BWXT Advanced Technologies LLC

Radioactive Material Packaging Quality Assurance Program Description

ATP-QAPD-115684

Revision 000

BWXT ADVANCED TECHNOLOGIES LLC

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REVISION HISTORY

Revision	Date	Section(s) or Page(s)	Description of Change
000	September 14, 2023		Initial issue.

Quality Policy

BWXT Advanced Technologies (BWXT AT) shall design and test the radioactive material shipping container package in a manner that will ensure the health and safety of the public and workers. These activities shall be performed in compliance with the requirements of the Code of Federal Regulations (CFR) and applicable laws and regulations of the state and local governments.

The BWXT AT Radioactive Material Packaging Quality Assurance Program (QAP) is the Quality Assurance Program Description (QAPD) provided in this document and the associated implementing documents. Together they provide for control of BWXT AT activities that affect the quality of components of packaging that are important to transportation safety and include all planned and systematic activities necessary to provide adequate confidence that such components will perform satisfactorily in service. The QAPD may also be applied to certain equipment and activities that are not important to transportation safety, but support safe package use, or where other NRC guidance establishes program requirements.

The QAPD is the top-level policy document that establishes the manner in which quality is to be achieved and presents BWXT AT's overall philosophy regarding achievement and assurance of quality. Implementing documents assign more detailed responsibilities and requirements and define the organizational interfaces involved in conducting activities within the scope of the QAP. The President establishes overall expectations for effective implementation of the quality assurance program and is responsible for obtaining the desired end result. Compliance with the QAPD and implementing documents is mandatory for personnel directly or indirectly associated with implementation of the Radioactive Package QAPD.

Joseph K. Miller
President, BWXT Advanced Technologies LLC

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PART I Introduction

This Quality Assurance Program Description (QAPD) describes the BWXT AT provisions in place to ensure compliance with 10 CFR 71, Subpart H. These provisions are applicable to all activities associated with the design, procurement, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, and modification of components of approved packages used to ship radioactive materials, reactors and components that fall under the jurisdiction of 10 CFR Part 71, Subpart H. Operation, maintenance, and repair are not covered in this QAPD.

The BWXT AT Quality Assurance Program (QAP) is comprised of the Quality Assurance Manual (QAM) and associated implementing procedures. The BWXT AT implementing procedures are designed and administered to meet the applicable requirements of 10 CFR Part 71, Subpart H.

This QAPD does not specify additional requirements, or supersede requirements, specified in the BWXT AT Quality Assurance Program, but merely provides a description of the requirements applicable to 10 CFR 71, Subpart H work.

The QAPD applies to the following BWXT AT locations and other locations when required by customer contract provisions:

BWXT AT
1720 Mt. Athos Rd
Lynchburg, VA 24504

BWXT AT
109 Ramsey Pl
Lynchburg, VA 24501

PART II Quality Assurance Manual Details

SECTION 1 ORGANIZATION

The BWXT AT organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality, safety and environment described within this QAPD are defined within the QAM, implementing documents and organizational charts. See Figure 1.

1.1 President

The President is responsible for all aspects of design, manufacturing, quality, and mission assurance at BWXT AT's facilities. The President is also responsible for all technical and administrative support activities provided by BWXT AT and contractors. The President directs the Director, Engineering; Director, Business Services; Director, Manufacturing Development; and the Director, Regulatory and Mission Assurance in fulfillment of their responsibilities.

1.2 Director, Regulatory and Mission Assurance

The Director, Regulatory and Mission Assurance reports to the President and is responsible for managing the overall Regulatory and Mission Assurance organization including assuring that Safety, Licensing, Quality Assurance support activities in accordance with the QAPD.

1.2.1 Director, Quality Assurance

The Director, Quality Assurance (DQA) reports to the Director, Regulatory and Mission Assurance and is responsible for developing and maintaining the BWXT AT QAM and this QAPD; ensuring that activities affecting quality are performed and documented in accordance with established requirements; is independent and has no direct responsibilities for product design, engineering services, or fabrication; evaluating compliance to Radioactive Material Package requirements, and managing Quality Assurance Organization resources.

If the DQA disagrees with any actions taken by the organization and is unable to obtain resolution, the DQA shall inform the Director, Regulatory and Mission Assurance and bring the matter to the attention of the President who will determine the final disposition.

