantity of the item or services procured. The supplier's quality performance also affects the extent of verification activities. The safety classification of an item is the major influence on the extent of verification activities. Qualified personnel who are assigned to check, inspect, assess, or witness the activities of suppliers will accomplish verification activities.

The performance of verification activities is recorded. Source surveillances and inspections, assessments, receiving inspections, nonconformances, dispositions, waivers, and corrective actions shall be documented. This documentation is evaluated to determine the effectiveness of the supplier's QA program. The manner of documentation shall be described in procedures.

7.3.5 Control of Supplier Generated Documents

Supplier generated documents shall be controlled, handled, and approved in accordance with the methods established in the procurement document and the purchaser's program requirements. Document submittal requirements shall be delineated in the procurement specifications. The WHC MWTF Project Office performs overview and assessment of these documents as necessary to provide assurance of procurement requirement compliance. Document verification provides for evaluation of technical, inspection, and test data against acceptance criteria.

Changes to procurement documents of procured items and services shall be communicated to suppliers in the procurement specifications. These changes are evaluated in the same manner and with the same criteria as the original documents.

7.3.6 Acceptance of Items and Services

Suppliers' QA programs will ensure that prior to offering the item or service for acceptance, the supplier will verify compliance with procurement requirements. When required by code, regulation, or contract requirement, documentary evidence that items conform to procurement documents is required to be available at the project prior to installation or use.

Four methods for acceptance have been established and can be utilized, either individually or in combination, as follows.

1. Evaluation of suppliers' certificates of conformance for services or items to ensure validity and authenticity of documentation and results. The following criteria must be met.
 - a. The certificate must identify the purchased material or equipment, such as by purchase order number.
 - b. The certificate must identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications, in a manner that clearly establishes conformance to procurement requirements.
 - c. The certificate must identify any procurement requirements that have not been met along with an explanation and the means for resolving the nonconformances.
 - d. The certificate is signed or otherwise authenticated by a person who is responsible for the supplier's QA function as described in the purchaser's or supplier's QA program.
 - e. The certification system is described in the supplier's QA program. The supplier has procedures to prepare certificates of conformance and review and approve the certificates for submittal to the purchaser. The purchaser has procedures for review of submitted certificates of conformance.

- f. A means to verify the validity of supplier certificates is provided by the purchaser. The effectiveness of the certification system is verified by assessments or by independent inspections or tests of items. The verification is conducted at intervals commensurate with the supplier's past quality performance.
2. Source inspection/surveillance, post-installation inspection. Source inspection is performed at intervals consistent with the importance and complexity of the item or service. It is implemented to monitor, witness, or observe activities in process. Source verification also is implemented in accordance with purchaser plans for performance of inspections, examinations, or tests at predetermined points. The procurement document provides the purchaser with the ability to perform verifications in the supplier's facility. Upon purchaser acceptance of an item or service by source verification, documented evidence of acceptance of the item or service is furnished to the receiving destination, as well as to the purchaser and supplier.
3. Receiving inspection. Purchased items are inspected upon receipt to verify conformance to specified requirements. The extent of the receiving inspection is influenced by the demonstrated quality performance of the supplier and by the source verification and assessment activities that have been previously performed for the procurement. Procedures for the conduct of receiving inspection shall be established to ensure that objective evidence is available to verify such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness. Receiving inspection is coordinated with review of supplier-generated documentation when procurement documents require such documentation to be furnished before receiving inspection. Detailed requirements for receiving inspection include inspection planning, inspection performance, and records of receiving inspection. Receipt inspection records identify characteristics inspected and objective evidence of the results, inspection criteria, identification of applicable drawings, specifications or procedures, and identification of material and test equipment used during the receipt.
4. Post-installation testing. When post-installation testing is used, requirements and acceptance documentation are mutually established by the purchaser and supplier. The requirements and acceptance documentation shall be specified in the procurement document.

In the case of procurement of services, the purchaser may accept the service by any or all of the following methods.

- Technical verification of data produced
- Surveillance and/or audit of the activity

- Review of objective evidence for conformance to the procurement document requirements, such as certifications and stress reports.

7.3.7 Control of Nonconformances

The project QA program requires that procedures be developed for the disposition of items and services that do not meet procurement requirements. The requirements for these methods shall be delineated in the participant's project procedure(s) for NCRs.

The participant's procedure(s) shall provide for the following:

- Evaluation of nonconforming items and services
- Submittal of nonconformances by supplier to purchaser as directed in procurement documents. These submittals are required to identify the supplier-recommended disposition and technical justification. Deviations from requirements of the procurement document or from purchaser-approved supplier documents are to be documented and submitted to the purchaser for concurrence and/or approval of the recommended disposition for the following conditions:
 - Technical or material requirement violations
 - Violations of requirements in supplier documents
 - Nonconformances that cannot be corrected by original work process or by rework
 - Items that do not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired
- Purchaser disposition of supplier recommendations and corrective action
- Verification of disposition implementation
- Records maintenance of nonconformances.

7.3.8 Commercial Grade Items

The project shall make provisions for the procurement of commercial grade items. Emphasis is placed on source evaluation and selection based on the item's complexity and importance to safety. When the design utilizes commercial grade items in safety class 1 or 2 applications, the following requirements are acceptable for use in procurement:

- The commercial grade item must be identified on an approved design output document.

- Source evaluation and selection shall be made based on the complexity of the item and importance to safety, when deemed necessary by the purchaser.
- The item must be identified in the procurement document by the manufacturer's published product description (for example, catalog number).
- Receipt inspection is performed by the purchaser.
- Additional testing is conducted if required by design document.

In addition to the above requirements for commercial grade items, the requirements of Supplement 7S-1 of ASME NQA-1 is applicable.

7.4 VERIFICATION

Each participant's QA program shall provide for verification of procurement document control according to ASME NQA-1 and DOE Order 5700.6C.

The WHC ~~Project/Site Support~~ QA group verifies control of purchased items and services by periodic assessment.

8.0 IDENTIFICATION AND CONTROL OF ITEMS

8.1 GENERAL

This section describes the controls necessary to ensure that only correct and accepted items are used and installed. As appropriate, these controls provide the necessary identification on items or in documents to ensure traceability and that identification is established and maintained. The project QA Program complies with the requirements as specified in ASME NQA-1 Basic Requirement 8, Supplement 8S-1 and DOE Order 5700.6C.

Each of the participants and suppliers to the CM and WHC shall be responsible for implementing appropriate portions of the project system for identification and control of items.

8.2 IDENTIFICATION METHODS

8.2.1 Item Identification

Items of production (i.e., batch, lot, component, or part) shall be identified from the initial receipt and fabrication of the item through installation and use. This identification relates an item to an applicable design or other pertinent specifying document.

8.2.2 Physical Identification

Physical identification is used to the maximum extent. If physical identification is not practical or is insufficient, then measures will be established to control the item by physical separation, procedural control, or other approved appropriate means.

8.2.3 Markings

Markings, when used, shall be applied using materials and methods that provide a clear and legible identification and will not affect the function or service life of the item. Markings shall be transferred to each part of the item prior to subdivision. Caution shall be observed to prevent the obliteration by any surface treatment or coatings.

8.3 TRACEABILITY

The project QA Program shall provide identification and traceability control. Specific identification traceability requirements that originate from codes, standards, or other specifications shall be observed. Examples of such requirements include markings to indicate the following: (1) the heat, batch, lot, part, or serial number; (2) the specified inspection, test, or other records; and (3) the identification or traceability of the item to an applicable specification and/or grade of material.

8.4 LIMITED LIFE OR SHELF LIFE ITEMS

Items that have a limited calendar or operating life, cycles, or shelf life shall be controlled to preclude the use of such items after these dates

have expired. Controls are employed to ensure that items of limited life are replaced before failure or expiration.

8.5 MAINTENANCE OF IDENTIFICATION

The project QA Program shall provide for the control of item identification during storage. These controls are consistent with the planned duration and conditions of storage. The controls include the following:

- Provisions for maintenance or replacement of markings and identification records damaged during handling or due to aging
- Protection of identifications on items subject to excessive deterioration resulting from environmental exposure
- Provisions for updating existing plant records.

8.6 VERIFICATION

The WHC Project/Site Support QA group verifies participants' conformance to item identification and control by periodic assessment.

9.0 CONTROL OF PROCESSES

9.1 GENERAL

This section describes measures established to control special processes, as defined in section 9.3, and ensure that they are accomplished by qualified personnel using written procedures qualified in accordance with applicable codes, standards, specifications, or other special requirements. Also described are those measures that ensure qualification of special processes, personnel performing special processes, and equipment are kept current and record files thereof are maintained.

9.2 PROCESS CONTROL

The term "process" is defined here as "a method of accomplishing a number of operations or steps that produce a result or product that conforms to an established specification."

Processes will be controlled by approved instructions, procedures, drawings, checklists, travelers, or other appropriate means. These means ensure that process parameters will be controlled, documented, and verified to provide a record of process compliance.

