QUALITY ASSURANCE
TABLE OF CONTENTS

SECTION **TITLE** **PAGE NO.**

This page intentionally left blank

QUALITY ASSURANCE

9.1 Introduction

This chapter describes the essential features and requirements of the Washington TRU Solutions LLC (WTS) Quality Assurance (QA) Program which are pertinent to the safety analysis at the WIPP. Ten quality criteria, grouped under management, performance, and assessment categories, are described. This organization is modeled on the organization of 10 CFR 830 Subpart A, Quality Assurance Requirements,[1] and DOE O 414.1A, Quality Assurance,[2] and DOE-STD-3009-94, Preparation Guide for U.S. Department of Energy Nonreactor Nuclear Facility Safety Analysis Reports,[3] Chapter 14. A discussion of the primary QA requirements documents imposed on WIPP is included.

The QA features described include:

- QA requirements imposed on WIPP

- QA Program and Organization

- Personnel Training and Qualification

- Quality Improvement processes

- Documents and Records

- Work Processes

- Design

- Procurement

- Inspection and Acceptance Testing

- Management Assessment

- Independent Assessment

This page intentionally left blank

9.2 Requirements

The following are the primary sources which impose QA requirements on WIPP operations and therefore form the basis for the WTS QA program:

10 CFR 830 Subpart A[1] applies to contractors' work at nuclear facilities. It requires contractors to have a written QA program based on the ten criteria in 10 CFR 830.122,[4] applied using a graded approach.

DOE 414.1A,[2] applies to all DOE work that is not regulated by other agencies/programs. It applies to non-nuclear work at WIPP. It requires both DOE and its contractors to have a written QA program based on the ten criteria in DOE 414.1A,[2] applied using a graded approach

40 CFR 194.22, Quality Assurance,[5] requires DOE to have a QA program at WIPP based on ASME NQA-1-1989 Edition, Quality Assurance Program Requirements for Nuclear Facilities.[6]

CAO-94-1012, U.S. Department of Energy Carlsbad Area Office Quality Assurance Program Document (CAO QAPD),[7] consolidates and incorporates the requirements from 10 CFR 830 Subpart A[1], DOE O 414.1A[2], and NQA-1[6], and other relevant requirements documents, as applicable to WIPP. CBFO requires that all contractors that do work related to WIPP comply with the CAO QAPD.

The application of requirements is based on the minimization of risk to the general public, facility personnel, the environment, and the facility.

This page intentionally left blank

9.3 Management

9.3.1 Program and Organization

9.3.1.1 Program

The WTS QA program is defined in WP 13-1, WTS Quality Assurance Program Description (WTS QAPD)[8], and implemented in WTS procedures and implementing documents. WTS has incorporated each requirement in the CAO QAPD [7] that is applicable to WTS into the WTS QAPD, and maintains a QA procedures matrix, which identifies the WTS implementing document and section which implements each applicable requirement of the CAO QAPD. In addition, WTS reviews requirements documents cited in Section 9.2, and revisions, and maintains the WTS QAPD current with their requirements.

The requirements contained in the WTS QAPD are based on the principle that work shall be planned, documented, performed under controlled conditions, and periodically assessed to establish work item quality and process effectiveness, and promote improvement. Effective implementation of the WTS QA Program is dependent on the efforts of all levels of the WTS organization. Responsibilities are assigned to management and personnel of all WTS departments for planning, achieving, verifying, and assessing quality and promoting continuous improvement. [9]

WTS applies a graded approach, in accordance with 10 CFR 830.7, DOE O 414.1A [2], and the CAO QAPD [7], for the application of QA requirements to WIPP items and activities. The graded approach process determines the level of controls appropriate for each item or activity, commensurate with the following criteria:

- The importance of an item or activity with respect to safety, waste isolation, and regulatory compliance

- The importance of the data to be generated

- The need to demonstrate compliance with specific regulatory, design, and QA requirements

- The impact on the results of performance assessments and engineering analyses

- The magnitude of any hazard or the consequences of failure

- The life-cycle stage of a facility or item

- The programmatic mission of a facility

- The particular characteristics of a facility, item, or activity

- The relative importance of radiological and non-radiological hazards

The WTS graded approach process is implemented in WP 13-QA3005, Graded Approach to Application of QA Controls.[10]

9.3.1.2 Organization

9.3.1.2.1   General Manager

The General Manager has overall responsibility and authority for the development and implementation of the QA program.