1.3 Director, Engineering

The Director, Engineering reports to the President and is responsible for the design and testing of the radioactive material package and components.

1.4 Director, Manufacturing Development

The Director, Manufacturing Development reports to the President, and is responsible for the fabrication, handling, testing, assembly, modification, shipping, cleaning, and storage of the radioactive material package and components.

1.5 Director, Business Services

The Director, Business Services reports to the President and is responsible for the procurement of material, components, and assemblies for the radioactive material package and document control.

1.6 Delegation of Work

Any authorized person under this QAPD may delegate the performance of that responsibility (in writing) to a qualified individual. However, the authorized person retains the overall responsibility for ensuring that delegated tasks remain compliance with this QAPD.

Organization Chart

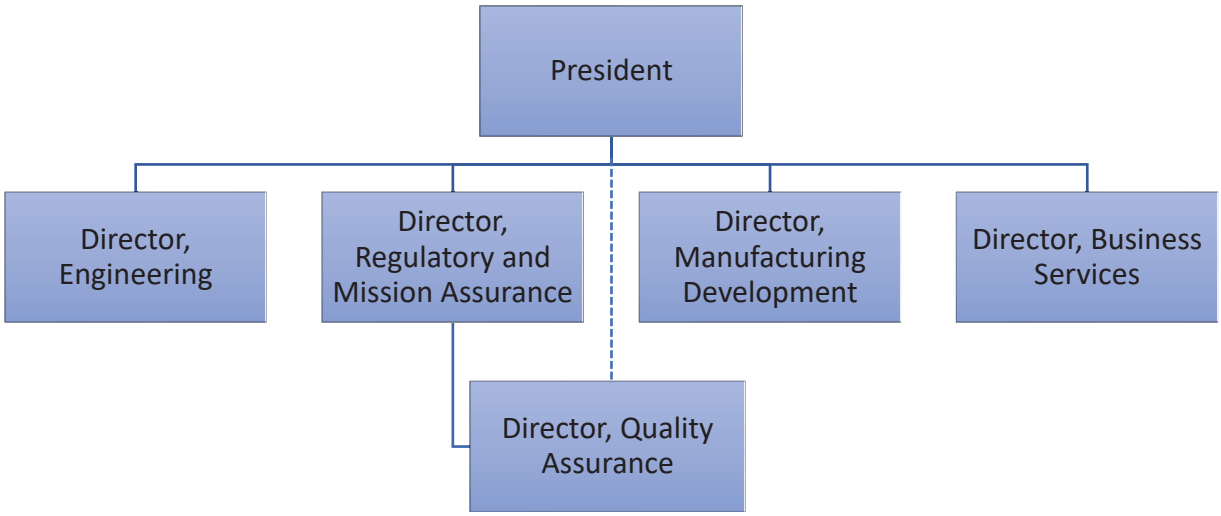

Figure 1

SECTION 2 QUALITY ASSURANCE PROGRAM

The Quality Assurance Program described by this QAPD is defined in the BWXT AT Quality Assurance Manual. The hierarchy of documents used to implement the program is defined within the BWXT AT Quality Assurance Manual and uses procedures and requirements wherever possible. These documents define the requirements to effectively and efficiently implement the requirements of 10 CFR 71, Subpart H and to comply with other codes, standards, regulatory and contract requirements.

Activities within this scope of the BWXT AT program include design, procurement, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, and modification of components of approved packages used to ship radioactive materials, reactors and components that fall under the jurisdiction of 10 CFR 71, Subpart H. Operation, maintenance, and repair are not covered in this QAPD.

The BWXT AT QAP establishes requirements for the planning and execution of activities affecting quality under suitably controlled conditions and ensures the provided prerequisites for the given activities are satisfied. Procedures have been established to ensure personnel are properly trained to achieve and maintain the required level of competence to perform activities affecting quality.

Any change to this QAPD that reduces a commitment previously approved by the US NRC shall be cause for the re-submittal of the QAPD to the US NRC for approval. The change shall include a description of the change, the reason for the change, and the supporting basis that the proposed changes continue to satisfy the applicable requirements to 10 CFR 71, Subpart H. Changes to the QAPD shall not be implemented prior to receiving the US NRC approval. Changes that do not reduce previously approved commitments by the US NRC need not be re-submitted for approval prior to implementation. However, changes to the QAPD that do not reduce the commitments shall be submitted to the US NRC every 24 months.