9.3 SPECIAL PROCESSES

The term "special process" is used herein as "a process--the results of which are highly dependent on the control of the process or the skill of the operators, or both--and in which the specified quality cannot be readily determined by inspection or test of the product."

Special processes require qualification of personnel, equipment, and/or procedures. Each special process will be performed in accordance with instructions or procedures that include or reference qualification requirements. The qualified procedures or instructions identify the information and conditions necessary to accomplish the process. These include proper equipment, controlled parameters, proper environmental conditions, calibration requirements, personnel qualifications, and acceptance criteria. In cases where existing codes and standards do not cover a special process, or where quality requirements specified for an item exceed those of existing codes or standards, the requirements for qualification of personnel, equipment, or procedures will be specified or referenced in the qualified procedures/instructions. The qualification and performance of special processes shall be controlled, documented, and verified to provide a record of process compliance. The QA personnel of each participant will monitor the development and implementation of special process qualification activities through inspections, reviews, assessments, or surveillances, as appropriate to the participant's work scope.

The process is designated as a special process when any of the following criteria are met.

- If the results of the process are highly dependent on precise control of the process

- If the results of the process are highly dependent on the skill of the operator
- If the results of the process are highly dependent on both the skill of the operator and precise control of the process
- If the specified quality for the end-product of the process cannot be readily determined by inspection or test

The following special process activities are to be controlled by affected participants:

- Nondestructive examination (NDE) processes (radiographic testing, penetrant testing, magnetic particle testing, ultrasonic testing, and visual examination)
- Welding
- Heat treating.

9.4 RESPONSIBILITY

It is the responsibility of affected participants to include in their QA program documents a list of special processes that will be performed by them or for which they are responsible. The CM is responsible for controlling processes before construction turnover (i.e., during construction, acceptance testing/inspection). The WHC MWTF PO is responsible for controlling processes after construction turnover (i.e., during cold test, hot test, cold start, and hot operations).

Each affected participant is responsible for the following:

- Adherence to approved procedures and processes
- Compliance with specified requirements for qualification of personnel, procedures, and equipment
- Development of documentation in accordance with this QAPP and other applicable requirements.

9.5 RECORDS

Records relating to the qualification of special processes, qualification of personnel and equipment, and to the performance of the process/special process shall be in accordance with Section 17.0 of this QAPP.

10.0 INSPECTION

10.1 GENERAL

This section describes the controls for inspections required of the project to verify conformance of items or activities to specified requirements.

Construction inspection/testing including the characteristics, extent, methods, and documentation requirements shall be described in approved design documents, procedures, and inspection planning documents. Inspection and testing activities shall be documented. Independent assessment of inspection and testing activities will be performed by the applicable QA organization supporting Project Management.

The assigned A/E will perform Title III acceptance inspection of construction activities. Acceptance inspection shall be planned, performed and documented. Acceptance inspection planning documents shall be approved in accordance with established procedures.

Construction Management shall coordinate the interface with the assigned Construction Contractors, Construction Forces and Title III Acceptance Inspection.

The "Project Critical Characteristics" establish a basis for the Quality Assurance Program planning and inspections required. As the design progresses more detailed inspection requirements will be defined in the individual design documents (i.e. design specifications, procurement specifications, and drawings) based upon the safety classification. Final safety classification for systems, components, and structures will be in accordance with the approved PSAR/FSAR and Safety Equipment List (SD-W236A-EL-002).

Safety Class is defined in the WHC, "Management Requirements and Procedures Manual", WHC-CM-1-3, MRP 5.46, "Safety Classification of Systems, Components, and Structures".

The PSAR and FSAR, when completed, are the formal documents which define safety classifications of components, structures and systems.

The requirements of ASME NQA-1, Basic Requirement 10 and Supplement 10S-1, and DOE Order 5700.6C will be met with the following amplifications.

10.2 PERSONNEL

Inspection of completed work is performed by persons other than those responsible for accomplishing or supervising the work being inspected.

Only qualified inspection personnel are utilized for inspection assignments. Activities performed by uncertified personnel engaged in on-the-job training are verified by a qualified inspector.

10.3 HOLD POINTS

Mandatory inspection hold points beyond which work cannot proceed shall be specified in the design specifications, CM work procedures or in final inspection planning documents.

Hold points may be waived only with prior approval by the agency imposing the hold point. Waiver approval will be recorded by the approval authority prior to continuation of work.

10.4 INSPECTION PLANNING

Planning for first-line inspection activities is performed by the CC. Planning for final inspection activities is performed by the A-E and CM as part of its Title III inspection responsibilities. Inspection plans include provisions for hold points, and description of methods, characteristics, and acceptance criteria. Inspection results will be recorded by the responsible inspection personnel as directed in the design documents.

Inspection planning will include criteria for the following: when inspections will be performed; identification of required drawings, specifications, or procedures with revisions; and necessary measuring or test equipment with accuracy requirements.

Recognized standard practices will be used for preparation of sampling inspections for acceptance.

10.5 IN-PROCESS INSPECTION

In-process inspection of construction is utilized for monitoring activities where proper verification of product quality is required.

Monitoring of process methods, equipment, and personnel shall be used when advantageous or direct inspection is impossible. Inspection and process monitoring shall be provided when control is inadequate without both.

When a combination of process control and inspection are used to verify quality, they are performed in a manner to ensure control of the process and quality of the item for the duration of the process.

Controls shall be established for documenting inspection points during the process or construction.

In-process inspections conducted during construction of the primary tank will be carried out by the tank constructors quality assurance organization, as required by its quality program and the ASME Boiler and Pressure Vessel (B&PV) Code Section III Division 1. This will include direct and indirect inspections, in-process monitoring, and nondestructive examination (NDE).

The Authorized Nuclear Inspector (ANI) will perform his inspection duties as described in ASME B&PV Code Section III Division 1 and the National Board of Boiler and Pressure Vessel Inspectors.

10.6 FINAL INSPECTIONS

Final inspections by the A-E or CM to accept work include a records review of inspection results and the resolution of nonconformances identified in previous inspections.

Final inspections provide documented conclusions regarding acceptability of the item to requirements, including completeness, markings, calibration, adjustments, protection, or other applicable characteristics.

Quality records shall be reviewed for adequacy and completeness if not previously examined.

Final acceptance is documented on inspection records and approved by authorized personnel.

Modifications, repairs, or replacements accomplished after final inspection are reinspected or retested, as appropriate, to verify acceptability.

10.7 RECORDS

Records will identify, as a minimum, the following:

- Item inspected
- Date of inspection
- Identity of the inspector
- Type of observation
- Results or acceptability
- Reference to action taken for nonconformances
- Identification of inspection procedure
- Characteristics inspected
- Traceability to acceptance criteria
- Inspection equipment used
- Identification of special expertise used.

10.8 INTERFACE

WHC provides necessary source and receipt inspection services as defined in the design documents.

The CC performs in-process inspections during the portion of the MWTF project prior to construction turnover of plant items, components, and/or systems for acceptance by the government. Planning, execution, personnel

qualification, and documentation for in-process inspections may be accomplished by the CM, when required. Inspection planning documents for in-process inspection and work packages of construction activities controlled by CM are provided to the A-E so that Title III inspection hold points can be included when appropriate. Overview and assessment activities of A-E and CM inspection activities are conducted by the WHC MWTF Project Office and the WHC Project/Site Support QA group.

The A-E and CM coordinate the responsibilities for performance of Title III inspections, as indicated in section 10.1. The Title III inspection personnel will perform final inspections at the point of turnover of plant items, components, and/or systems by the CC for acceptance by the government. Upon acceptance of the item, component, or system by the Title III inspection personnel, WHC assumes custody for the DOE. Items, components, and/or systems determined not to meet acceptance criteria at the point of construction turnover are corrected through the CM. The WHC Project/Site Support QA group will overview the Title III inspection activities of the A-E and CM.

The Title III inspection personnel are responsible for providing complete validated documentation packages of acceptance inspections for review by WHC. After review, the packages are processed as QA records.

11.0 TEST CONTROL

11.1 GENERAL

This section provides a description of the activities and controls, for test control on the MWTF Project. Test requirements and acceptance criteria for inclusion in the procurement and construction specifications are prepared by the A-E. These tests are executed to provide verification of conformance to requirements. Detailed test plans and/or acceptance test procedures are prepared by the CC and vendors/subcontractors in accordance with the requirements of the procurement and construction specifications.

Test plans and procedures identify characteristics to be tested and methods to be used. These detailed test plans and/or acceptance test procedures will be reviewed and approved by the A-E and/or the WHC MWTF Project Office personnel as defined in the design media.

All tests shall be conducted using approved procedures and/or detailed test plans and trained personnel. Data collected as a result of these tests are reviewed and evaluated for acceptability.

