QUALITY ASSURANCE
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QUALITY ASSURANCE

This chapter describes the essential features of the Westinghouse Waste Isolation Division (WID) Quality Assurance Program (QAP) and the Quality Assurance (QA) requirements which affect the safety of the Waste Isolation Pilot Plant (WIPP). The essential features described include:

- QA requirements imposed on WIPP
- QA Program and Organization
- Personnel Training and Qualification
- Quality Improvement processes
- Document Control
- Quality Assurance Records
- Work Processes
- Design
- Procurement
- Inspection and Acceptance Testing
- Assessment Processes

9.1 Introduction

This chapter is organized to provide a description of general, management, performance, and assessment quality assurance (QA) requirements based on the graded approach that applies to all items and activities at the WIPP. The WID will maintain complete and accurate records as necessary to substantiate its compliance with the requirements.

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9.2 General Requirements

To provide a comprehensive QA program, Title 10 CFR 830.120,[1] *Quality Assurance Requirements,* provides 10 general quality assurance requirements, which are presented in the following three categories; management, performance, and assessment. Additionally, the Environmental Protection Agency (EPA) has further imposed the QA requirements through Title 40 CFR 194.5,[2] Publications Incorporated by Reference. The EPA requires that the QA Program also address sampling, scientific investigations, and software quality requirements. The WID Quality Assurance Program Description (QAPD)[3] meets the requirements of both DOE and the EPA. The specifics of the QA Program are accomplished by using the following sources of QA requirements of the 1989 edition of ASME NQA-1,[4] ASME NQA-2, Part 2.7,[5] ASME NQA-3,[6] 10 CFR 71 Subpart H,[7] and others as reflected in the CAO QAPD, CAO-94-1012.[8] Application of requirements is based on the minimization of risk to the general public, facility personnel, environment, and facility.

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9.3 Management

9.3.1 Program

The requirements and guidance contained in the WID QAPD[3] are based on the principle that work shall be planned, documented, performed under controlled conditions, and periodically assessed to establish work item quality, process effectiveness, and promote improvement. The requirements described in this document reflect the responsibilities assigned to management and personnel of all WID departments and their responsibility for planning, achieving, verifying, and assessing quality and promoting continuous improvement. The Quality Assurance Program delineates the quality contributions of all personnel and encourages their active participation in accomplishing the WID's quality objectives.

Effective implementation of the WID QA program is dependent on the efforts of all levels of the WID organization. The organization is structured such that the individual performing the work is responsible for achieving and maintaining quality; line management is responsible for verifying the quality; and an independent assessor is responsible for independently assessing the quality of the work. Active participation by all personnel is required to accomplish the WID's quality objectives. Quality Assurance Programs, a section of the Quality Assurance (QA) Department, is responsible for defining, integrating, and ensuring effective implementation of QA activities. The WID has applied a graded approach for the application of QA requirements to the WID Quality-affecting activities. All quality-affecting activities performed by the WID will be subjected to all applicable QA requirements.

During the design and construction phase of the WIPP, the QA program was based on ANSI/ASME NQA-1-1979,[9] basic and supplementary requirements. Therefore, the WIPP Design Class system, showing a graded approach to application of the QA requirements for design and construction of WIPP systems, also reflects ANSI/ASME NQA-1-1979.[9]

9.3.2 Organization

The QA Department Manager reports directly to the WID General Manager, and is authorized to establish QA policy and ensure its effective implementation. The QA Department's primary responsibility is the QA oversight of WIPP activities, including verification of adequate QA Program implementation through audit, surveillance, inspection, and assessment; and review of purchase requisitions, design documents, and work packages. The purpose of specifying requirements and associated guidance for a quality assurance program is to ensure that the WID develops and implements an effective QA management system and this management system meets or exceeds the requirements.

Independence of QA personnel in QA oversight of WID activities is assured in two ways:

- The QA Department Manager reports directly to the WID General Manager
- QA is the only function of QA personnel (other than miscellaneous administrative duties)

9.3.3 Personnel Training and Qualification

Personnel performing work will be qualified and capable of performing their assigned tasks. Management shall establish methods for the evaluation, selection, indoctrination, training, and qualification of personnel performing work and qualification requirements will be commensurate with the functions associated with the work performed. An evaluation of experience and educational

requirements are assured through the manager's and the hiring authority's position interview and will be documented for position justification.

