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RADIOACTIVE MATERIAL

SHIPPING CONTAINER

QUALITY ASSURANCE PROGRAM

B&W FUEL COMPANY
COMMERCIAL NUCLEAR FUEL PLANT
LYNCHBURG, VIRGINIA

Section	Subject	Revision
ii	**TABLE OF CONTENTS**	1

COMPLETE MANUAL REVISION **EFFECTIVE DATE:** _____

Section	Subject	Revision
ii	**TABLE OF CONTENTS**	1

Approved: _____ Date 5/17/94
R. L. Gardner, Manager
Quality

Approved: _____ Date 5/18/94
C. W. Carr, Vice President
Manufacturing and Services

Section	Subject	Revision
iii	**STATEMENT OF POLICY AND AUTHORITY**	1

It is the policy of the B&W Fuel Company - Commercial Nuclear Fuel Plant to establish a high standard of quality for radioactive material shipping containers by:

(a) Designing, fabricating, and using radioactive material shipping containers in accordance with applicable regulations, codes, and standards.

(b) Instilling in all personnel a desire to perform in a quality manner and providing them with feedback on their performance.

(c) Identifying areas in need of improvement and taking appropriate action.

(d) Imposing applicable requirements through appropriate procurement documents on each B&W Fuel Company supplier.

The quality assurance practices established by this Manual describe the B&W Fuel Company method of implementing the above policy and complying with the applicable regulations, codes, and standards for radioactive material shipping containers. These practices have the unqualified support of all levels within the B&W Fuel Company and are an essential activity of each of the organizations within the B&W Fuel Company.

The Manager of Quality of the B&W Fuel Company has the responsibility, authority, and organizational freedom to enforce and monitor compliance with the above policy and the practices described in this Manual. This includes direct access to all levels of management by Quality personnel necessary to accomplish their assigned duties.

In addition, the Quality organization has the authority and duty to: identify quality problems; initiate, recommend, or provide solutions; verify implementation of solutions; and limit or control further processing, delivery, or installation of nonconforming items or unsatisfactory conditions until proper disposition has occurred.

Any quality related problems that arise within the B&W Fuel Company that cannot be resolved by the Manager of Quality will be resolved by the President.

Section	Subject	Revision
0	**INTRODUCTION**	**1**

0.1 PURPOSE AND SCOPE

This Manual describes the Quality Assurance Program (QAP) for the design, fabrication, inspection, test, use, modification, and maintenance of radioactive material shipping containers at the Commercial Nuclear Fuel Plant of the B&W Fuel Company. It applies to activities for new shipping containers or modifications to existing shipping containers performed after the effective date of this Manual (See Manual Section 0.3).

This QAP is in compliance with and fulfills the requirements of 10CFR71 Subpart H. Each section of this Manual describes the controls in place to accomplish compliance. Typical policies, procedures, and instructions which detail how these controls are implemented are listed in Appendix B.

The B&W Fuel Company (BWFC) is headquartered at 3315 Old Forest Road, Lynchburg, Virginia, with manufacturing and field operations activities at its Commercial Nuclear Fuel Plant (CNFP) on Mt. Athos Road, just outside of Lynchburg. Shipments of radioactive material from CNFP consist chiefly of: unirradiated, low enriched fuel assemblies; unirradiated scrap and waste materials such as uranium dioxide powder, pellets, or contaminated material for either disposal or recycle; and sealed beta/gamma emitting sources for activation analysis, calibration, and other analytical purposes.

0.2 RESPONSIBILITY

The Vice President of Manufacturing & Services has the overall responsibility for the quality of work. The Manager of Quality is responsible for developing this QAP and assuring its proper implementation. All personnel are responsible for implementing this QAP for work they perform.

0.3 MANUAL REVISION POLICY

The Lead, Quality Audits & Programs, is responsible for the preparation, maintenance, and revision of this Manual. The Manager of Quality and the Vice President of Manufacturing & Services sign and date the Table of Contents of the Manual as evidence of their approval. The effective date of the Manual is established by the Lead, Quality Audits & Programs, and it is usually the date of NRC approval of the Manual. The Manual is authorized for use on the effective date and shall be implemented within sixty days of that date.

This Manual is reviewed once each calendar year by the Lead of Quality Audits &

Programs, and revised as necessary to assure that it continues to accurately describe the Radioactive Material Shipping Container QAP.