11.2 TEST REQUIREMENTS

Test requirements and acceptance criteria are provided or approved by the organization responsible for the design or use, unless otherwise designated. Required tests, including applicable verification tests, hardware integration tests, and in-use tests, are planned, controlled, and documented. The items and characteristics to be inspected and the inspection methods to be employed for each item shall be specified in inspection planning documents. The characteristics to be tested are determined from the design of the item. The test methods selected for a specific item are appropriate to the characteristics to be inspected. Tests are executed in accordance with plans, and results shall be documented. Testing for the purpose of accepting an item or service is performed by personnel other than those who performed or directly supervised the work being tested.

11.3 TEST PROCEDURES

The CC is responsible for the planning and control of construction testing activities. Test planning and identification of mandatory hold points shall be identified by the construction and/or procurement specifications. Test procedures include or reference test objectives and provisions for ensuring that prerequisites for the given test have been met, adequate instrumentation (precision and accuracy) is available and used, necessary monitoring is performed, and suitable environmental conditions are maintained.

Test procedure prerequisites include applicable requirements for calibrated instrumentation, proper equipment, trained personnel, the condition of equipment and item to be tested, suitable environmental conditions, and provisions for data collection.

Potential sources of uncertainty or error will be identified in test plans and procedures, including affected parameters, which are controlled. Precision and accuracy requirements shall be identified in test procedures.

11.4 TEST RESULTS

Test results shall be documented by the participant performing the test, and results are evaluated by the WHC MWTF Project Office and A-E, as requested, to ensure that test requirements have been satisfied.

11.5 TEST RECORDS

Test records include items tested, date of test, test equipment identification and calibration period, tester or data recorder, results and acceptability, acceptance criteria, type of observation, action taken for deviations, and person(s) evaluating test results.

11.6 COMPUTER PROGRAM TESTING

Commercially available or specially developed computer software used for ASME NQA-1 controlled activities shall comply with the following requirements.

11.6.1 Test Requirements for Computer Programs

Test requirements and acceptance criteria for computer programs are based on applicable design or other pertinent technical documents and provided or approved by the organization responsible for the program design or use. Tests such as verification and hardware integration tests shall be controlled through specific testing procedures.

Verification tests are conducted to demonstrate the capability of the computer to produce valid results for test problems that encompass the range of permitted usage for the program. Acceptable means for verifying a computer program include the following:

- Hand calculations
- Calculations using comparable proven programs
- Empirical data and information from technical literature.

For programs that are to be used for operational control, testing is accomplished to demonstrate that required performance is acceptable. The complexity of the computer program determines the number of verification tests to be performed for a program or individual module of the program. If a series of verification tests is used, then testing will verify a correct translation between stages and that the individual modules work properly. Verification testing achieves its purpose by establishing that test requirements are satisfied and the computer program produces a valid result for its intended use. When a program is installed on a different computer or when the operating system configuration is changed, the program shall be verified to confirm the adequacy of the results.

11.6.2 Test Procedures for Computer Programs

Test procedures for computer programs specify the following, as applicable:

- Required tests and test sequence
- Required ranges of input parameters
- Identification of the stages at which testing is required
- Criteria for establishing test cases
- Requirements for testing logic branches
- Requirements for hardware integration
- Anticipated output values
- Acceptance criteria
- Reports, records, standard formatting, and conventions.

11.6.3 Test Results for Computer Programs

Results of verification tests for computer programs shall be documented and the results are evaluated by a qualified individual who is not directly involved in the development or testing of the computer program. The purpose of the evaluation is to ensure independently that test requirements have been satisfied. Requirements and qualifications of the evaluator shall be documented.

11.6.4 Test Records for Computer Programs

Test records for verification tests of computer programs shall be prepared by the organization responsible for conducting the tests. Records of verification tests shall identify the following:

- Version of computer software tested
- Computer hardware used
- Test problems and procedures
- Output results and acceptability
- Action taken in connection with any deviations noted
- Name and qualifications of the individual evaluating the test results.
- Test equipment and calibration, if applicable
- Date of test
- Tester or data recorder
- Simulation models used, if applicable

11.7 INTERFACE

The CC controls all construction testing by procedures that are conducted using approved test plans and trained personnel. Test results will be provided in accordance with the requirements of the design documents.

WHC MWTF Project Office is responsible for overview of testing, construction and the CM test activities. Inspection/surveillance will be controlled by procedures and conducted using approved test plans and checklists. The WHC Project/Site Support QA group is responsible for conducting overview and surveillances of test activities and documentation.

Test reports shall be provided to the WHC MWTF Project Office for tests performed.

The WHC MWTF Project Office provides completed test reports/records to the DPC for processing and retention as QA records.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 GENERAL

This section describes the activities and controls of measuring and test equipment (M&TE) for the project.

Each organization responsible for using M&TE shall have controlled procedures for calibration and control of that equipment. Any M&TE used for acceptance testing or verification is subject to these controls. These controls shall provide for calibration and adjustment at specified intervals to maintain accuracy within necessary limits.

12.2 SELECTION

Selection of M&TE is controlled to ensure proper type, range, accuracy, and tolerance to determine conformance to requirements. The basis for selection of appropriate M&TE is the design documents, which drive the selection by citing either the specific M&TE needed or the attributes to be measured or tested. If the design documents cite specific M&TE (either by direct specification or by reference to a measurement/test standard), then the selection is already accomplished. But if the design documents cite the attributes to be measured or tested, then only that M&TE which is appropriate for those attributes can be selected.

12.3 CALIBRATION

Calibration shall be performed using certified equipment of known relationship to a nationally accepted standard or to a documented calibration basis. Calibration, adjustment, and maintenance of M&TE shall be conducted on prescribed intervals or prior to use. Calibration is not required for devices such as rulers, tape measures, levels, and other devices if normal commercial equipment provides adequate accuracy. Calibration is not required for measuring or testing devices if the results of the measurement or test are not used to accept or reject the item or test. Equipment shall be marked to indicate calibration status or traceability to calibration records.

Calibration standards should have greater accuracy than the equipment or standards that are being calibrated. Calibration standards of the same accuracy may be used if they can be shown to be adequate for the requirements, and the basis for acceptance is documented and authorized by responsible management. Calibration standards are cited in calibration procedures: approval of these procedures by management constitutes acceptance of the standards.

12.4 CONTROL

The method and frequency of M&TE calibration shall be based on the equipment or instrument type, stability characteristics, required accuracy, intended use, or other applicable conditions.

For M&TE found to be out of calibration, an evaluation of the validity of previous inspections and test results is made and documented as well as the acceptability of any items inspected or tested using the suspect M&TE.

Equipment that is out of calibration is tagged, segregated, and not used until recalibrated. Any M&TE consistently found out of calibration is either repaired or replaced.

A calibration is performed if the accuracy of equipment is suspect.

The M&TE is handled and stored to provide protection and maintain accuracy.

12.5 RECORDS

Records of calibration and repair, including "as found" condition, shall be maintained.

12.6 VERIFICATION

The WHC ~~Project/Site Support~~ QA group will ensure adequacy of project M&TE control through periodic assessment of participant activities.

13.0 HANDLING, STORAGE, AND SHIPPING

13.1 GENERAL

The responsibility for developing procedures and instructions and implementing the requirements for handling, storage, and shipping rests with the CC. As appropriate, the CC will delegate these requirements to their suppliers and subcontractors.

13.2 REQUIREMENTS

The need for special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert atmosphere, moisture content, and temperature levels) is considered and specified in the preparation of design documents or purchase specifications, and their existence verified.

13.3 INSTRUCTIONS/PROCEDURES

The A-E and CC, their suppliers, and subcontractors establish work, shipping, and inspection instructions, and drawings and specifications as necessary to prevent damage and preserve items used in the MWTF facilities.

The tasks associated with handling, storage, and shipping of items shall be conducted in accordance with approved procedures, instructions, drawings, specifications, or other documents applicable to the activities being performed.

13.4 TOOLS AND EQUIPMENT

Special handling and lifting equipment and tools are utilized and controlled as specified in approved documents to ensure safe and adequate handling. Tools and equipment shall be inspected and tested at specified intervals in accordance with procedures to verify that the tools and equipment are adequately maintained. Inspections and tests shall be documented and records maintained in accordance with section 17.0 of this QAPP.

13.5 OPERATORS

Operators of special handling and lifting equipment shall be experienced or trained in the use of that equipment.

13.6 MARKING

Instructions for marking and labeling as required to adequately identify, maintain, preserve, and indicate the presence of special environments or controls shall be addressed in instructions and/or procedures.

13.7 QUALITY ASSURANCE/INSPECTION

Documents developed to direct handling, storage, and shipping activities are reviewed and approved by the responsible participant,s QA organization to verify that quality requirements have been included. Special handling tools

and equipment will be inspected and tested initially in accordance with procedures, drawings, and specifications and at specified time intervals to verify adequate maintenance.

13.8 VERIFICATION

Each participant will conduct assessments of its handling, storage, and shipping activities to verify compliance to this QAPP, the participant's respective QA program, and the applicable documents relating to those activities.

Assessments shall be performed and documented in accordance with DOE Order 5700.6C and ASME NQA-1, Section 10, "Inspection," and Section 18, "Audits," as defined in the participants' QA programs.