SECTION 3 DESIGN CONTROL

BWXT AT has established procedures to control design and licensing activities to ensure that:

- Design and licensing activities are planned, controlled, and documented.
- Regulatory requirements, stakeholder requirements, design bases and appropriate quality, environmental and safety standards are correctly translated into design and procurement documents.
- Qualified personnel independently review design documents for completeness and technical accuracy. Verification methods may include independent review of design documents and design analyses or design verification testing.
- Design interface controls are established and adequate to ensure the appropriate design, organizational and technical interfaces are considered.
- Design and development changes are identified, documented and controlled in the same manner as the original documents.
- Design errors and nonconformances are documented and corrected.
- Design organization(s) and their responsibilities and authorities are defined and controlled through written procedures.

Additionally, design control measures have been established for the following:

- Criticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyses;
- Compatibility of materials;
- Accessibility for in service inspection, maintenance, and repair;
- Features to facilitate decontamination, and
- Delineation of acceptance criteria for inspections and tests.

SECTION 4 PROCUREMENT DOCUMENT CONTROL

Procedures have been established to ensure that procurement documents are prepared to clearly define the appropriate technical and quality requirements for purchased items and services, including requirements specified in customer contracts, regulatory standards or legal requirements.

Procurement activities are performed in accordance with procedures that establish requirements for preparation, review, approval and control of procurement documents. Changes to procurement documents are subject to the same review and approval as the original documents.

Procedures have been established to assure the assignment of quality requirements for the procurement of items or services that are important to transportation safety. These procedures assure the procurement documents specify the appropriate quality and regulatory requirements using a graded approach into the scope of procurement, and include the following:·

- Technical requirements,
- Quality, Safety and/or Environmental requirements,
- Right of access to supplier facilities for source inspection and/or audit,
- Inspection and Test requirements,
- Requirements specifying the supplier must flow down requirements to sub-tier suppliers,
- Special process requirements,
- Documents required for submittal for BWXT AT review and/or approval,
- Documentation requirements such as inspection and test records, certification documents,
- Record retention requirements,
- Reporting and disposition of nonconformances, and
- Reporting defects and nonconformance per the requirements of 10 CFR Part 21.

SECTION 5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Procedures have been established to ensure the activities affecting quality are controlled in accordance with appropriate instructions, procedures, drawings and design documents necessary for complying with the Quality Assurance Manual requirements for items and services classified as important to transportation safety.

Changes to instructions, procedures and/or design documents receive the same level of review and approval as the original.

Compliance with approved instructions, procedures, drawings, and design documents is mandatory for all performance of work activities in accordance with the Quality Assurance Manual and implementing procedures. These procedures incorporate by reference or include appropriate quantitative or qualitative acceptance criteria to assure the activity has been satisfactorily completed.

SECTION 6 DOCUMENT CONTROL

Procedures have been established to control the issuance of documents that prescribe requirements for activities affecting quality associated with items or services classified as important to transportation safety. These procedures ensure the adequate preparation, review, approval, distribution, authorized release, use and revision of documents.

Measures are taken to ensure that only current documents are available at the locations where documents are used. These measures include the control of electronic data bases used to control documents.

Changes to documents are reviewed and approved by the same organizations that reviewed and approved the original.

SECTION 7 CONTROL OF PURCHASED MATERIALS, ITEMS AND SERVICES

Procedures have been established to ensure purchased material, equipment and services conform to procurement documents.

Procurement documents are reviewed and approved by authorized personnel for acceptability of proposed suppliers based on the classification of the item being purchased.

Approved suppliers are listed on, the Approved Supplier List (ASL) for items and services they provide. The ASL Is controlled in accordance with approved procedures.

Procedures have been established to ensure suppliers are adequately selected and evaluated according to the importance of the purchased item or service. These evaluations are based on one or more of the following criteria:

- Supplier's third-party certificates and references.
- Direct evaluation of the ability of the supplier's quality program to meet the technical and quality requirements applicable to the scope of work.
- Review of previous records to establish past performance of the supplier.
- Review of supplier's facility, technical equipment and/or personnel.