9.3.1.2.2   Quality Assurance Department

The QA manager reports directly to the General Manager, and has overall authority and responsibility to execute the QA function, delegated by the General Manager.

The QA manager has the following specific responsibilities and authorities (delineated in the WTS QAPD [8]):

- Develop, establish, and interpret the overall WTS QA policy and ensure effective implementation

- Maintain liaison with QA organizations from other WIPP participants and other affected organizations

- Ensure QA department involvement in decisions or commitments which directly affect nuclear safety or waste isolation at the WIPP

- Prepare, maintain, and improve the WTS QAPD [8]

- Prepare and maintain QA plans and procedures that implement the QA program

- Review WTS procedures that implement the QA program

- Schedule and conduct QA independent oversight, including assessments

- Evaluate the adequacy of and approve supplier QA Programs

- Track and perform trend analysis of quality problems, and report quality problem areas

- Provide for the administrative processing of documentation concerning conditions adverse to quality

- Be sufficiently independent from cost and schedule considerations

- Have the organizational freedom to effectively communicate with other senior management positions

- Have no assigned responsibilities unrelated to the quality assurance program that would prevent appropriate attention to QA matters

- Assist other departments and sections with quality planning, documentation, measurement, problem identification, and the development of problem solutions

- Provide guidance to all applicable subordinate organizations concerning identification, control, and protection of QA records

- Have sufficient authority, access to work areas, and organizational freedom to:

  - Identify quality problems

  - Participate in development of solutions

  - Verify implementation of solutions

  - Ensure that unsatisfactory conditions are controlled until proper disposition has occurred

- Disseminate information pertinent to quality performance, including:

  - The status of development and implementation of the QA program

- The status and resolution of significant quality problems

- The lessons learned from significant quality problems and adverse conditions

- Quality management practices and improvements

- Trend analysis results

- Prepare and maintain a procedures matrix which identifies the implementing documents for the CAO QAPD[7].

Section managers reporting to the QA manager oversee specific QA functions, including:

- Assessments

- Inspections

- QA engineering

- QA programs

- Continuous improvement programs

The QA department maintains sufficient staffing levels to support its responsibilities at WIPP.

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

- The QA manager reports directly to the WTS General Manager

- QA is the only function of QA personnel (other than miscellaneous administrative duties)

9.3.1.2.3   WTS Departments

Department managers representing the primary functional organizations (including the QA department) report directly to the General Manager. The WTS organizational structure is described in Chapter 8.

Department managers are responsible for implementing the WTS QAPD[8] and have the following specific QA responsibilities (delineated in the WTS QAPD):

- Provide the necessary organization, direction, control, resources, and support to achieve their defined objectives

- Plan, perform, assess, and improve the work

- Establish and implement policies and procedures that control the quality of work in accordance with the QA program

- Provide technical and QA training for personnel performing work

- Ensure compliance with applicable regulations, DOE Orders, requirements, and laws

- Ensure that personnel adhere to procedures

- Halt unsatisfactory evolutions if necessary to ensure that cost and schedule do NOT override environmental, health, safety, and quality considerations

- Develop, implement, and maintain plans, policies, and procedures that implement applicable portions of the QA program

- Identify, investigate, report, and correct quality problems

- Disseminate information pertinent to quality performance

Line managers are responsible for defining quality requirements for work, and supporting and verifying the achievement of quality.

Workers are responsible for achieving and maintaining quality in their work, and for promptly reporting to management any condition adverse to quality.

9.3.2 Personnel Training and Qualification

Qualification requirements for personnel performing quality related work, including managers, designers, scientists, independent assessment personnel, operators, maintenance personnel, technicians, and inspectors, are established and documented in the WTS training program.