As organizational changes occur, the Lead, Quality Audits & Programs, or his designee, will evaluate the impact of these changes on the QAP and he will notify holders of controlled Manuals of changes that significantly alter the QAP. These changes will be incorporated into the Manual during subsequent revisions.

Revisions to this Manual are made by section. The Manual section revision will be indicated on the Table of Contents. When a change is made to this Manual, the revised section(s) and a revised Table of Contents will be issued. The latest changes will be identified by the revision number in the margin opposite the first line of the paragraph changed. Previous changes identified in the margins will be deleted. Each revised section will have the revision number written on all pages of the section. When a section is revised extensively, the words "Complete Revision" will be typed in the upper right corner of the first page of the section in place of the margin notations. This option may also be used for pages that are revised extensively. In the event this Manual is revised in its entirety, the Table of Contents will indicate this and no notations will be included in individual sections.

0.4 MANUAL ASSIGNMENTS

All copies of this Manual are issued and plainly identified as either "controlled" or "uncontrolled" on the Manual cover page.

0.4.1 Controlled Manuals

Controlled copies of this Manual are distributed to convenient manual stations located within BWFC. Quality distributes controlled copies to selected BWFC employees and to organizations outside of BWFC. Individual Manual holders are listed on a distribution list maintained by Quality. Quality is responsible for keeping this list up-to-date and for sending any Manual revisions to individuals on the distribution list.

0.4.2 Uncontrolled Manuals

Uncontrolled Manuals are issued for information only and will not be kept up-to-date.

Section	Subject	Revision
1	**ORGANIZATION**	1

1.1 B&W FUEL COMPANY (FIGURE 1.1)

B&W Fuel Company (BWFC) is a partnership with ownership by Framatome and Cogema. The President of BWFC reports to a partnership board. The BWFC organizations involved in this QAP are shown in Figure 1.1 and described below.

1.2 MANUFACTURING AND SERVICES (Figure 1.2)

The Vice President of Manufacturing and Services reports to the President. He is responsible for the fabrication and assembly of BWFC manufactured products at CNFP including radioactive material shipping containers. Manufacturing & Services organizations supporting this QAP are shown in Figure 1.2.

1.2.1 Manufacturing Engineering

The Manager of Manufacturing Engineering reports to the Vice President of Manufacturing & Services. Manufacturing Engineering is responsible for the design and manufacturing processes for radioactive material shipping containers used by CNFP. In the performance of shipping container design and analysis activities, Manufacturing Engineering may utilize the services of other BWFC organizations such as Fuel Engineering (Refer to Figure 1.1) or certain activities may be subcontracted to qualified suppliers or consultants. In addition, shipping container fabrication may be internally at CNFP or at the facilities of approved suppliers. For either case, Manufacturing Engineering is responsible for any necessary manufacturing process development and qualification.

1.2.2 Safety & Licensing

The Manager of Safety & Licensing reports to the Vice President of Manufacturing & Services. Safety & Licensing is responsible for coordinating radioactive material shipping container licensing activities under the provisions of 10CFR71. In addition, Safety & Licensing is responsible for preparing and implementing procedures for the control of nuclear & radiological safety; performance of appropriate inspections and radiation surveys; proper labeling of radioactive material shipping containers and vehicle; generation of safety documentation; and overall enforcement of health physics and nuclear safety standards.

The Manager of Safety & Licensing has the freedom and authority, if necessary, to terminate the use of a radioactive material shipping container if the nuclear or radiological requirements are not met.

1.2.3 Materials

The Manager of Materials reports to the Vice President of Manufacturing & Services. Materials is responsible for obtaining items and services that meet specification requirements on a schedule that is consistent with production requirements. Materials activities include purchasing and procurement engineering.

1.2.4 Other Manufacturing & Services Organizations

Other Manufacturing & Services Organizations that may be involved in this QAP are Fuel Manufacturing and Production & Inventory Control. These organizations are involved when radioactive material shipping containers are fabricated at CNFP.

1.3 Quality (Figure 1.3)

The Manager of Quality reports to the President. He directs the activities summarized in Figure 1.3 and assures compliance with the Statement of Policy and Authority in front of this Manual.