Training shall emphasize correct performance of work, provide a description of why quality and nuclear safety requirements exist, and describe the fundamentals of the work and its context. Training shall be subject to ongoing review to determine instruction and program effectiveness.

9.4 Quality Improvement

The focus of quality improvement is to reduce the variability of every process influencing the quality of the product. Management at all levels is to be involved in the quality improvement process to ensure that proper focus is given, adequate resources are allocated, and difficult issues are resolved. Quality improvement programs in place include the work authorization program, the process improvement program, and the corrective action program:

- The work authorization program ensures the work is performed under controlled conditions, and that items are maintained to prevent their damage, loss, or deterioration.

- The process improvement program encourages all personnel to identify and suggest improvements.

- The corrective action program provides for correction of adverse conditions and actions to prevent recurrence.

All employees have the responsibility and authority to request that any activity that appears to be unsafe be suspended until the unsafe condition is resolved. Appropriate corrective actions are required to address the following:

- Determine the root cause of the problem
- Resolution of the initial problem
- Describe actions to preclude recurrence of the problem
- Identify the impact of the problem on related items or activities
- Forecast completion dates for the required actions and the individuals responsible for follow-up

The extent of the root cause analysis for nonconforming items and processes is commensurate with the importance or significance of the problem. A condition adverse to quality requires a statement of the probable cause, and a significant condition adverse to quality requires a formal root cause analysis. In addition, all nonconforming items are identified and controlled to prevent inadvertent use. Corrective actions will be implemented in a timely manner and verification/validation will include evaluation of the effectiveness of the actions taken.

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9.5 Documents and Records

The scope of the document control system includes drawings, specifications, system design descriptions, plans, procedures, and instructions. Management shall identify the individuals or organizations responsible for the preparation, review, and approval of controlled documents. The processes for the distribution and use of controlled documents and forms that document or prescribe work shall be reviewed for adequacy, correctness, and completeness prior to approval and issuance and are controlled as follows:

- Documents used to perform work are available to personnel for use at the work location
- Effective dates are established and placed on approved documents
- Major changes shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents.
- Obsolete or superseded documents and forms are controlled to avoid their inadvertent use
- Controls are established and maintained to identify the current status/revision of controlled documents and forms.

9.5.1 Quality Assurance Records

Quality assurance records are completed documents (regardless of medium) that furnish evidence of the quality of items and/or activities affecting safety or waste isolation.

Quality assurance records are identified, prepared, collected, stored, maintained, and dispositioned by all WID departments involved in the performance or control of quality-related activities. Quality assurance records provide documentary evidence that activities are adequately controlled and that associated parts, components, systems, facilities, and services comply with applicable requirements. Requirements and responsibilities for quality assurance record transmittal, distribution, retention, maintenance, disposition, and retrievability are established and documented. All records will follow the guidelines of the Records Inventory and Disposition Schedule for storage and disposition. The records storage arrangements shall provide adequate protection of records to preclude damage from moisture, temperature, rodent infestation, excessive light, electromagnetic fields, or stacking as deemed appropriate for the type of record being stored.

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9.6 Performance

9.6.1 Work Processes

Work shall be performed to established, approved, and documented technical standards and administrative controls, and under controlled conditions using approved instructions, procedures, drawings, or other appropriate means. Equipment/systems shall be identified and controlled to ensure their proper use, and maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection shall be calibrated and maintained. Requirements and responsibilities are as follows:

9.6.1.1 Work

Personnel performing work are responsible for the quality of their work. Because the individual worker is the first line in ensuring quality, personnel will be knowledgeable of requirements for work they perform and the capability of the tools and processes they use. Line managers will ensure that personnel working under their supervision are qualified and are provided the necessary training, resources, and administrative controls to accomplish assigned tasks. Criteria describing acceptable work performance shall be defined for the worker. Line managers will periodically assess work and related information to ensure that the desired quality is being achieved, and to identify areas needing improvement. Work shall be planned, authorized, and accomplished under controlled conditions using technical, quality, and implementing procedures commensurate with the complexity and risk of the work.

9.6.1.2 Implementing Procedure

Implementing procedures shall be reviewed, approved, and controlled. Implementing procedures shall be developed, reviewed, and validated by technically competent personnel, and approved by authorized personnel. Administrative process procedures may not require validation. Work process parameters are controlled in accordance with approved instructions or procedures that abide by established technical standards and administrative controls. In addition, conditions necessary for accomplishment of work processes are also listed in procedures or instructions. These conditions include proper equipment, controlled parameters of the process (such as temperature, pressure, flow rate, etc.), and calibration requirements. Specified environmental conditions (e.g., atmospheric conditions, moisture content levels, temperature, etc.) are required to be maintained and specified in the implementing procedure.