WP 13-QA.04, Quality Assurance Department Administrative Program,[11] defines training and indoctrination requirements for all WTS QA personnel. Inspection and test, nondestructive examination, and assessment personnel are qualified in accordance with the WTS QAPD;[8] WP 13-QA.04[11]; and WP 14-TR.01, WIPP Training Program,[12] to meet the requirements of NQA-1-1989[6] and supplements.

The WTS training program is described in Chapter 8.

9.3.3 Quality Improvement

WTS has established processes to detect and prevent adverse quality conditions and to promote quality improvement. Preventive actions are taken, through design, procurement, and other process controls and assessment activities described in the WTS QAPD[8], to prevent or reduce the probability of occurrence of quality problems. Items and processes that do not meet established requirements are identified, controlled, and corrected. Correction includes identifying the causes of adverse conditions and taking actions to prevent recurrence. All personnel are responsible for identifying nonconforming items, activities, and processes and are encouraged by management to suggest improvements. Quality improvement requirements are delineated in the WTS QAPD[8].

9.3.3.1 Nonconformance Reports

Control of nonconforming items, i.e., items and materials that do not conform to specified requirements or whose conformance is indeterminate, is implemented in WP 13-QA3004, Nonconformance Report.[13] Nonconforming items are documented on Nonconformance Reports; controlled to prevent inadvertent use; identified by marking, tagging, or other appropriate means; and segregated or controlled administratively. The nonconforming characteristics are reviewed, and recommended dispositions are proposed and approved. The cause of the nonconformance and actions to prevent recurrence are identified. Implementation of the disposition and actions to prevent recurrence are verified by the QA department before the Nonconformance Report is closed.

9.3.3.2 Corrective Action Requests

Control of conditions adverse to quality, i.e., programmatic and/or process failures, malfunctions, deficiencies, and nonconformances, is implemented in WP 13-QA3003, Corrective Actions Program.[14] Conditions adverse to quality are documented on Corrective Action Requests. All WTS personnel are responsible for identifying and reporting conditions adverse to quality. Responsible management investigates conditions adverse to quality and determines the corrective action response, including remedial action, extent and impact of the condition, actions to prevent recurrence, and root cause, as appropriate. The QA department verifies implementation of the corrective actions before the Corrective Action Request is closed.

Significant conditions adverse to quality, as defined in the WTS QAPD [8], are reported to and evaluated by the QA department, relevant regulatory compliance functions, and the appropriate management responsible for the condition, to determine if a work suspension order is necessary. If necessary, work is suspended until the condition is corrected and verified by the QA department. Any WIPP employee having a concern for employee safety, the safety of the environment, or the quality or regulatory compliance of an activity has the responsibility and authority to suspend the performance of that activity.

9.3.3.3 Improvement Analysis

The WTS improvement analysis process is implemented in WP 13-QA3006, Data Analysis and Trending.[15] WTS performs a periodic site evaluation and trend analysis of performance indicating data. Performance data is identified, collected, and analyzed to identify adverse quality trends and opportunities to improve items, activities, and processes. Results are reported to responsible management and organizations responsible for corrective action.

9.3.4 Documents and Records

9.3.4.1 Documents

Document review, approval, issuance, and control requirements are delineated in the WTS QAPD [8]. Documents which prescribe processes, specify requirements, or establish design are prepared, approved, issued, and controlled in accordance with approved procedures. Documents are reviewed for adequacy, correctness, and completeness, by designated technically competent reviewers, prior to approval and issuance as controlled documents. The QA department reviews documents that translate QA requirements into implementing documents, to ensure that QA program requirements are properly implemented.

Document changes are indicated in the changed document and reviewed by the organizations or technical disciplines affected. Editorial or minor changes may be made without the same level of review and approval as the original or otherwise changed document.

The distribution and use of documents and forms is controlled. Documents used to perform work are distributed to affected personnel and used at the work location. Effective dates are established for and placed on approved documents. Controls are established and maintained to identify the current status/revision of documents and forms. Obsolete or superseded documents and forms are controlled to avoid their inadvertent use.