Section	Subject	Revision
1	ORGANIZATION	1

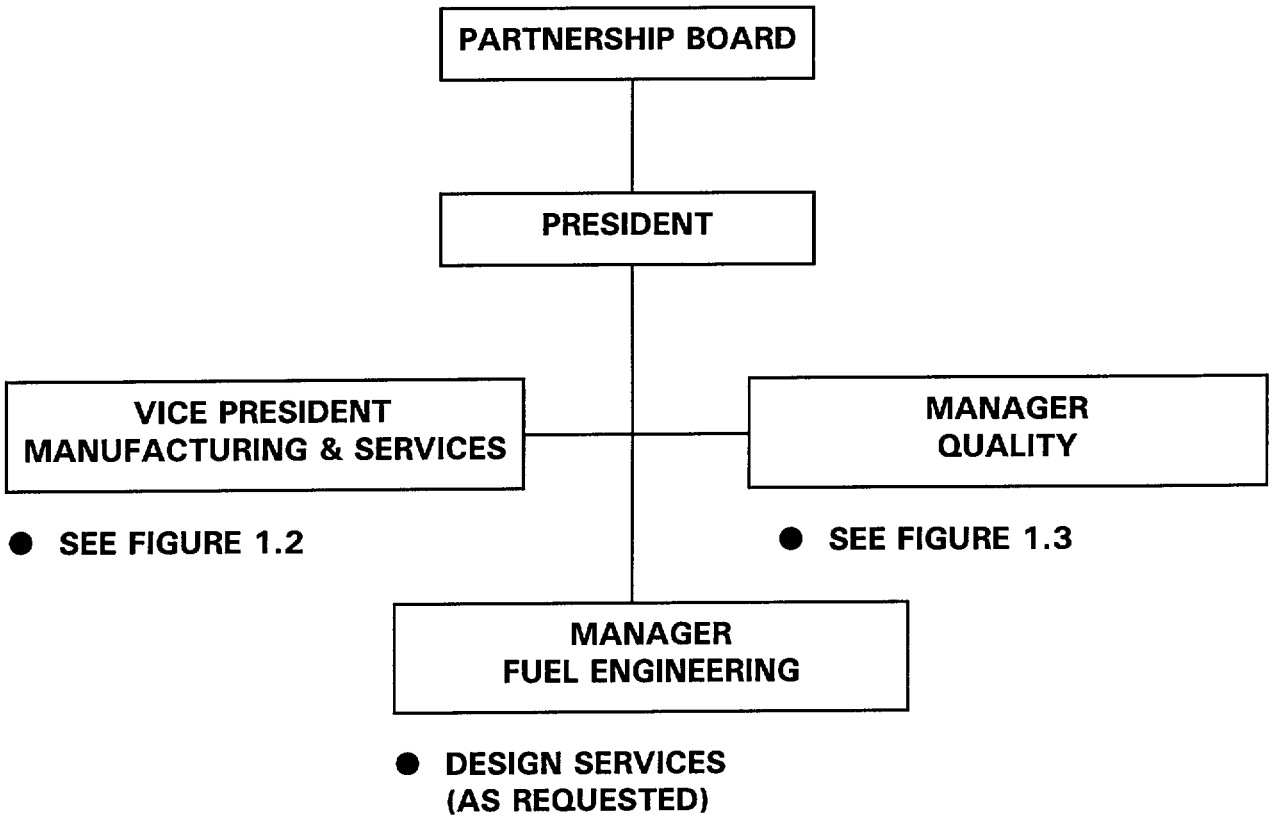

FIGURE 1.1: **B&W FUEL COMPANY ORGANIZATIONS INVOLVED IN THE SHIPPING CONTAINER QAP**

Section	Subject	Revision
1	ORGANIZATION	1

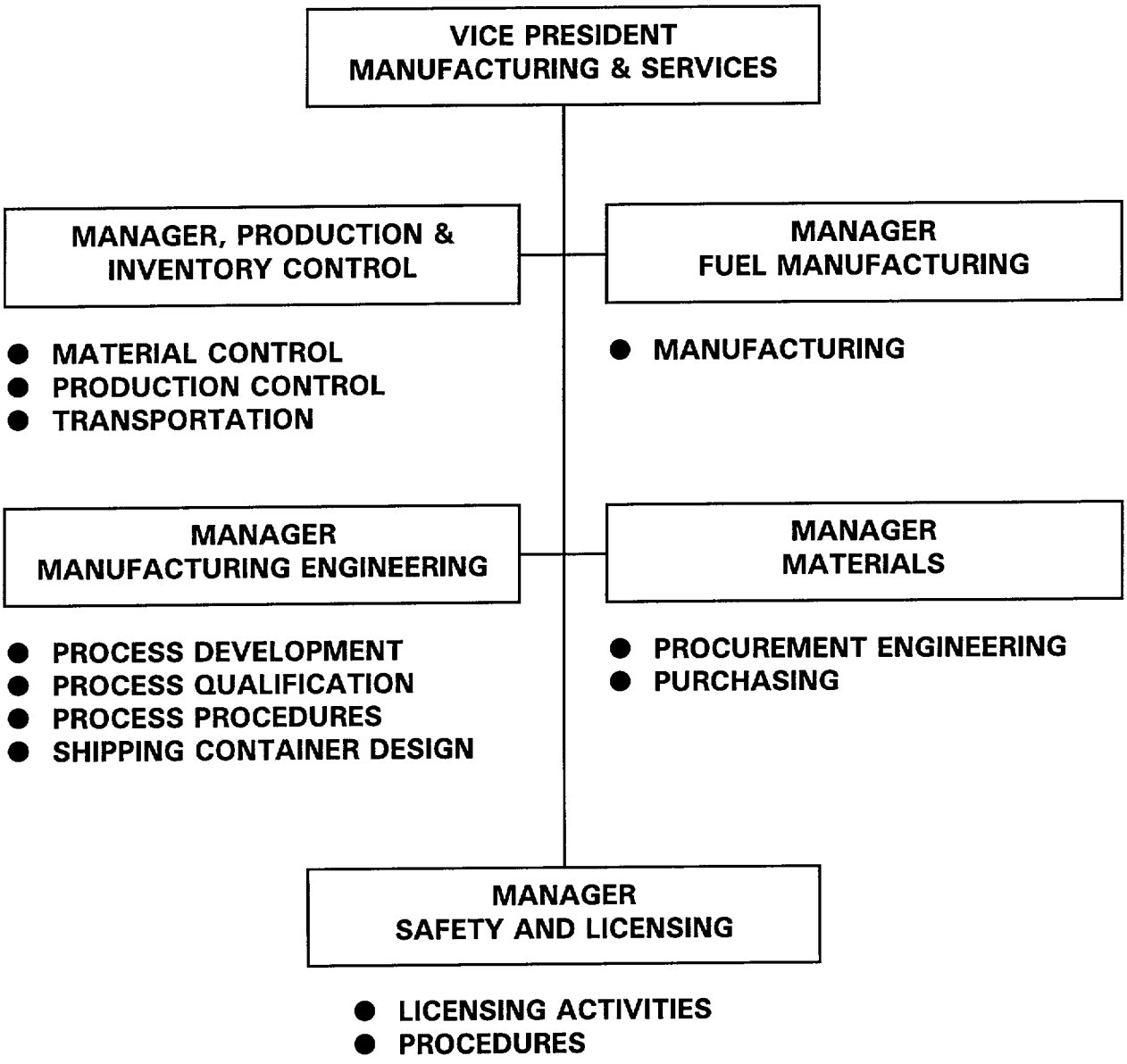

FIGURE 1.2: BWFC MANUFACTURING & SERVICES ORGANIZATIONS INVOLVED IN SHIPPING CONTAINER QAP

Section	Subject	Revision
1	ORGANIZATION	1

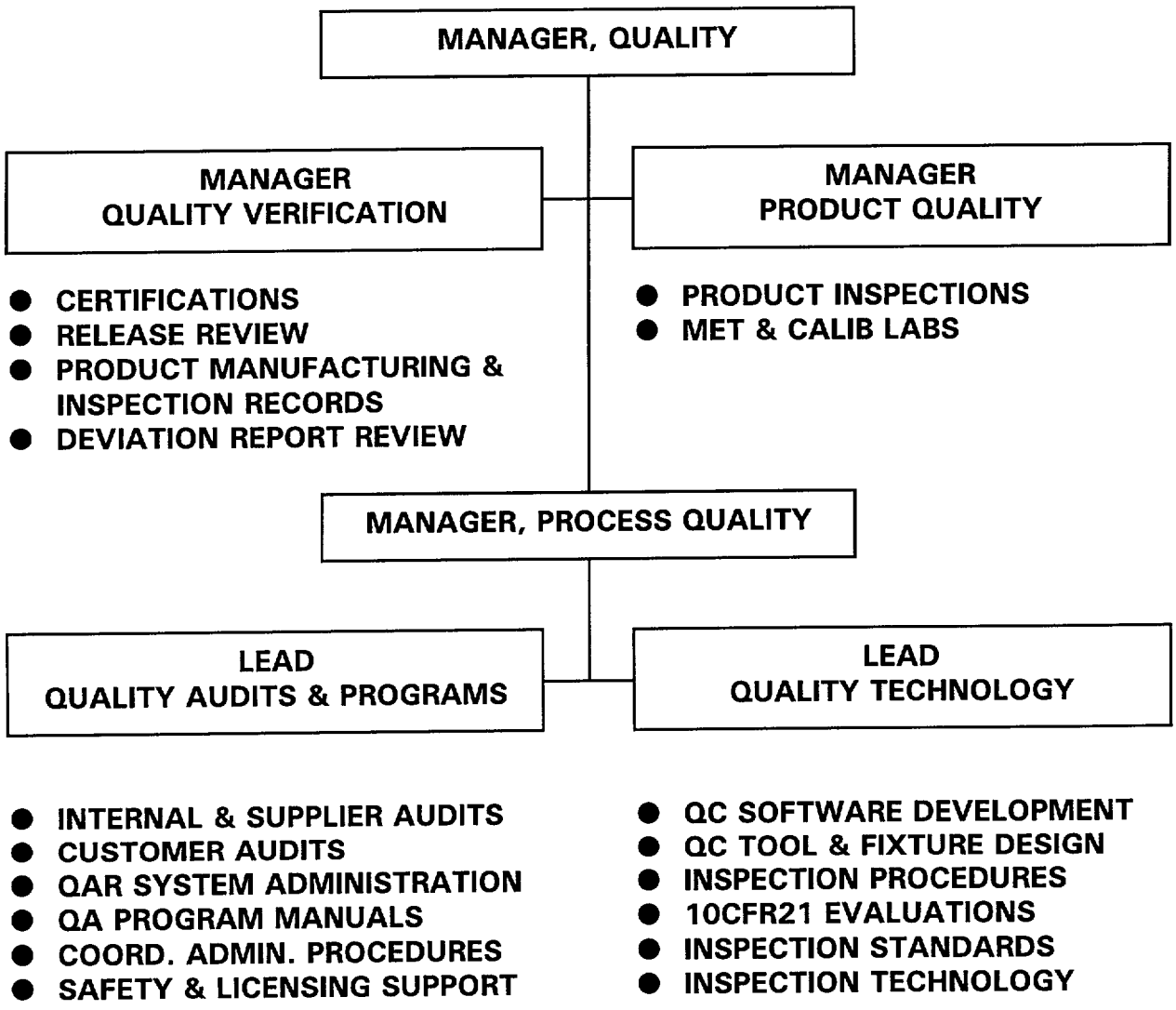

FIGURE 1.3: QUALITY ORGANIZATION

Section	Subject	Revision
2	**QUALITY ASSURANCE PROGRAM**	1

2.1 SCOPE

This Quality Assurance Program (QAP) takes into account the prerequisites for achieving quality, such as the need for specialized equipment and skills; use of suitable administrative, process, and environmental controls; training and indoctrination of personnel performing activities affecting quality; and the need for verification of quality by inspection and test. It also provides for the development, control and use of computer programs.

For purposes of this QAP, radioactive material shipping containers are classified as safety related. As outlined in NRC Regulatory Guide 7.10, items used in the construction of shipping containers may be categorized as being critical to safe operation or having a major or minor impact on safe operation depending upon their function and the consequences of their failure as related to the overall integrity of the container. Guidelines for the categorization of items and the application of appropriate provisions of this QAP are contained In Appendix C of this QAP.

2.2 QAP REQUIREMENTS

This QAP is organized and administered to comply with 10CFR Part 50 Appendix B, 10CFR Part 71 Subpart H, and 10CFR Part 21.

2.3 QAP IMPLEMENTATION

This QAP establishes and maintains standards of quality through the development and use of quality engineering and manufacturing practices, which are documented by written procedures. These procedures are controlled as described in Sections 5 and 6 and they have been coordinated with and are mandatory for each of the organizations within BWFC.