The WHC Project/Support QA group ensures project control of handling, storage, and shipping by periodic assessment of participant activities.

14.0 INSPECTION, TEST, AND OPERATING STATUS

14.1 GENERAL

Status indicators shall be used to segregate accepted items from those that are nonconforming or awaiting inspection or test. The status of inspection and test activities is identified either on the items or in documents traceable to the items. This status-indicator process ensures that only items passing the required inspections or tests are installed, used, or operated. Status indicators, such as physical location, tags, markings, shop travelers, stamps, inspection records, or other suitable means, are used and maintained. As appropriate, these indicators provide the necessary assurance that required inspections and tests have been performed.

14.2 RESPONSIBILITIES AND INTERFACES

Responsibility for control of inspection, test, and operating status before construction turnover (i.e., during plant construction, procurement of plant equipment, and acceptance testing) has been delegated to the CM. The CM is responsible for the application and removal of status indicators for construction activities.

Following construction turnover, the WHC MWTF Startup and Operations Integration group has responsibility for statusing until plant operations begin, at which time WHC MWTF Operations will assume this responsibility.

Hold tags shall be applied and removed by authorized personnel. Tags will be removed by the personnel who placed the tag, when possible. The CM is responsible to administer the status indicator system until construction/system turnover to WHC. The CM coordinates and administers a lock and tag system to control operating status until the system has been turned over to WHC. The WHC MWTF Startup and Operations Integration group will administer a lock and tag status control system after construction turnover and before WHC MWTF Operations assumes custody of the facilities.

14.3 VERIFICATION

The WHC ~~Project/Site Support~~ QA group will overview the project inspection, test, and operating status through periodic assessments, as applicable.

15.0 CONTROL OF NONCONFORMING ITEMS

15.1 GENERAL

This section describes the activities and controls for reporting nonconforming items or conditions at the project.

The nonconformance report (NCR) procedures are used to promote consistency, timeliness of problem resolution, and processing of the necessary documentation. Participant activities shall be controlled by procedures. All participants can initiate an NCR.

Items that do not conform to specified requirements, or whose conformance is indeterminate, shall be documented on an NCR and controlled to prevent inadvertent installation or use. Controls for nonconformances are provided for notification of affected organizations and for identification, documentation, evaluation, segregation (when practical) and disposition. Nonconformances shall be tracked to closure to ensure that approved dispositions are properly implemented. All personnel associated with the project are responsible for documenting nonconformances and for seeking resolution.

15.2 IDENTIFICATION

Nonconforming items shall be identified by marking, tagging, or other methods that do not adversely affect the item. Identification is required to be legible and recognizable. The form of identification selected is required to not adversely affect the end use of the item. When identification of nonconforming items is not practical segregated storage is required.

15.3 SEGREGATION

Nonconforming items are segregated by placing them in an identified and designated hold area until disposition is complete.

When segregation is not practical or impossible because of size, weight, or access limitations, other precautions shall be employed to preclude use of a nonconforming item. (i.e. status indicating system, with tags securely affixed to the item and displayed in a readily accessible area)

15.4 DISPOSITION

Documentation is required to adequately identify and describe the nonconformance. Nonconforming characteristics are reviewed and dispositions of items are proposed and approved in accordance with approved procedures. These procedures specify the responsibility and authority for evaluation and disposition of nonconformances. Personnel who perform evaluations to approve dispositions are required to be competent in the specific area they are evaluating, have adequate understanding of the requirements, and have access to pertinent background information. Each organization identifies, in writing, the personnel (by job title) who are authorized to evaluate and approve (by signature) proposed NCR dispositions.

Control of further processing, delivery, installation, or use of a nonconforming item is effected pending resolution of NCR's.

Dispositions shall be limited to "accept-as-is," "reject," "repair," or "rework" and identified and documented by signature of the person authorized to accept the disposition.

Technical justification for the acceptability of a nonconformance dispositioned "repair" or "accept-as-is" is documented. Nonconformances to design requirements dispositioned "accept-as-is" or "repair" are subject to design controls commensurate with those applied to the original design.

Repaired or reworked items are reexamined to original requirements unless new requirements have been established.

The disposition of "reject" means that the nonconforming item is scrapped and replaced with a conforming item. Scrapped items/materials are controlled or destroyed to prevent inadvertent installation or use in the project.

"As-built" records, where applicable, are changed to reflect the accepted deviation including identification of the NCR, and identification of the records in the NCR.

Recommended disposition may allow for conditional release of nonconforming items for further processing or assembly. Conditional release of NCRs will be used only for unusual circumstances and must not create a situation that will obstruct or hinder the resolution of the nonconforming condition. Examples of unusual circumstances include, but are not limited to, the following conditions: (1) unacceptable consequences due to excessive schedule delays; (2) results in high cost of equipment (related or unrelated to the nonconforming item; (3) physical interferences result if installed at a later time.

In addition, ~~criteria for conditional release will meet the following:~~

- Those responsible for approval of the NCR agree with conditional release
- The nonconforming characteristic is not rendered inaccessible for implementation of the disposition or for reinspection
- Control of the nonconforming item and its documentation are maintained until the approved disposition for the nonconformance has been acceptably implemented and verified.

Action taken to correct nonconformances are required to be verified and the verification documented.

15.5 INTERFACES

Each of the participants and suppliers to the CC are responsible for implementing a portion of the project nonconformance control system.

The nonconformance control system is designed so personnel from any project organization can initiate an NCR. Nonconformances originating from a supplier shall be reported through the procuring organization.

Identification of nonconforming items is the responsibility of the organization that has custody of the item. The CM will be the onsite custodian for all suppliers.

In cases where the custodian proposes a disposition of either "accept-as-is" or "repair," a written justification must be documented. This justification can be prepared either by the custodian or by the A-E, but in either case, it must be reviewed by the A-E. The A-E is responsible for reviewing the proposed disposition and justification and determining approval, including need for approval by the WHC MWTF Project Office (except for ASME Code applications, in which case the jurisdictional authority has final approval). If the A-E cannot agree with the proposed disposition, it will provide a new disposition and prepare a written justification to explain the change in disposition. Dispositions approved as "rework" or "reject" will not require evaluation or concurrence by the A-E.

Nonconformance control shall be monitored by periodic assessment by the WHC Project/Site Support QA personnel.

16.0 CORRECTIVE ACTION

16.1 GENERAL

Each participant will implement a corrective action system that complies with Basic Requirement 16 of ASME NQA-1 and DOE Order 5700.6C.

Conditions adverse to quality shall be promptly identified, documented, and corrected as soon as practical. The corrective action process applies to conditions adverse to quality and to significant conditions adverse to quality.

A WHC TWRS Project Corrective Action Board (CAB), comprised of management personnel, has been established to (1) evaluate the significance of adverse conditions, and (2) ensure effective corrective action by allocation of adequate resources (i.e., time, material, equipment, personnel, procedures, etc). This CAB is convened on a regular basis to evaluate information from adverse condition reports (ACR). The CAB will determine what information is to be considered and trended.

The organization that detects an adverse condition is responsible for initiating action to document the condition. If the adverse condition involves an item(s) that is described by a released design document, then an NCR is initiated and processed in accordance with approved procedures. If the adverse condition is discovered as a result of an audit or surveillance, then an audit finding, audit observation, or inspection/surveillance report is initiated and processed. If the condition is a significant condition adverse to quality, then a Corrective Action Request (CAR) or Stop Work Order is initiated and processed.

Each of the types of ACR previously identified can be an integrated ACR if more than one MWTF Project participant organization has collaborated to perform the overview function. When an integrated overview occurs, the lead participant organization tracks and trends the integrated overview according to the lead organization's internal procedure.

The criteria for a significant condition adverse to quality is defined to be any one of the three conditions cited in Section 16.3. In the case of a significant condition adverse to quality, the cause of the condition is determined and corrective action is taken to remedy the immediate problem and to preclude recurrence. The identification, cause, and proposed corrective action for significant conditions adverse to quality are concurred with by WHC Project/Support QA and reported to the highest levels of management. Follow-up action is taken by the Project/Support QA group to verify satisfactory implementation of approved corrective action within prescribed time limits for all types of adverse conditions.

16.2 TREND ANALYSIS

A trend analysis system and procedures shall be developed and implemented by all participants to analyze quality information they generate such as audit reports, surveillance reports, NCRs, CARs, and other deficiency documents for possible adverse quality trends. The WHC Project/Support QA organization will summarize and maintain an overall project assessment and

reporting of quality trends. Trend analysis will adhere to the following criteria:

- Be performed in a manner and at a frequency that provides for prompt identification of adverse quality trends
- Be reported to affected organizations and participants' project management
- Be performed by the QA organization.

16.3 CORRECTIVE ACTION CRITERIA

Criteria for determining the existence of significant conditions adverse to quality are as follows:

- Imperilment of the uninterrupted progress of the MWTF Project due to an imminent health or safety concern for personnel or the public
- A single, serious breach of requirements (i.e., a single instance of a problem that is determined by the CAB or functional line management to have a serious impact)
- A repeated breach of requirements (i.e., multiple instances of recurring problems for which individual corrective actions have not been effective in precluding repetition).