Implementation of the WTS procedures program is described in Chapter 8.

9.3.4.2 Records

Records management requirements are delineated in the WTS QAPD[8]. The WTS records management program is implemented in WP 15-PR, WIPP Records Management Program,[16].

Records are specified, prepared, reviewed, approved, controlled, and maintained to accurately reflect completed work and facility conditions and to comply with statutory or contractual requirements. QA records are completed documents (regardless of medium) that furnish evidence of the quality of items and/or activities. Implementing procedures identify the records they generate. Such records are designated as QA records when applicable in the Records Inventory and Disposition Schedule (RIDS), defined in WP 15-PR[16]. QA records are classified according to their retention times in the RIDS.

QA records are provided reasonable protection from damage until completed, authenticated, and submitted to the records management system. Requirements and responsibilities for QA record transmittal, distribution, receipt, indexing, retention, maintenance, storage, disposition, and retrievability are established in WP 15-PR[16]. Disposition requirements for individual records are documented in the RIDS. The records storage arrangements 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.

9.4 Performance

9.4.1 Work Processes

WTS's policy is that each person who performs work is responsible for the quality of his or her work, and he or she will have the goal of doing work correctly the first time. Work is performed to established, approved, and documented technical standards and administrative controls, and under controlled conditions using approved instructions, procedures, drawings, or other appropriate means. Items are identified and controlled to ensure their proper use, and maintained to prevent their damage, loss, or deterioration.

9.4.1.1 Performance of Work

Quality requirements for performance of work are delineated in the WTS QAPD[8] and implemented in WP 10-2, Maintenance Operations Instruction Manual[17] and WP 04-CO, Conduct of Operations.[18] Specific QA requirements which affect the performance of work by all departments are incorporated into each department's procedures, as documented in the QA procedures matrix.

Personnel performing work are responsible for the quality of their work. Because the individual worker is the first line in ensuring quality, personnel are required to be knowledgeable of requirements for work they perform and the capability of the tools and processes they use. Line managers 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 are defined for the worker. Line managers periodically assess work and related information to ensure that the desired quality is being achieved, and to identify areas needing improvement. Work is planned, authorized, and accomplished under controlled conditions using technical, quality, and implementing procedures commensurate with the complexity and risk of the work.

Individuals performing work comply with applicable implementing procedures. When work can not be accomplished as described in the implementing procedure or accomplishment of such work would result in an undesirable situation, condition adverse to quality, or an unacceptable safety risk, the work is suspended and the procedure changed in accordance with the approved procedure change process.

9.4.1.2 Item Identification and Control

Quality requirements for item identification and control are delineated in the WTS QAPD[8]. Items are identified and controlled to ensure their proper use, and maintained to prevent their damage, loss, or deterioration. Traceability requirements are specified in design documents or supporting implementation procedures. Items are identified by physical marking or by other appropriate means. Records are maintained to ensure that the item can be traced at all times from its source through installation or end use. The status of inspections, tests and special controls is identified either on the item(s) or in documents traceable to the item(s). Items with limited operating or shelf life are identified to prevent the use of items whose shelf life or operating life has expired.

WP 09-CN3021, Component Indices,[19] and WP 15-PM 3517, Stores Inventory Control,[20] implement requirements for item identification and control. Suspect/counterfeit items are controlled in accordance with WP 13-QA.05, Suspect/Counterfeit Items Program.[21]

9.4.1.3 Handling, Storage, and Shipping

Quality requirements for handling, storage, and shipping are delineated in the WTS QAPD [8]. Handling, storage, cleaning, shipping, and other means of packaging, transporting, or preservation of items is conducted in accordance with established work and inspection implementing procedures, shipping instructions, or other specified documents. Items are marked or labeled as necessary to adequately identify, maintain, and preserve them. Special environments or controls are indicated as necessary.