9.6.1.3 Item Identification and Control

The identification of items will be maintained to ensure appropriate traceability. Traceability requirements shall be specified in design documents or supporting implementation procedures. Processes will be established and implemented to control consumables and items with limited operating or shelf life, and prevent the use of incorrect or defective items. Marking and labeling of items is done at the time of receipt through installation or end use. Records shall be maintained to ensure that the item can be traced at all times - from its source, through the item's installation or end use. The status of inspections, tests and special controls to preserve its integrity shall be identified either on the item(s) or in documents traceable to the item(s).

9.6.1.4 Handling, Storage, and Shipping

Handling, storage, cleaning, shipping, and other means of packaging, transporting, or preservation of quality-affecting items shall be conducted in accordance with established work and inspection implementing procedures, shipping instructions, or other specified documents. If required for protection or maintenance of particular items, special equipment (such as containers, shock absorbers, and accelerometers), and special protective environments (such as inert gas and specific moisture and temperature levels) shall be specified, planned for, and provided.

Measuring and Test Equipment (M&TE) used in the collection of monitoring data for the establishment of test conditions and the collection of general data is calibrated, adjusted, and maintained at prescribed intervals, or prior to use, against certified equipment having known valid relationships to nationally recognized standards.

9.6.2 Design

Items and processes shall be designed using sound engineering/scientific principles and appropriate standards. Design work, including changes, shall incorporate appropriate requirements such as general design criteria and design bases. Design interfaces shall be identified and controlled. The adequacy of design products shall be verified by individuals or groups other than those who performed the work. Verification work shall be completed before approval and implementation of the design. In establishing design controls, management is responsible to ensure that design inputs are technically correct; that design interfaces are identified; that authorities, responsibilities, and lines of communication are clearly defined; and that the design processes clearly define the acceptance criteria for the product.

Applicable design inputs will be controlled by those responsible for the design. The design process shall be controlled by the Design Classification System, as defined in Section 3.1.3.1 of the SAR. All design analysis shall be planned, controlled, and documented so that the originator and reviewer can be identifiable for each subject. Also, computer software used to perform design analyses shall be developed and qualified. Design interfaces shall be identified and controlled so that efforts are coordinated among affected organizations.

Design verification shall be performed using one or a combination of the following methods: design review, alternate calculations, or qualification testing. Design verification takes place prior to release for procurement or manufacture, construction, or to another organization for use in other design work: and, shall be completed before relying on the item to perform its function, equipment operation, or experimentation. Design verification is performed by qualified individuals other than those who performed the design. Formal design review processes have been established at the WID that independently verify compliance of the design with applicable requirements specified in design input documents. Assumptions, design method, and output will be compared and considered to disclose any discrepancies. Alternative calculations are calculations or analysis that are made with alternate methods to verify correctness of the original calculations or analyses. Qualification testing will demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions on all components of the system or structure. All changes to existing designs must undergo design verification, and be approved by the same groups or organizations that reviewed and approved the original design documents.

9.6.3 Procurement

Procurement planning, development of documentation, selection of suppliers and evaluation of supplier performance are the elements of procurement control implemented for WIPP items and services. Purchased items and services are accepted using specified methods such as: review of manufacturing process control data, source verification, receipt inspection, preinstallation and postinstallation tests, certificates of conformance, or a combination of these methods. Non-conformances consist of one or more of the following: a technical or material requirement is violated; a requirement in a WID-approved supplier document is violated; the deficiency cannot be corrected by continuation of the original manufacturing process or by rework; the item or service does not conform to the original requirement. Methods for disposition of supplier non-conformances must contain provisions for (a) through (e) below:

(a) Submittal of notice of non-conformance by the WID
(b) Evaluation of non-conformances
(c) WID approval of supplier-recommended disposition
(d) Verifying implementation of the approved disposition
(e) Maintenance of records of supplier-submitted non-conformances

Supplier selection shall be based on an evaluation of the supplier's capability to provide items or services in accordance with procurement document requirements that identify the organizational responsibilities for determining the source selection based on the design class and supplier selection, as defined in Section 3.1.3.1 of the SAR, and the risks associated with the end use of the product/service.