Qualified personnel perform supplier assessments and surveys. Assessment and survey results are maintained as a quality record. Suppliers are assessed at planned intervals to verify compliance with quality requirements and to assess continued effectiveness of their QA program.

Established procedures include provisions, as appropriate, for objective evidence of quality furnished by the supplier, inspection at the supplier source, and examination of products on delivery.

BWXT AT may accept commercial grade items or services by the performance of a commercial grade dedication. Procedures are established to identify critical characteristics, methods of acceptance, review of documents, and final acceptance.

SECTION 8 IDENTIFICATION AND CONTROL OF MATERIAL, PARTS AND COMPONENTS

Procedures have been established for the identification and control of materials, parts and components. These procedures are designed to prevent inadvertent use of incorrect or nonconforming items. Additionally, these procedures are established to indicate the status of inspections and tests of items by appropriate means, from receipt of the item to end use.

Requirements for identification are established during the preparation of design drawings and specifications.

Items having limited shelf or operating life are controlled to prevent their inadvertent use.

SECTION 9 CONTROL OF SPECIAL PROCESSES

Procedures have been established to control special processes such as welding, heat treatment, and nondestructive examination. Special Processes are performed by qualified personnel using qualified procedures in accordance with applicable codes, standards and regulatory requirements in a controlled manner. Procedures and personnel qualifications associated with special processes are maintained as Quality Records.

SECTION 10 INSPECTION

Procedures have been established to verify conformance with specified requirements for accomplishing activities affecting quality.

Inspection/surveillance and process monitoring are both required where either one by itself will not provide assurance of quality.

Inspection and surveillance activities are performed in accordance with procedures and results are documented. Personnel performing inspection and surveillance activities are trained and qualified In accordance with these approved procedures. Inspections and surveillances are performed by individuals other than those who performed or supervised the subject activities.

Inspection and surveillance planning includes the determination of hold points, inspection equipment requirements, acceptance criteria, personnel qualification requirements, variable and/or attribute recording instructions, reference documents, and other requirements as applicable.

SECTION 11 TEST CONTROL

Procedures have been established that govern the planning, administration, and documentation of tests conducted by or on behalf of BWXT AT. Procedures are prepared to conduct tests that demonstrate or verify the function, or the performance, of important to transportation safety items or services, that provide design input, or that provide test results for validation of safety analysis methods. Additional procedures provide instruction and requirements for the specification and performance of tests, and for the reporting of test results.

Procedures have been established that define the process for planning test activities that verify conformance of an item (system, process, component, or structure) to specified requirements, or that provide information required to complete the design of a not important to transportation safety item.

Procedures have been established that define the requirements, instructions, and guidelines to establish data traceability for tests performed by or for BWXT AT and govern the acquisition, storage, and transmittal of important to transportation safety and other designated test data.

Tests are performed by qualified personnel in accordance with approved procedures.

SECTION 12 CONTROL OF MEASURING AND TEST EQUIPMENT

Procedures have been established to ensure that tools, gages, instruments and other measuring and testing equipment (M&TE) used in activities that are important to transportation safety are properly controlled, calibrated and adjusted to maintain accuracy within required limits.

Calibration of M&TE is performed in accordance with approved procedures or by approved calibration suppliers. The procedures include the following requirements:

- Traceability of calibration standards to national or international standards.
- Basis of calibration is documented when no national or international standard exists.
- M&TE is calibrated to the required degree of accuracy, repeatability, and traceability.
- Calibration intervals are based on required accuracy and stability of the equipment.
- M&TE calibration status is identified by tag, label or other appropriate means.
- Nonconforming M&TE is clearly identified and its use prohibited or suitably restricted until repaired or calibrated.
- Environmental conditions for calibration.
- Handling and safeguarding of equipment.
- Use of test hardware.
- Reference standards used for calibration will have a minimum accuracy of four times greater than the M&TE being calibrated. If a 4:1 ratio between the standard and M&TE cannot be achieved, a technical justification will be provided.

M&TE used to determine product acceptance that is found to be out of calibration will be removed from service and recalibrated prior to use. Furthermore, an evaluation will be performed and documented determining acceptability of items inspected or tested using that M&TE since the last acceptable calibration.