Handling, storage, and shipping requirements are implemented in WP 15-PM3517, Stores Inventory Control [20], and WIPP shipping procedures for various departments.

9.4.1.4 Special Processes

Quality requirements for control of special processes are delineated in the WTS QAPD [8]. Special process parameters are controlled, and specified environmental conditions are maintained through implementing procedures, which specify requirements for qualification of personnel, process(es), and equipment, and conditions necessary for completing the special process.

Nondestructive examination processes are controlled in accordance with WP 13-QA.06, QA Department Nondestructive Examination Program [22]. Code welding is controlled through the work instruction process in accordance with WP 10-2, Maintenance Operations Instruction Manual. [17]

9.4.2 Design

Quality requirements for design control are delineated in the WTS QAPD [8] and implemented in WP 09, Engineering Conduct of Operations [23]. The WTS Engineering department provides centralized engineering services for the WIPP. Engineering is responsible for design, design modifications, associated design documentation such as drawings and specifications, procurement, installation instructions, and testing of structures, systems and components (SSCs) at WIPP.

Items and processes are designed using sound engineering/scientific principles and appropriate standards. Design work, including changes, incorporates appropriate requirements such as general design criteria and design bases. Design interfaces are identified and controlled. The adequacy of design products is verified by individuals or groups other than those who performed the work. Verification work is 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 are controlled by those responsible for the design. The design process is controlled by the Design Classification System, as defined in Section 3.1.3 of the RH PSAR. Design analyses are planned, controlled, and documented so that the originator and reviewer can be identifiable for each subject. Computer software used to perform design analyses is developed and qualified. New designs or modifications to existing designs undergo design verification. Design verification is 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 is completed before relying on the item to perform its function. Design verification is performed by qualified individuals other than those who performed the design. Formal design review processes independently verify compliance of the design with applicable requirements specified in design input documents. Assumptions, design method, and output are compared and considered to disclose any discrepancies. Alternative calculations are made

with alternate methods to verify correctness of the original calculations or analyses. Qualification testing demonstrates the adequacy of performance under conditions that simulate the most adverse design conditions on all components of the system or structure. Modifications to existing designs are approved by the same groups or organizations that reviewed and approved the original design documents.

9.4.3 Procurement

Quality requirements for procurement are delineated in the WTS QAPD.[8] Procurement planning, documentation, selection of suppliers, evaluation of supplier performance, and acceptance of purchased items and services are the elements of procurement control implemented at WIPP. The WTS has established processes that ensure that procured items and services meet established technical and QA requirements and that they perform as specified.

Procurement planning and document requirements are implemented in WP 15-PC3609, Preparation of Purchase Requisitions and Purchase Requisition Change Notices,[24] and WP 13-QA3012, Supplier Evaluation/Qualification.[25] Procurement of items and services is planned and controlled to ensure that technical and QA requirements are accurate, complete, and clearly understood by suppliers. Procurement documents define the scope of work and requirements applicable to the item or service being procured. Procurement documents are prepared by WIPP personnel who complete training, as specified in WP 15-PC3609 [24], and are reviewed prior to issuance to verify that the documents include appropriate provisions to ensure that items or services meet the prescribed requirements. Procurement document reviews include representatives from affected technical organizations and the QA department.

The QA department is responsible for performing supplier evaluations for quality-related items and services, in accordance with WP 13-QA3012[25]. Supplier selection is based on an evaluation of the supplier's capability to provide items or services in accordance with procurement document requirements. The evaluation is based on the supplier's history documentation or an on-site evaluation of the supplier's facilities, personnel, and quality program implementation. Suppliers are evaluated and accepted by the QA department before starting work. Approved suppliers are evaluated periodically to verify that they continue to provide acceptable items and services.

Purchased items and services are accepted using specified methods such as source verification, receipt inspection, post-installation tests, certificates of conformance, or a combination of these methods. The QA department accepts quality-related items and services, in accordance with QA inspection procedures.