Typical procedures that implement this QAP are referenced in Appendix B. BWFC may add, modify, and/or delete these referenced documents without changing the intent of the QAP. Therefore, the references should only be considered as representative and they will be updated, as necessary during subsequent revisions of this Manual.

Quality personnel are charged with escalating to the Manager, Quality, for resolution, any quality related problem that cannot be resolved at their level. In turn, the Manager of Quality will escalate to the President any quality related problem that he cannot satisfactorily resolve.

Authority to temporarily deviate from this QAP or from any referenced procedure, is reserved for the President. Such deviation shall be documented and approved by the President and distributed to affected organizations.

2.4 QAP ASSESSMENT

Assessments of the scope, status, adequacy, and compliance of this QAP with Appendix B of 10CFR50 and other QAP commitments are performed by BWFC staff management in several ways.

This Manual is evaluated once every calendar year by the Lead, Quality Audits & Programs, and updated to incorporate any administrative or operational changes necessary to ensure that it accurately describes the QAP. During this evaluation, the Lead of Quality Audits & Programs solicits input from affected staff managers as to the status, adequacy, and effectiveness of that part of the QA Program for which they have been designated responsibility. In addition, an independent audit of the functions of BWFC Quality is performed by qualified auditors once each calendar year and the results of this audit are provided to the President and to the Manager of Quality.

The President also conducts staff meetings periodically, during which each staff manager, including the Manager of Quality, presents the status of activities within his organization and any problems that require resolutions by BWFC management. In addition, written monthly reports are made by each staff manager describing their significant activities and problems during the month. The President also receives copies of the results of internal audits performed by Quality.

The President, through customer feedback, personal observations, staff meetings, monthly reports, annual evaluations, and internal audit reports, assures himself of the adequacy and effectiveness of this QAP.

2.5 QAP INDOCTRINATION AND TRAINING

2.5.1 BWFC Personnel

Indoctrination and training in the requirements of this QAP are provided to involved personnel. This indoctrination and training is conducted in accordance with written procedures and includes instruction as to the purpose, scope, and implementation of the quality related manuals, policies, procedures, and instructions.

2.5.2 Quality Personnel

In addition to the indoctrination and training described above, personnel performing inspection, surveillance, and audit activities are qualified and this qualification is conducted and documented in accordance with the applicable requirements of the codes, standards, and regulatory requirements listed in Section 2.2.

Section	Subject	Revision
3	**DESIGN CONTROL**	**1**

3.1 SCOPE

Design control measures are applied to radioactive material shipping containers as defined in written procedures and instructions.

3.2 DESIGN DOCUMENTS

Procedures have been established for the preparation and review of design documents, including the correct translation of applicable Regulatory requirements and design bases into design and procurement documents. Included are such activities as: criticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for in-service inspection, maintenance, and repair; decontamination features; and delineation of acceptance criteria for inspection and tests.

Manufacturing Engineering is responsible for the preparation, review, approval, and verification of design documents for radioactive material shipping containers. As explained in Section 1.2.1, Manufacturing Engineering may utilize the services of other BWFC organizations or outside consultants or suppliers in the performance of these activities.

Design documents include such documents as specifications, drawings, analyses, computer program documentation, and safety analysis reports. These documents specify technical and quality requirements appropriate to the activities they cover. Safety analysis reports summarize the description and evaluation of shipping container designs as required by 10CFR71. Design documents are independently reviewed for completeness and technical accuracy as described in Section 3.4.1.

Quality provides an overview of design documents during internal audits, and reviews design documents such as drawings and specifications used as procurement documents or as manufacturing requirements for the inclusion of appropriate quality requirements.

Errors and deficiencies in approved design documents, including design methods such as computer programs that could adversely affect safety related items and services, are documented and corrected. Deviations from specified quality standards are identified and controlled in accordance with written procedures.

3.3 DESIGN INTERFACES

Procedures establish methods for the identification and control of design interfaces and for their coordination among participating design organizations. These procedures establish methods for review, approval, release, distribution, and revision of documents.

The Manager of Safety & Licensing coordinates radioactive material shipping container design licensing activities with the NRC.