SECTION 13 HANDLING, STORAGE, AND SHIPPING

Procedures have been established to ensure that materials, parts, assemblies, spare parts, special tools, and equipment are handled, stored, packaged and shipped in a manner to prevent damage, loss of identity or deterioration.

When necessary, storage procedures address special requirements for environmental protection such as inert gas atmospheres, moisture control and temperature levels.

SECTION 14 INSPECTION, TEST, AND OPERATING STATUS

Procedures have been established to ensure that the inspection, test and operating status of materials, items, structures, systems and components throughout fabrication, installation, operation and testing are clearly indicated by suitable means (e.g. tags, labels, Inspection and Test Plans (ITPs)).

Bypassing of required inspections, testing or other critical operations is prevented through the use of approved procedures.

As appropriate, the operating status of nonconforming, inoperative, or malfunctioning components (e.g. valves, switches) is indicated to prevent inadvertent operation. The application and removal of status indicators is performed in accordance with approved instructions and procedures.

SECTION 15 CONTROL OF NONCONFORMING ITEMS

Procedures have been established to control items which do not conform to requirements in order to prevent their inadvertent use. These procedures include instructions for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items are reviewed and accepted, repaired, reworked, or rejected in accordance with applicable procedures. The evaluations include a technical justification, an independent engineering review, engineering management approval, evaluation for 10 CFR 21 reportability, and corrective action if appropriate. Rework and/or repair of nonconforming items are inspected with the applicable inspection requirements applied to the original items or as specified in the rework or repair procedures.

SECTION 16 CORRECTIVE ACTION

Procedures have been established to ensure conditions adverse to quality, such as nonconforming conditions; unsatisfactory conditions revealed by audit; inspection or surveillance of products; and customer complaints are promptly identified and corrected to prevent recurrence. Such situations are documented in the Corrective Action Program (CAP), classified by significance level, and analyzed for root or apparent causes. For significant conditions adverse to quality the measures are taken to assure that the cause of the condition is determined and corrective action taken to preclude repetition. Results are reported to appropriate levels of management for review and disposition.

When necessary, follow up is performed to verify corrective action requirements have been completed and are effective in preventing recurrence. Periodically, CAP trends are evaluated and appropriate corrective actions taken.

Evaluation and reporting of potential defects and noncompliance related 10 CFR Part 21 is controlled in accordance with approved procedures.

SECTION 17 QUALITY ASSURANCE RECORDS

Procedures have been established to ensure the control of quality records, including those prepared by customers and external sources. The quality assurance records system ensures that documented evidence pertaining to activities that are important to transportation safety is maintained in accordance with BWXT AT customer and/or regulatory requirements, as applicable.

Procedures have been established to ensure Quality Assurance Records are identified as to the type of record to be retained and classified as permanent or non-permanent records. The measures also include instructions for receipt and storage of records, as well as preservation, retrieval and disposition. Records are provided to customers in accordance with contract requirements.

If any portion of this QAPD, written procedures or instructions is superseded, BWXT AT shall retain the superseded material for 3 years after it is superseded.

SECTION 18 AUDITS

Procedures have been established to provide a comprehensive system of planned and periodic audits. Audits are performed to verify compliance with all aspects of the Quality Assurance Program. Those areas and activities to be audited, such as design, procurement, fabrication, and inspection and testing of radioactive material shipping containers, are identified in audit planning.

Audits are planned and scheduled in a manner to provide coverage and coordination with ongoing Quality Assurance Program activities commensurate with the status and importance of the activities.

Audits are performed by trained and qualified personnel not having direct responsibilities in the areas being audited and are conducted in accordance with approved procedures. Audit results are documented and reviewed with the appropriate level of management having the responsibility for the area audited. Audit reports include an objective evaluation of the quality-related practices, procedures, and instructions for the areas or activities being audited and of the effectiveness of the implementation.

Responsible management undertakes corrective actions as a follow-up to audit reports when appropriate. Audit results are evaluated for indications of adverse trends that could affect quality. When results of such assessments so indicate, appropriate corrective actions are implemented.

Follow-up of actions including re-audit of deficient areas are performed when determined necessary to ensure corrective actions taken are effective.