9.4.4 Inspection and Acceptance Testing

Quality requirements for Inspection and testing are delineated in the WTS QAPD.[8] Inspections and tests are planned and performed in accordance with approved implementing procedures, using established performance and acceptance criteria.   Items and processes are inspected to verify quality at all stages, including source, receipt, in-process, final, and in-service inspections.   Items and processes to be inspected or tested, parameters or characteristics to be evaluated, techniques to be used, acceptance criteria, hold points, and the organizations responsible for performing the tests and inspections are identified during the work planning process. Inspection and test requirements are incorporated into the work process and documented using work instructions and hold and witness points, in accordance with WP 10-2, Maintenance Operations Instruction Manual.[17] Inspection and test results are documented, and conformance to acceptance criteria is evaluated and documented.

Inspection for acceptance of quality-related items and processes is performed by the QA department. The QA department performs nondestructive examinations, receipt, source, and plant inspections, and verifies tests as required by work instructions. Inspection and nondestructive examination requirements are implemented in the QA department procedures.

Test procedures include or reference test objectives and provisions for ensuring that prerequisites 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 test requirements have been satisfied. Test requirements are implemented in WP 09-SU.01, WIPP Start-Up Test Program,[26] and accomplished through test procedures or work instructions in accordance with WP 10-2 [17]. The Engineering department is responsible for determination, implementation, and verification of start-up, acceptance, and post-modification testing.

The status of inspections and tests is identified either on the items, or in documents traceable to the items, to ensure that required inspections and tests are performed, and that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated. Nonconforming items and conditions adverse to quality found during inspections and tests are controlled in accordance with WTS's nonconformance procedures.

Personnel who perform inspections or tests to verify conformance of items to specified acceptance criteria are qualified in accordance with approved procedures to meet qualification requirements established in the WTS QAPD [8]. Qualification requirements are implemented in WP 13-QA.04, Quality Assurance Department Administrative Program[11], and WP 09-SU.01.[26]

Equipment used for inspections and tests is calibrated and maintained. WTS has established a system to ensure that monitoring, measuring, testing, and data collection equipment used for quality-related inspections and tests is controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits. Equipment used for inspections and tests is verified to have a current calibration label and documented. Equipment whose calibration has expired, which has been damaged, or whose calibration is suspect is removed from service and controlled until recalibrated. The validity of results obtained using such equipment is evaluated. Calibration requirements are implemented in WP 10-AD.01, Metrology Program[27] and WIPP maintenance procedures.

9.5 Assessments

Planned and periodic assessments are conducted to measure management effectiveness, item and service quality and process effectiveness, and to promote improvement. Management assessments are performed or directed by managers to assess the effectiveness of their organizations' management processes. Independent assessments are performed by a group or organization having authority and freedom, sufficient to carry out its responsibilities, from the line organization being assessed. Persons conducting assessments are technically qualified and knowledgeable of the items and processes to be assessed.

9.5.1 Management Assessments

Managers at every level periodically assess the performance of their organizations to determine their effectiveness and promote quality improvement. Managers are responsible for management assessments of processes and organizations under their cognizance. The WTS management assessment process involves direct participation by all levels of management, and is supported by the QA department.

Processes assessed include strategic planning, organizational interfaces, cost control, use of performance indicators, staff training and qualifications, procedures, work processes, and supervisory oversight and support. Management assessments focus on the identification and resolution of management issues and problems. Problems that hinder the organization from achieving its objectives are identified and corrected. Conditions adverse to quality found during management assessments are controlled in accordance with WTS's assessment and nonconformance procedures.

The QA department prepares a summary report of management assessment results for each department at least annually. Overall management assessment results are reported to the General Manager at least annually.

Management assessment requirements are delineated in the WTS QAPD.[8] and are implemented in WP 13-QA.08, Quality Assurance Management Assessment Program.[28]

9.5.2 Independent Assessments

WTS has implemented a process of planned periodic independent assessments, including audits and surveillances. Independent assessments are conducted to evaluate compliance with applicable QA requirements and implementing procedures, as well as the effectiveness of the overall quality program. Independent assessments are planned, performed, documented, and reported to responsible management. The types and frequencies of independent assessments are based on items' and processes' status, risk, complexity, and importance to waste isolation and the demonstration of compliance to regulatory and other statutory requirements.