3.4 DESIGN VERIFICATION

Procedures are provided to assure verification of designs. Verification methods include independent review of design documents, design analyses (calculations), design review boards, and design verification testing. Manufacturing Engineering determines the design verification methods to be used.

3.4.1 Independent Review of Design Documents

All design documents are independently reviewed for completeness and technical accuracy. The reviewer may be any technically qualified individual other than the preparer of the document.

3.4.2 Design Analyses

Design analyses (calculations) are used to establish design requirements or to verify the design. The analyst is required to document the calculations as to purpose, assumptions, method, input data, results, and conclusions in such a manner that an independent reviewer can verify its technical accuracy independent of the analyst. Design analyses are checked by independent reviewers who are competent in the particular type of analysis being checked.

Computer programs used for design analyses are verified and, except for those that can easily be verified by an user, certified for use as stipulated in written procedures.

3.4.3 Design Review Boards (DRB)

DRBs are convened and conducted in accordance with written procedures which define the conditions under which DRBs are held and the topics to be considered. They are convened for new designs and major changes to existing designs as

determined by the Manager of Manufacturing Engineering.

DRBs consist of a Chairman and other members, as required, who are technically competent but are independent of the design under review. Quality representation on DRBs is optional and is at the discretion of the Manager of Quality.

A DRB verifies the adequacy of a design by assuring that it is based on sound technical principles and that it meets specified requirements. DRBs may be conducted at the conceptual, preliminary, and/or final design stages. In any event, they are completed, as appropriate, prior to release for procurement, manufacture, shipment, or to another organization for use in other design activities. In those cases where this timing cannot be met, completion of portions of the DRB may be deferred, provided that the justification for this action is documented and the unreviewed portions of a design are identified and controlled.

Results of DRBs are documented and the Manager of Manufacturing Engineering must address DRB comments, as he determines appropriate, to close out the DRB.

3.4.4 Design Verification Testing

Design verification by testing is used whenever engineering judgment leads to the conclusion that design analyses or previous experience cannot substantiate a design or design feature.

Design verification testing is conducted by the test organization using written test procedures which incorporate the requirements of design specifications that establish the design limits of the items or features being tested. If verification of a design or design feature is solely by test, the testing is conducted under the most adverse design conditions that can be practically achieved as determined by analysis. When a test program is used to verify the adequacy of an entirely new radioactive material shipping container design, qualification tests of a prototype unit will be performed as required by 10CFR71.

Test results are reviewed by Manufacturing Engineering to determine if they verify the design or design feature tested.

3.5 DESIGN CHANGES

Design changes are subject to the same design controls that were applicable to the original design and they are documented, reviewed, approved and incorporated into

the design documents as described in written procedures. Changes to NRC approved radioactive material shipping container designs must be approved by the NRC prior to implementation. This is usually accomplished by a revision to the safety analysis report for the shipping container design being changed.

3.6 RELEASE OF DESIGN DOCUMENTS

Design documents such as drawings, specifications, and calculations are released for use via release media prepared by designated personnel as described in written procedures. Computer programs are released for use upon completion of their certification process as defined in written procedures.

Section	Subject	Revision
4	**PROCUREMENT DOCUMENT CONTROL**	1

4.1 GENERAL

Procedural controls are established to assure that procurement documents contain appropriate quality, technical, and manufacturing requirements.

4.2 PROCUREMENT PROCESS

The technical, manufacturing, quality, and other requirements prescribed in approved drawings, specifications, and other documents are transferred into procurement documents by inclusion in or referenced on procurement authorization documents. These documents are prepared, reviewed, and approved as stipulated in procedures.

Orders to be placed with suppliers are processed through Purchasing. Purchasing converts the procurement authorization document into a Purchase Order (PO) or Change Order (CO). The PO/CO is then sent to the supplier.

4.3 PROCUREMENT DOCUMENT CONTENT

Procurement documents include or reference the following information and requirements, as applicable:

(a) Scope - Statement of the work to be performed and schedule.

(b) Technical Requirements - Drawings, specifications, regulatory requirements, codes, standards, test and inspection requirements including acceptance criteria and equipment to be used, and special process instructions for such activities as fabrication, inspection, cleaning, packaging, handling, shipping, and storage.

(c) Documentation Requirements - Identification of supplier documents and records to be prepared, maintained, submitted, and made available for BWFC review and/or approval. Such documents and records include: drawings, specifications, procedures, inspection and fabrication plans, inspection and test records, personnel and procedure qualifications, material chemical and physical test results, and product certificates of conformance.