Procedures for corrective action specify the QA organization's responsibility to concur with proposed corrective action, verify corrective action implementation, and prescribe time limits for closeout of corrective action implementation.

16.4 TRACKING

A tracking system for all deficiencies will be established by WHC ~~Project/Site Support~~ QA personnel to ensure that the deficiencies are appropriately addressed, prioritized, trended, and closed.

16.5 REMEDIAL ACTION

Remedial action is documented and initiated after a deficiency is reported. The following actions shall be carried out by the responsible organization:

- Concurrence with the remedial action to ensure QA requirements are satisfied
- Follow-up to verify proper implementation of remedial action
- Closeout of the remedial action in a timely manner.

17.0 QUALITY ASSURANCE RECORDS

17.1 GENERAL

This section describes the activities and controls, for control of records for the project.

The term "records", used throughout this section, is to be interpreted as QA records as defined in ASME NQA-1, Supplement 17S-1.

17.2 RECORDS SYSTEM

Each participant shall develop a quality records program appropriate for its scope of work.

A records system consistent with the schedule for accomplishing work activities and in compliance with the general requirements of Supplement 17S-1 shall be established. The records system shall be defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation.

Records that furnish documentary evidence of quality shall be specified, prepared, and maintained. Measures are established to ensure that records are legible, identifiable, traceable, and retrievable. Records shall be protected against damage, deterioration, or loss. Requirements and responsibilities for record generation, transmittal, evaluation, distribution, retention, maintenance, and disposition are established and documented in procedures. Each participant organization is responsible for generating records that furnish documentary evidence of quality according to scoping statements appearing in work authorizing documents. The description of controls for records only applies to QA records that have been completed. Documentary evidence of quality that is not completed is not subject to the controls described.

17.3 RECORDS ADMINISTRATION

The design specification, procurement documents, test procedures, quality procedures, contractors operating procedures, or other documents specify the records to be generated, supplied, or maintained by or for the owner.

Documents that become records are reviewed for legibility, accuracy, traceability, and completeness appropriate to the work accomplished.

17.4 RECORD VALIDATION

Documents are considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. This authentication may take the form of a statement by the responsible individual or organization. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization. Authentication (or validation) involves reviewing the document to ensure that the information appearing on the document is complete, and that the document will receive no more entries unless subjected to a formal change control

process. Following validation, the document is regarded as a completed QA record and submitted to the DPC for processing. The A-E shall have responsibility for maintaining control of QA records until the project has been completed and the records are formally dispositioned and transferred to or requested by WHC for retention. These records may be originals or legible reproductions.

17.5 INDEX

The records shall be indexed in accordance with an indexing system that includes record retention time and location of the record within the record system.

17.6 DISTRIBUTION

The procedures developed and used by the DPC to process QA records specify the distribution, handling, and control appropriate for each record. Standard distribution lists are augmented by the designation of specific personnel affected by the document.

17.7 IDENTIFICATION

Records and indexing systems provide sufficient information to permit identification between the record and the item or activity to which it applies.

17.8 CLASSIFICATION

QA Records are classified as "lifetime" or "nonpermanent" in accordance with the following criteria.

- Lifetime Records--Lifetime records are those that meet one or more of the following criteria:
 - Those which would be of significant value in demonstrating capability for safe operation
 - Those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item
 - Those which would be of significant value in determining the cause of an accident or malfunction of an item
 - Those which provide required baseline data for in-service inspections
 - Those which substantiate development or major decisions involving safety, the environment, etc.
 - Those which evidence conformance to code and specifications
- Lifetime records are required to be maintained by or for the facility owner for the life of the particular item while it is installed in the facility.

- ASME Section III lifetime records are defined in ASME Section III Subsection NCA and shall be used for ASME Section III code work.
- Nonpermanent Records--Nonpermanent 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.

17.9 RETENTION OF RECORDS

Records shall be retained in accordance with the lifetime and non-permanent classifications previously defined.

- Lifetime records are identified by the DPC for the DOE. Lifetime records that relate to the physical configuration of the MWTF will be maintained through plant decommissioning.
- Non-permanent records are retained by the DPC in accordance with controls established in internal implementing procedures.

17.10 CORRECTED INFORMATION IN RECORDS

Records shall be corrected in accordance with procedures that provide for appropriate review or approval by the originating organization. The correction includes the date and identification of the person or organization authorized to make such corrections, and a single line drawn through the deleted text.

17.11 RECORDS RECEIPT

Each organization responsible for receipt of records designates a person or organization responsible for receiving the records. The designee is responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage. For the MWTF Project, the DPC (a Hanford Site services function administered by WHC) receives records.

The DPC provides for protection of records against damage or loss during and after receipt. A system for receipt control is established to safeguard records during processing. Incoming documents are logged, and their processing is tracked to permit a current and accurate assessment of the status of records during the receiving process.

- As a minimum, a receipt control system shall include the following:
 - A method for designating the required records
 - A method for identifying records received
 - Procedures for receipt and inspection of incoming records
 - A method for submittal of completed records to the storage facility without unnecessary delay.

Each control system is structured to permit a current and accurate assessment of the status of records during the receiving process.

Records are processed at the DPC for turnover to RL's Records Holding Area for interim storage before sent to the long-term storage destination. The DPC is not a storage facility; however, while records are being processed they are protected and secured. Upon turnover to RL, WHC is no longer responsible for the records.

17.12 STORAGE, PRESERVATION, AND SAFEKEEPING

A written processing procedure has been prepared for the DPC and responsibility assigned for enforcing the requirements of the procedure. This procedure includes the following:

- A description of the facility
- The filing system to be used
- A method for verifying that the received records are in agreement with the transmittal document and the records are legible
- A method for verifying that the records are those designated
- The rules governing access to, and control of, records during processing
- A method for maintaining control of, and accountability for, records removed from the facility
- A method for identifying supplemental information and disposing of superseded records to RL's Records Holding Area.

To preclude deterioration of the records while they are being processed at the DPC, the following requirements apply.

- Provisions are made to prevent damage from moisture, temperature, and pressure.
- Records are firmly attached in binders, or placed in folders/envelopes, for preparation for long-term storage in steel file cabinets or in containers on shelving at the long-term storage destination.
- Provisions are made for special processed records (such as radiographs, photographs, negatives, microfilm, and magnetic media) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity.

Measures shall be established at the DPC to preclude unauthorized access to records during processing. These measures guard against larceny and vandalism. Measures are also taken to provide for replacement, restoration, or substitution of records lost or damaged during processing.

Records being processed at the DPC shall be protected in a facility constructed and maintained in a manner that minimizes the risk of damage or destruction from the following:

- Natural disasters such as winds, floods, or fires
- Environmental conditions such as high and low temperatures and humidity
- Infestation of insects, mold, or rodents.

Records maintained by a supplier at the supplier's facility or other location shall be accessible by the project.

Records accumulated at various locations prior to transfer shall be accessible to the project directly or through the procuring organization.

Suppliers' nonpermanent records are disposed of only after the applicable following conditions are satisfied.

- A code data report is signed or a code symbol stamp is affixed for items released for shipment.
- Warranty considerations are satisfied.
- Purchase requirements are satisfied.

Each participant shall develop a quality records program appropriate for its scope of work.

The DPC uses one-hour, fire-rated, Underwriters Laboratory-approved containers for storage of records during processing. Procedures specify the maximum allowable period before records must be turned over to the RL Records Holding Area.

17.13 INTERFACES

Each of the participants and suppliers to the CM and WHC are responsible for implementing portions of the MWTF QA Records System as it applies to their work assignment. Specific responsibilities for identifying, preparing, validating, authenticating, logging, indexing, reviewing, classifying, correcting, safekeeping, storing, protecting, transmitting, distributing, retaining, dispositioning, retrieving, maintaining, and tracking when not in storage shall be described in controlling procedures. The WHC MWTF Project Office, with the assistance of the A-E and CM, coordinates activity between organizations to effect consistent processing of QA records.

18.0 Audits

18.1 GENERAL

All MWTF Project participants shall have established requirements for the MWTF Project QA Audit Program to provide independent verification of status, adequacy, compliance, and implementation effectiveness of this QA program and its elements. These independent verifications result in audits and surveillances, which comprise the independent assessments conducted for MWTF.

Independent assessments are performed by personnel from oversight groups independent of line responsibilities for achievement of quality. These independent assessments are performed by oversight personnel to objectively evaluate compliance to (and effectivity of) requirements. Independent assessments differ from management assessments (discussed elsewhere) in that management assessments evaluate one's own performance.

Section 2.9, "Independent Assessment", describes provisions for surveillances. This section describes provisions for implementing the QA audit program.

18.2 REQUIREMENTS

Planned and scheduled audits are performed to verify compliance with the QA program and to determine its effectiveness. These audits are performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited. Audit results shall be documented and reported to, and reviewed by, responsible management. Follow-up action shall be taken where indicated. The MWTF Project QA Audit Program complies with ASME NQA-1 and Supplement 18S-1.