Independent assessment requirements are delineated in the WTS QAPD [8] and implemented in WP 13-QA.03, Quality Assurance Department Assessment Program.[29]

9.5.2.1 Audits

The QA department plans and performs audits to determine the effectiveness of the QA program and compliance with QA implementing procedures. The QA department develops an annual audit schedule. An audit plan is developed and documented for each audit. The audit plan includes the scope, requirements, purpose, audit personnel, work to be assessed, organizations to be notified, and schedule. Audits include technical evaluations of procedures, instructions, activities, and items. Past audit results are reviewed to determine whether corrective actions were effective.

Audit team members are selected on the basis of technical qualification and knowledge of the item and/or process being audited. A lead auditor is appointed to indoctrinate and supervise the team, organize and direct the audit, and coordinate the preparation and issuance of the audit report. Lead auditors are qualified in accordance with WP 13-QA.04, Quality Assurance Department Administrative Program[11], and 14-TR.01, WIPP Training Program[12], to meet qualification requirements in the WTS QAPD [8].

Audit results are documented and reported to responsible management. Conditions adverse to quality are controlled in accordance with WTS's assessment and nonconformance procedures. Responsible management investigates and corrects audit findings and conditions adverse to quality. The QA department evaluates and approves the adequacy of proposed corrective actions and verifies their implementation.

9.5.2.2 Surveillances

QA department personnel perform surveillances of activities to verify conformance with specified requirements and to evaluate their adequacy and effectiveness. Surveillances are used to monitor work in progress; review documentation; document compliance or noncompliance with established requirements and procedures; identify actual and potential deficiencies; and provide notification to responsible managers of the status and performance of work under assessment.

Surveillance results are documented and reported to responsible management. Conditions adverse to quality are controlled in accordance with WTS's assessment and nonconformance procedures. Responsible management investigates and corrects surveillance findings and conditions adverse to quality. The QA department evaluates and approves the adequacy of proposed corrective actions and verifies their implementation.

References for Chapter 9

1. 10 CFR 830 Subpart A, Quality Assurance Requirements.

2. DOE O 414.1A, Quality Assurance.

3. DOE-STD-3009-94, Preparation Guide for U.S. Department of Energy Nonreactor Nuclear Facility Safety Analysis Reports.

4. 10 CFR 830.122, Quality Assurance Criteria

5. 40 CFR 194.22, Quality Assurance.

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

7. CAO-94-1012, U.S. Department of Energy Carlsbad Area Office Quality Assurance Program Document, November 1999.

8. WP 13-1, WTS Quality Assurance Program Description.

9. 10 CFR 830.7, Graded Approach.

10. WP 13-QA3005, Graded Approach to Application of QA Controls

11. WP 13-QA.04, Quality Assurance Department Administrative Program

12. WP 14-TR.01, WIPP Training Program

13. WP 13-QA3004, Nonconformance Report

14. WP 13-QA3003, Corrective Actions Program

15. WP 13-QA3006, Data Analysis and Trending

16. WP 15-PR, WIPP Records Management Program

17. WP 10-2, Maintenance Operations Instruction Manual

18. WP 04-CO, Conduct of Operations

19. WP 09-CN3021, Component Indices

20. WP 15-PM 3517, Stores Inventory Control

21. WP 13-QA.05, Suspect/Counterfeit Items Program

22. WP 13-QA.06, QA Department Nondestructive Examination Program

23. WP 09, Engineering Conduct of Operations

24. WP 15-PC3609, Preparation of Purchase Requisitions and Purchase Requisition Change Notices

25. WP 13-QA3012, Supplier Evaluation/Qualification

26. WP 09-SU.01, WIPP Start-Up Test Program

27. WP 10-AD.01, Metrology Program

28. WP 13-QA.08, Quality Assurance Management Assessment Program

29. WP 13-QA.03, Quality Assurance Department Assessment Program