9.6.4 Inspection and Acceptance Testing

Inspections, tests, or surveillances required to verify conformance of an item or activity to specified requirements are planned and executed. Characteristics to be inspected, and inspection methods to be employed, are required to be specified, and results documented. Inspection or tests for acceptance are performed by qualified personnel other than those who performed or directly supervised the work. Results are documented, and conformance to acceptance criteria is evaluated. Test procedures are required to include or reference test objectives, and provisions for ensuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, that necessary monitoring is performed, and that suitable environmental conditions are maintained. Test results are evaluated by a responsible authority to ensure that those test requirements have been satisfied. Tools, gauges, instruments, and other M&TE used for quality affecting activities are controlled, and are calibrated and adjusted to maintain accuracy within necessary limits and at specified periods. The status of inspection, test, and operation activities is required to be identified either on the items, or in documents traceable to the items to ensure that required inspections and tests are performed, and to ensure that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated. In addition, a nonconformance program is in place to ensure correction of adverse quality conditions and promote improvement.

9.6.5 Assessment

9.6.5.1 Management Assessment

The overall goal for the performance of planned and periodic management assessment is quality improvement. The WID management assessment process involves all levels of management: first-line (group) managers, intermediate (section) managers, senior management, and the General Manager's Office. Senior management directly participates in management assessment in the evaluation of identified areas for quality improvement from two separate sources, including self-assessments performed by line management, and independent assessments of the activities performed by the QA department. Management assessments focus on the identification and resolution of management issues and problems. Problems that hinder the organization from achieving its objectives shall be identified and corrected. Effective management assessments evaluate such conditions as the state of employee knowledge, motivation, and morale; the amount of mutual trust and communication among workers and organizations; the existence of an atmosphere of creativity and improvement; and the adequacy of human and material resources. Once areas for improvement are positively identified and documented, senior management directs the implementation of preventive or corrective actions.

9.6.5.2 Independent Assessment

The WID independent assessment program includes surveillances and audits. Independent assessment is conducted to evaluate compliance with applicable QAP requirements and implementing procedures, as well as the effectiveness of the overall quality program. Such assessments are performed as an administrative control for activities carried out to comply with the Technical Safety Requirements (TSRs), as described in Chapter 6. Independent assessment is also used to provide independent oversight of self-assessment performed by WID line management. For audits only, an audit plan shall be developed and documented for each audit. The audit plan shall include the scope, purpose, audit personnel, organizations to be notified, and schedule. This plan shall include the scope, purpose, assessment personnel, work to be assessed, organizations to be notified, and schedule. Assessments shall include technical evaluations of the applicable procedures, instructions, activities, and items. The scope will include the work to be assessed and corrective actions taken since the previous assessment. Assessment team members will be selected on the basis of technical qualification, knowledge of the item and/or process being assessed and shall be independent from the items and/or processes being assessed. An assessment team leader is appointed to indoctrinate and supervise the team, organize and direct the assessment and coordinate the preparation and issuance of the assessment report. The technical specialists selected for independent assessment assignments shall be indoctrinated by the team leader commensurate with the scope, complexity, or special nature of the work being assessed. In addition they shall be trained to the requirements of the assessment process associated with their duties. The independent assessment report shall be prepared by the assessment team leader, and issued to the management of the assessed organization and any affected organizations. Results from independent assessments are transmitted to senior management as input for determination of the effectiveness of the integrated QA program. In this regard, personnel performing independent assessments act in a management advisory function.

References for Chapter 9

1. 10 CFR 830.120, Quality Assurance Requirements, 1999.

2. 40 CFR 194.5, Publications Incorporated by Reference, 1998.

3. WP 13-1, WID Quality Assurance Program Description.

4. ASME NQA-1, Quality Assurance Program Requirements for Nuclear Facilities, 1989.

5. ASME NQA-2A-1990 Addenda, Part 2.7, Quality Assurance Program Requirements of Computer Software for Nuclear Facility Applications.

6. ASME NQA-3, Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories, 1989.

7. 10 CFR 71, Subpart H, Quality Assurance, 1999.

8. CAO-94-1012, Rev. 2, U.S. Department of Energy Carlsbad Area Office Quality Assurance Program Description, September 1998.

9. ANSI/ASME NQA-1-1979, Quality Assurance Program Requirements for Nuclear Facilities, 1979.

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