18.3 AUDIT PROGRAM IMPLEMENTATION

Project procedures describe the methods and responsibilities applicable to audit activities to determine compliance with requirements and to assess programmatic compliance and implementation effectiveness of the participants' QA programs. The audit program includes technical and programmatic verifications.

The manager of WHC Compliance Assurance (CA) is responsible for the development, implementation, and maintenance of the WHC Audit Program. The A-E, CM, and CC are responsible for the development, implementation, and maintenance of their respective audit programs and procedures. Participants' audit procedures are submitted to WHC Project/Site Support QA for information to ensure that a consistent approach is practiced across the MWTF Project. The WHC CA section provides overall coordination, training, and records maintenance of all WHC auditing functions. Audit performance duties are the responsibility of the WHC CA section. The WHC Project/Site Support QA group plans and conducts independent assessments of the participant organizations' scheduled activities as necessary. WHC CA audits the quality affecting activities of other WHC MWTF Project entities.

18.4 AUDIT PROCESS

Project procedures for audit activities address the accomplishment of the planning and scheduling of audit activities. This is to ensure that program deliverable products and processes are evaluated commensurate with importance to achieving mission objectives or scheduled completion dates assigned to the products or processes. Audits of the implementation effectiveness of the participating contractors' quality programs are performed as deemed necessary by the WHC CA group.

18.5 AUDIT SCHEDULING

The WHC CA group develops, maintains, and implements an audit schedule that covers applicable program elements. Auditing shall begin early in the life of the project, and shall continue at intervals consistent with the schedule for accomplishing the activities. This schedule is coordinated with RL to ensure comprehensive overview of all participants. Project participants/contractors shall be responsible for their suppliers.

The project suppliers' QA programs are evaluated by the responsible contractor. (ASME Section III code stamp holders are subject to ASME Code rules for vendors).

18.6 AUDIT TEAMS

Audit team leaders are selected before the start of each audit and they are required to be certified lead auditors. Qualifications of lead auditors comply with requirements of the ASME NQA-1, Supplement 2S-3, and Appendix 2A-3. The lead auditor is responsible to organize and direct the audit, coordinate the preparation and issuance of the audit report, evaluate the responses, and ensure that the audit team is prepared prior to the audit.

Members of the audit team shall be independent with respect to activities they will audit (i.e., no audit team member audits an activity for which they were directly responsible). Management personnel of audited activities are prohibited from participating in the selection of audit team members who will audit their activities.

Collectively, audit team members will have the necessary programmatic and technical expertise in the work being audited by virtue of experience and/or specific, documented orientation or training.

Audit teams may include members from appropriate technical disciplines who will verify adequacy of technical processes employed to ensure validity and correctness of technical work.

18.7 AUDIT PREPARATION

As a minimum, preparation for individual audits should include the following: preparation of an audit plan and an audit checklist or procedure; study of auditee procedures applicable to the activities to be audited; evaluation of relevant surveillance results; results of previous audits of the same activities; relevant corrective action history; review of trend data; and review of the current status of work.

The audit plan identifies the scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists.

The scope of each audit is based on an evaluation of the activities to be audited. The evaluation considers the following:

- Results of previous internal audits
- Results of previous external audits
- Impact of significant changes in personnel, organization, or QA program.

The scope of an audit may include verification of product quality and technical adequacy of work being done as well as programmatic compliance and implementation effectiveness. If personnel with appropriate technical knowledge are assigned as audit team members, they shall evaluate technical aspects of processes and acceptability of the quality of products resulting from the process. Technical requirements are selected for audit verification from the governing technical requirements documents and included in audit checklists.

18.8 AUDIT PERFORMANCE

Audit team members perform document reviews, interviews, and other activities described in the audit checklist or procedure under the direction of the audit team leader. Objective evidence is examined, as necessary, to determine if the checklist items are being effectively implemented.

Audit team members regularly communicate the status of assigned activities as well as problems and potential problems to the audit team leader. The audit team leader ensures problems that require immediate attention are relayed to the audited organization's representatives in a timely manner. Regular discussions with the audited organization's representatives are held to communicate the status of audit activities and promote effective communication between the auditor and the auditee.

Management of the audited organization is actively involved into the audit process commencing with the audit planning phase. Audit performance includes documentation of the evidence examined and conditions observed so that a sound basis exists for reported conclusions.

Results of the audit are presented to the audited organization's representatives by the audit team leader (and team members) in a post-audit conference to complete the audit performance phase. The audit team assesses the adequacy and effectiveness of the program and reports the results to responsible management for appropriate action.

18.9 AUDIT REPORTING

The audit reports should contain the following information, as appropriate:

- A description of the audit scope
- Identification of the audit team members
- Identification of personnel contacted during the audit
- A summary of the audit results, including a statement describing the effectiveness of the quality elements audited
- A clear description of each audit finding that will allow the audited organization to understand the finding and take corrective action.

Before transmittal and distribution, the audit report will be signed by the audit team leader and approved by the QA manager of the organization leading the audit. The audit is issued to the audited organization for review, assessment, and appropriate action. Copies of the audit report also are distributed to other affected organizations as well as to upper management of the audited organization.

Audit findings require responses from the affected organization, including specified action dates.

18.10 POST-REPORT ACTION

Management of the affected organization investigates audit findings and determines root cause(s), schedules corrective action, and notifies (in writing) the auditing organization of actions planned or taken. The affected organization will examine other areas of similar activity for related deficiencies. Past work shall be evaluated to determine if remedial corrections are required. Audit findings will be tracked to ensure that actions are taken to address, prioritize, and close each finding.

Management of the auditing organization shall evaluate the responses to determine the following:

- Adequacy of cause determinations
- Acceptability of commitments for correcting the deficient (and similar) conditions (past and present)
- Acceptability of committed actions to preclude recurrence of the deficient conditions and of the schedule for completing such actions
- Adequacy of the evaluation of impact of the deficient work performed and the generic implications to the program
- Appropriateness of corrective action responsibility assignments.

Followup shall be performed by the auditing organization to verify satisfactory implementation of corrective and preventive actions taken to resolve audit findings. Verification of corrective and preventive action implementation shall be documented to support closeout of findings.

18.11 AUDIT RECORDS

Audit records include audit plans, audit reports, written replies, and the record of completion of corrective action.

19.0 COMPUTER SOFTWARE

19.1 GENERAL

The MWTF Project participants developing or using computer software programs that affect project activities will have approved procedures defining how work will be performed to comply with the requirements as indicated in this section of the QAPP.

Computer software used for ASME NQA-1 controlled activities shall comply with the testing requirements of Section 11.6 of this QAPP.

19.2 REQUIREMENTS

Both developers and users of project-related software are required to have a Software Quality Assurance Plan (SQAP) and/or procedures which provide for software validation and configuration control. SQAP and/or procedure content shall be based on whether the software is specifically developed for project use or has been previously developed/purchased and validated.

Organizations that use existing software shall provide a SQAP and/or procedures that, as a minimum, validate that the software is appropriate for the intended use and provides for configuration control of the software. Additionally existing software must meet the requirements of 19.6.

Organizations that undertake computer software development activities shall adhere to a computer software life-cycle model. The relative emphasis placed on each phase of the computer software life cycle depends on the nature, complexity, and importance of the computer software being developed.

The elements of the life-cycle model can be spread among multiple organizations. For example, the A-E may specify the software requirements so that a vendor can develop the software. In such a case, the product of the vendor is submitted to the A-E at the end of the development phase for the A-E to accomplish the remainder of the life-cycle model. Thus, affected organizations are those that have responsibilities for accomplishing one or more of the software life-cycle development phases.

The documentation for each phase of the computer software life cycle is reviewed and approved as specified in each affected organization's computer Software QA Plan (SQAP).

Computer software development requirements will be furnished by the WHC MWTF Project Office to software developers and/or users and will include, as a minimum, the Hanford Site data value standards and the American National Standards Institute (ANSI)/Institute of Electrical and Electronics Engineers (IEEE) software standards.

19.3 SOFTWARE QUALITY ASSURANCE PLAN

Participants developing computer software that affects project activities shall describe their computer software development, test, and configuration management system in their SQAPs and/or procedures. The SQAPs and/or procedures prepared by the participants are submitted to the A-E and/or

the WHC MWTF Project Office for review and approval. The SQAPs and/or procedures prepared by WHC are submitted to RL for review and approval. The SQAP is used for the following:

- Indicate the methods used to develop computer program requirements, to translate those requirements into a detailed design and to implement that design in executable code.
- Identify the types of documentation to be prepared, reviewed, and maintained during computer software design, code implementation, test, and use.
- Describe the methods for managing interfaces involving computer software documentation.
- Identify the methodology for establishing computer software baselines and baseline changes and for tracking changes throughout the life of the computer software.
- Specify the process used for verification of the computer software and validation of models developed or applied to analyses.
- Identify the procedures for reporting and documenting computer software discrepancies (including sources), evaluating impacts of discrepancies on previous calculations, and determining appropriate corrective action.