Appendix 1 BWXT AT Implementation Matrix

(For Information Only)

Implementing Document	Title	Regulatory Position	Description
BWXT-QAM-001, Part II, Section 1	Organization	71.103	Identifies the QA organization, its relationship to other organizations within the company, and its responsibilities for activities affecting quality.
BWXT-QAM-001, Part II, Section 2	Quality Assurance Program	71.101 & 71.105	Describes the method for establishment and implementation of a documented Quality Assurance Program to meet the requirements of 10 CFR 71, Subpart H, and identifies the activities to which It applies.
BWXT-QAM-001, Part II, Section 3 Procedures ENG100 series, ENG200 series, and ENG400 series.	Design control	71.107	Describes the measures established to ensure that design control measures are established to for structures, systems and components.
BWXT-QAM-001, Part II, Section 4 Procedures PM300 and PM301	Procurement document control	71.109	Describes the measures established to ensure the necessary technical and quality requirements are included or referenced in procurement documents for items and services.
BWXT-QAM-001, Part II, Section 5 Procedures BUS403 and BUS404	Instructions, procedures, and drawings	71.111	Describes the measures established to assure items that are important to transportation safety or activities affecting quality are prescribed by, and performed in accordance with documented instructions, procedures, or drawings.
BWXT-QAM-001, Part II, Section 6 Procedures BUS404 and ENG400	Document Control	71.113	Describes the measures established to ensure control the issuance of documents that prescribe requirements for activities affecting quality associated with items or services classified as important to transportation safety.
BWXT-QAM-001, Part II, Section 7 Procedures QA200, QA204, QA207, OPS100, OPS102, and ENG200.	Control of Purchased Items and Services	71.115	Describes the measures established to ensure the procurement of items or services classified as important to transportation safety conform to specified requirements. Measures include source selection and evaluation, source inspection, audit, and receipt inspection of items or services upon delivery or completion.

BWXT-QAM-001, Part II, Section 8 Procedures ENG203, OPS100, OPS200, OPS202, OPS303	Identification and Control of Items	71.117	Describes the measures established to ensure the identification and control of materials, parts and components from receipt to end use.
BWXT-QAM-001, Part II, Section 9 Procedures QA102, QA500 Series, OPS300 Series	Control of Special Processes	71.119	Describes the measures established to ensure special processes are controlled in accordance with specified requirements.
BWXT-QAM-001, Part II, Section 10 Procedures QA400 Series	Inspection	71.121	Describes the measures established to ensure inspections that are required to verify conformance with specified requirements are accomplished.
BWXT-QAM-001, Part II, Section 11 Procedures ENG501, ENG502, and ENG503	Test Control	71.123	Describes the measures established to ensure tests area controlled and performed by qualified personnel in accordance with written procedures.
BWXT-QAM-001, Part II, Section 12 Procedure OPS002	Control of Measuring and Test Equipment	71.125	Describes the measures established to ensure measuring and test equipment used in activities that are important to transportation safety are controlled, calibrated and adjusted to the accuracy required;
BWXT-QAM-001, Part II, Section 13 Procedure OPS600	Handling, Storage, and Shipping	71.127	Describes the measures established to ensure products that are handled, stored, or shipped are properly maintained in order to preserve the quality of the product.
BWXT-QAM-001, Part II, Section 14 Procedures OPS003, OPS004, OPS600, OPS601, and QA400 series	Inspection, Testing, and Operating Status	71.129	Describes the measures established to ensure that the inspection, test and operating status of items are clearly indicated by suitable means.
BWXT-QAM-001, Part II, Section 15 Procedure OPS003	Control of Non-Conforming Items	71.131	Describes the measures established to ensure product that does not conform to requirements are controlled to prevent their inadvertent use.
BWXT-QAM-001, Part II, Section 16 Procedures QA004, and QA300	Corrective Action	71.133	Describes the measures established to ensure that conditions adverse to quality are promptly identified and corrected to prevent recurrence.
BWXT-QAM-001, Part II, Section 17 Procedures BUS405, BUS411, and ENG411	Quality Assurance Records	71.135	Describes the measures established to ensure the control of quality records related to activities that are important to transportation safety.

BWXT-QAM-001, Part II, Section 18 Procedures QA201 and QA205	Audits	71.137	Describes the measures established to ensure internal and external audits are performed.