A Software Development/Project Plan shall be prepared for each computer software development or application effort at the start of the computer software life cycle. These Project Plans should be tailored to the specific needs of the project depending on the nature, complexity, and importance of the computer software being developed. The Software Development/Project Plan shall identify the following as a minimum:

- Computer software products to which it applies
- Organizations responsible for computer software quality and their tasks and responsibilities
- Required documentation
- Required computer software and documentation reviews.

Standards, conventions, techniques, or methodologies that guide software development shall be compliance verified in accordance with approved procedures.

The results of unverified and/or unvalidated software codes may not be used for any activities/processes, etc., that affect project activities until verification and validation have been documented and a computer software baseline established. The computer SQAP clearly indicates when developmental codes will be controlled in accordance with this MWTF QAPP.

19.4 COMPUTER SOFTWARE VERIFICATION AND VALIDATION

Verification of computer software and model validation shall be planned and performed prior to the use of such computer software to perform technical calculations.

The responsible participant develops verification and validation plans that employ methods such as inspection, analysis, demonstration, and test to ensure that the software adequately and correctly performs all intended functions and that it does not perform any function that, either by itself or in combination with other functions, can degrade the entire system.

Verification, validation, and documentation of the final version of the software product--with respect to its intended application--is accomplished by an independent individual or organization (one who did not work on the original computer software) before use for project activity.

19.4.1 VERIFICATION

Verification activities shall be integrated into the software life cycle and verification performed to ensure that software requirements are implemented in the design and that the design is correctly implemented in code. When testing is performed to verify computer software related to ASME NQA-1 controlled activities, ASME NQA-1 and Supplement 11S-2 is used except as modified by Section 11.6 of this QAPP.

19.4.2 VALIDATION

Validation activities shall be documented and performed to demonstrate that the model, as embodied in the software, is a correct representation of the process or system for which it is intended.

19.5 CONFIGURATION MANAGEMENT

A computer software configuration management system shall be established by each participant to ensure positive identification of computer software and control of software baselines and changes. This system includes the following:

- Configuration identification
 - Uniquely identifies each configuration item or version, including identification of software version in the output, when feasible
 - Identifies changes to configuration items by revision
 - Places the configuration item in a relationship with other configuration items
 - Directly relates each code version with its associated documentation.
- Configuration change control

- This documentation contains a description of the change(s) as follows:
 - The identification of the originating organization
 - The rationale for the change
 - The identification of affected baselines and computer software configuration items
 - Evidence of evaluation, coordination, and approval.

Changes to computer software are subject to the same level of approval, verification, and validation as the original computer software.

- Configuration status accounting
 - The following information is recorded and reported:
 - A listing of the approved configuration identification
 - The status of proposed changes to the configuration
 - The implementation status of approved changes
 - A brief chronology of the software versions, including descriptions of the changes made between versions
 - Information to support the function of configuration identification and configuration control.

19.6 QUALIFICATION OF EXISTING SOFTWARE

Existing software may be qualified for use based on the ability of the software to provide acceptable results for specific applications. Existing software can be accepted for use if the following conditions are met.

- Software is verified and validated.
- A computer software baseline is established prior to its use.

19.7 DOCUMENTATION

Life-cycle documentation of software specified in the SQAP includes, as a minimum, the following:

- Software configuration management plans
- Software requirements specification
- Software design and change documentation (data models, data dictionary)

- Verification and model validation documentation
- User documentation (reference or technical manuals)
- Description of mathematical models and numerical methods
- Code assessment and support (verification and validation records)
- Continuing documentation and code listings (problem reports and change notifications)
- Software summary.

19.8 REVIEWS

Reviews of software development activity are performed by participants that develop or use project-related computer software, as each life-cycle phase is completed. This ensures the completeness and integrity of each development phase. Procedures for reviews shall identify the participants and their specific responsibilities during the reviews and in the preparation and distribution of the reports.

19.9 DISCREPANCY REPORTING AND CORRECTIVE ACTION

A formal MWTF Project computer software discrepancy reporting and corrective action system shall be established. The reporting system will be integrated with the configuration management system to provide current correct information to software developers and users. Discrepancy reporting and corrective action systems will ensure, as a minimum, the following:

- Defects are documented and corrected
- Defects are assessed for criticality and impact on previous applications
- Corrections are reviewed and approved before changes to the software configuration are made
- Preventive and corrective actions provide for appropriate notification of affected organizations
- Deficiencies are analyzed for impacts on previous work
- Deficiencies are documented and controlled in accordance with Section 16 of this QAPP.

19.10 MEDIA CONTROL AND PHYSICAL SECURITY

Procedures that specify measures to physically protect media containing the images of computer software and prevent their inadvertent damage or degradation shall be prepared by each participant that develops or uses computer software.

Special software developed by the participants shall be properly protected such that any required change is incorporated by authorized personnel only. The program output should be a "read only" file.

19.11 ACQUIRED COMPUTER SOFTWARE

Participants procedures shall control the transfer of computer software, as applicable.

19.12 COMPUTER SOFTWARE APPLICATION

Technical calculations using computer software shall be performed with computer codes and software operating procedures sufficiently defined to allow independent repetition of the entire computation. Model validation is performed for the specific application of the software. If model validation has not been previously performed, the model will be validated and documented.

Procedures shall provide for the following:

- Controlling application of verified software and/or validated models to technical calculations
- Determining which technical calculations are subject to controls
- Documenting and reviewing software applications and analyses
- Ensuring that results are accurate and reproducible
- Identifying or marking record copies of analyses and supporting documentation
- Generating and documenting software used to perform technical calculations
- Conducting independent review and approval to ensure that software is applicable to the problem being solved and that input and assumptions are valid and traceable.

Software application outputs shall be traceable to the software and hardware configuration status used to produce those outputs. Output documents, including designs, reports, spreadsheets, charts, etc., shall be traceable to the software and its revision identification, the hardware configuration, date, user identification, and input data source, as a minimum. This information shall be maintained in logs or by other methods of traceability for each application run that is used to support a formally released output (e.g., design, design analysis, environmental report, etc.)

Input data controls shall be specified in procedures, operating instructions, user manuals, or special application plans. Input controls include, but are not limited to, calibration of input devices, such as measuring and test equipment, plant instruments and lab equipment; independent verification of physical measurements; and physical verification of items, such as lot quantities or equipment positioning.

20.0 REFERENCES

- ASME, 1989, *Quality Assurance Program Requirements for Nuclear Facilities*, ASME NQA-1-1989 with addenda 1a-1989, 1b-1991, and 1c-1992, American Society of Mechanical Engineers, New York, New York.
- DOE, 1991, *Quality Assurance*, DOE Order 5700.6C, U.S. Department of Energy-Headquarters, Washington, D.C.
- RL, *Functional Design Criteria for the "Multi-Function Waste Tank Facility"*, Project W236A, Revision 0, U.S. Department of Energy, Richland Field Office, Richland, Washington.
- WAC, 1991, *Washington Administrative Code, "Dangerous Waste Regulations"*, Chapter 173-303.

21.0 GLOSSARY

ABBREVIATIONS, ACRONYMS, AND INITIALISMS

A-E	Architect-Engineer
B&PV	ASME Boiler and Pressure Vessel Code
CA	Compliance Assurance
CAB	Corrective Action Board
CAR	Corrective Action Request
CC	Construction Contractor
CM	Construction Manager
DOE	U.S. Department of Energy
DOE-HQ	U.S. Department of Energy-Headquarters
DPC	Document Processing Center
FDC	functional design criteria
FSAR	Final Safety Analysis Report
LOI	letter of instruction
M&TE	measuring and test equipment
MRF	Multi-Function Waste Remediation Facility
MWTF	Multi-Function Waste Tank Facility
NCR	nonconformance report
NDE	nondestructive examination
participants	Project Participants
PO	Multi-Function Waste Tank Facility Project Office
PSAR	Preliminary Safety Analysis Report
QA	quality assurance
QAP	Quality Assurance Program
QAPI	Quality Assurance Program Index
QAPP	Quality Assurance Program Plan
QC	quality control
RL	U.S. Department of Energy, Richland Field Office
SDD	Software design description
SDRD	Supplemental Design Requirements Document
SOW	Statement of Work
SQAP	Software Quality Assurance Plan
TWRS	Tank Waste Remediation System (WHC)
WHC	Westinghouse Hanford Company

APPENDIX A
QUALITY ASSURANCE PROGRAM INDEX

Quality Assurance Program Index

DOE Order 5700.6C criteria	NQA-1 (basic requirement) supplements	QA requirement title	Implementing Procedures ^a				
			WHC Controlled Manuals				
			ADMIN (B)	QA (A)	ENG (B)	PROJ (B)	ENV
1	NQA-1 (1) 1S-1	Organization	CM-1 CM-1-3	QR 1.0	CM-6-1	CM-6-2	--
1	--	General Provisions ^b	--	--	--	--	CM-7-5
1	NQA-1 (2)	Quality Assurance Program	CM-1-3 CM-1-5	QR 2.0	--	CM-6-2	--
1	--	QA Program Planning Project Type Activities	--	QI 2.1	CM-6-1	--	--
1	--	QA Program Planning	--	QI 2.2	CM-6-1	--	--
2	NQA-1 2S-2	Qualification and Certification of NDE Personnel	--	QI 2.6 CM-4-39	--	--	--
2	NQA-1 2S-1, 2S-3 2S-4, 2A-1 2A-3	QA Qualifications and Instructions	--	CM-4-5	--	--	--
9	--	QA Self-Assessments	--	CM-4-5	--	--	--
4	--	Guidance for the QA review of Documents	--	CM-4-5	--	--	--
2	--	Environmental Training ^b	--	--	--	--	CM-7-5
6	NQA-1 (3) 3S-1	Design Control	CM-1-3	QR 3.0	CM-6-1	CM-6-2	--
6	--	Design Verification Overview	--	CM-4-5	--	--	--
7	NQA-1 (4) 4S-1	Procurement Document Control	CM-1-3 CM-2-1 CM-2-2	QR 4.0 QI 4.1	CM-6-1	CM-6-2	--
7	--	External Services Control	CM-2-5	QI 4.2	--	--	--
4	NQA-1 (5)	Instructions, Procedures, and Drawings	CM-1-3	QR 5.0	CM-6-1	CM-6-2	--
4	NQA-1 (6) 6S-1	Document Control	CM-1-3 CM-3-5	QR 6.0	CM-6-1	CM-6-2	--
4	--	Control of QA Controlled Manuals	--	CM-4-5	--	--	--
4	--	Records and Reporting Requirements ^b	--	--	--	--	CM-7-5
7	NQA-1 (7) 7S-1	Control of Purchased Items and Services	CM-1-3 CM-2-1	QR 7.0	CM-6-1	CM-6-2	--
7	--	Preprocurement, Planning, and Proposal Evaluation	CM-2-1	QI 7.1	--	--	--
7	--	Receiving Inspection	CM-2-2	CM-4-5	--	--	--
7	--	Supplier Evaluation	--	QI 7.2	--	--	--
7	--	Source Surveillance and Inspection	--	QI 7.3	--	--	--

Quality Assurance Program Index

DOE Order 5700.6C criteria	NQA-1 (basic requirement) supplements	QA requirement title	Implementing Procedures ^a				
			WHC Controlled Manuals				
			ADMIN (B)	QA (A)	ENG (B)	PROJ (B)	ENV
7	--	Acquisition of Instruments and Vendor Measurement Services	--	QI 7.6	--	--	--
7	--	Procurement ^b	--	--	--	--	CM-7-5
5	NQA-1 (8) 8S-1	Identification and Control of Items	CM-1-3	QR 8.0	CM-6-1	CM-6-2	--
5	NQA-1 (9) 9S-1	Control of Processes	CM-1-3	QR 9.0	CM-6-1	CM-6-2	--
5	NQA-1 2S-2	Control of Nondestructive Examination	--	QI 9.1 CM-4-38	CM-6-10	--	--
5	--	Control of Welding and Brazing	CM-4-3	QI 9.2	CM-6-10	--	--
8	NQA-1 (10) 10S-1	Inspection and Surveillance	CM-1-3 CM-1-4	QR 10.0	CM-6-1	CM-6-2	--
8	--	Inspection Instruction for Operations, Maintenance, and Modification	--	CM-4-5	--	CM-6-2	--
8	--	Inspection Instruction for Manufacturing and Fabrication	--	QI 10.2	--	--	--
8	--	Inspection and Identification Stamp Control	--	CM-4-5	--	--	--
10	--	Surveillance	--	CM-4-5	--	--	--
8	--	Visual Weld Inspection	--	CM-4-5	--	--	--
8	--	Visual Hydrostatic and System Leakage Test Procedure and Acceptance Criteria	--	CM-4-5	--	--	--
10	--	Environmental Monitoring ^b	--	--	--	--	CM-7-5
5, 8	NQA-1 (11) 11S-1	Test Control	CM-1-3	QR 11.0	CM-6-1	CM-6-2	--
8	--	Test Verification	--	CM-4-5	--	--	--
5, 8	NQA-1 (12) 12S-1	Control of Instruments	CM-1-3	QR 12.0	CM-6-1	CM-6-2	--
5, 8	--	Operator Calibrated M&TE	--	QI 12.2	--	--	--
5, 8	--	Calibration Control of Plant-Installed Instrumentation	--	QI 12.3	--	--	--
5, 8	--	Calibration Control of M&TE	--	QI 12.4	--	--	--
5, 8	--	Statistically Controlled Analytical Instruments	--	QI 12.5	--	--	--

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DOE Order 5700.6C criteria	NQA-1 (basic requirement) supplements	QA requirement title	Implementing Procedures ^a				
			WHC Controlled Manuals				
			ADMIN (B)	QA (A)	ENG (B)	PROJ (B)	ENV
5, 8	--	Determinately Controlled Laboratory Instruments	--	QI 12.6	--	--	--
5, 8	--	Assuring Availability of Laboratory Instruments	--	QI 12.7	--	--	--
5	NQA-1 (13) 13S-1	Handling, Storage, and Shipping	CM-1-3 CM-2-14	QR 13.0	CM-6-1	CM-6-2	--
5	--	Hazardous Materials Transportation and Packaging	CM-1-3	CM-4-5	--	--	CM-5-16
5	--	Handling of Corrosion Resistant Materials During Receipt, Storage, and Transportation	--	QI 13.3	--	--	--
5	--	Chain-of-Custody for samples of Environmental Media and Wastes	--	QI 13.4	--	--	CM-7-7
8	NQA-1 (14)	Inspection Test and Operating Status	CM-1-3	QR 14.0	CM-6-1	CM-6-2	--
3	NQA-1 (15) 15S-1	Control of Nonconforming Items	CM-1-3	QR 15.0	CM-6-1	CM-6-2	--
3	--	Nonconforming Item Reporting	--	QI 15.1	--	--	--
3	--	Administration of a Nonconformance Reporting System	--	CM-4-5	--	--	--
3	--	Nonconformance Report Processing	--	QI 15.2	--	--	--
3	--	Control of Suspect/Counterfeit Items	--	QI 15.6			
3	--	Compliance Plan ^b	--	--	--	--	CM-7-5
3	NQA-1 (16)	Corrective Action	CM-1-3 CM-1-4	QR 16.0	--	--	--
3	--	Trend Analysis	--	QI 16.1	--	--	--
4	--	Corrective Action Request Records	--	CM-4-5	--	--	--
4	--	Corrective Action Request	--	QI 16.2	--	--	--
3	--	Quality Assurance Bulletins	--	QI 16.3	--	--	--
4	NQA-1 (17) 17S-1	Quality Assurance Records	CM-1-3 CM-3-5	QR 17.0	CM-6-1	CM-6-2	--
4	--	Quality Assurance Records Control	--	QI 17.1	--	--	--
4	--	Reduction and Reporting of Chemical Analysis Results	--	QI 17.2	--	--	--

Quality Assurance Program Index

DOE Order 5700.6C criteria	NQA-1 (basic requirement) supplements	QA requirement title	Implementing Procedures ^a				
			WHC Controlled Manuals				
			ADMIN (B)	QA (A)	ENG (B)	PROJ (B)	ENV ^b
10	NQA-1 (18) 18S-1	Audits	CM-1-3 CM-1-4	QR 18.0 CM-4-6	CM-6-1	CM-6-2	--
10	--	Audit Programming and Scheduling	--	QI 18.1	--	--	--
10	--	Planning, Performing, Reporting, Follow-up, and Closure of Quality Assurance Audits	--	CM-4-5	--	--	--
9	--	Environmental Compliance Verification ^b	--	--	--	--	CM-7-5
4, 6, 8	NQA-1 11S-2	Software QA requirements	CM-3-10	QR 19.0	--	--	--

1 = Program.
2 = Personnel training and qualification.
3 = Quality improvement.
4 = Documents and records.
5 = Work processes.
6 = Design.
7 = Procurement.
8 = Inspection and acceptance testing.
9 = Management assessment.
10 = Independent assessment.

ADMIN = Administrative.
CM = Controlled Manual.
ENG = Engineering.
ENV = Environmental.
M&TE = Measuring and Test Equipment.
PROJ = Projects.
QA = Quality Assurance.
QI = Quality Instruction.
QR = Quality Requirement.

^a Revisions are not shown in this index as it is a reference list to show relationships and is not a requirements list of established mandatory procedures.

^b Indicates Environmental interfaces related to 5700.6C criteria.

NOTE: A. QR and QI Procedures are contained within the Level II WHC-CM-4-2 "Quality Assurance Manual".

B. WHC-IP-1026, EPG 1.0, Table 2 of the "Engineering Practices Guidelines" manual lists practices and requirements which implement QR 1.0 through QR 19.0.

END DATE

9-14-95