(d) QA Program Requirements - Identification of the requirements of the BWFC quality specifications such as Specification 09-1212 to be met by the supplier. These quality specifications address all 18 criteria of 10CFR50 Appendix B.

(e) Source Inspection & Audit - Identification of source inspection and audit

requirements including right of access to the supplier's (and his subtiers) facilities and records for source inspection and audit.

(f) Subtier Procurements - Extension of applicable procurement document requirements to lower tier procurements.

(g) Nonconformances - Requirements for the reporting to BWFC and approval of supplier nonconformances by BWFC.

(h) Applicability of 10CFR21.

4.4 PROCUREMENT DOCUMENT REVIEW

Procedures are established for the review of procurement documents by Quality to determine that quality requirements are correctly stated, inspectable, and controllable; that there are adequate acceptance and rejection criteria; that the procurement documents have been prepared, reviewed, and approved in accordance with QAP requirements; and that the supplier has been evaluated as specified in Section 7.

Quality has the responsibility and authority to order termination or suspension of procurement actions when procurement documents conflict with the requirements of the QAP. Such orders will indicate the action to be taken to allow resumption or reinstatement of the procurement activity.

4.5 CHANGES TO PROCUREMENT DOCUMENTS

Changes to procurement documents are processed in the same manner as the original procurement documents.

Processing and approval of supplier nonconformance that deviate from the procurement document requirements is described in Section 15.

Section	Subject	Revision
5	**INSTRUCTIONS, PROCEDURES, & DRAWINGS**	1

5.1 GENERAL

Activities affecting quality are prescribed by documented instructions, procedures, or drawings appropriate to the circumstances and accomplished accordingly. Procedures are established to assure that instructions, procedures, and drawings include or reference adequate quantitative or qualitative criteria for determining that important activities have been satisfactorily accomplished.

5.2 ADMINISTRATIVE PROCEDURES

The QAP is implemented through written administrative procedures. These procedures are prepared by responsible personnel, reviewed by other organizations to whom they apply, and then reviewed and approved by Quality for the application of appropriate quality requirements before the documents are approved and distributed for use.

Approved administrative procedures are published in manuals maintained current by Quality. The manuals are kept at manual stations located throughout BWFC.

5.3 DRAWINGS AND SPECIFICATIONS

Drawings and specifications for radioactive material shipping containers are discussed in Section 3.0.

5.4 MANUFACTURING, INSPECTION, TEST, AND SPECIAL PROCESS PROCEDURES

Manufacturing, inspection, and other operative procedures such as radiation protection and health/safety for use in BWFC activities are prepared/reviewed/approved, as applicable, by the responsible engineering, manufacturing, safety & licensing, and quality organizations as stipulated in written procedures/instructions. They are controlled, distributed for use, and maintained current by the issuing organization.

Content of inspection procedures is defined in Section 10. Test procedures are discussed in Section 11 and special process procedures are addressed in Section 9.

5.5 MANUFACTURING INSPECTION, & TEST PLANS

Route Cards are prepared as described in Section 14 to define the manufacturing and inspection sequences for items fabricated or assembled in BWFC manufacturing

facilities and to define the applicable drawings, specifications, and procedures to be used in performing these sequences.

Test plans are discussed in Section 11.

Section	Subject	Revision
6	**DOCUMENT CONTROL**	1

6.1 GENERAL

The following types of documents are prepared, reviewed, approved, and issued in accordance with procedures or instructions:

(a) Design documents (e.g. calculations, drawings, specifications, safety analysis reports) including documents related to computer codes, as described in Sections 3 and 5.

(b) Procurement documents, as described in Section 4.

(c) Instructions and procedures, including Administrative Manuals, this Manual, and procedures describing activities affecting quality, as described in Sections 0&5.

(d) Manufacturing, inspection, test, special process, and other operative procedures as described in Sections 5, 9, and 11.

(e) Reports of nonconformances, as described in Section 15.

Established procedures assure technical adequacy of, and inclusion of appropriate requirements in, the above documents by requiring review by qualified reviewers prior to their implementation. In addition, changes to these documents are processed in the same manner as the original documents and are reviewed/approved by the same organizations or by other qualified organizations when the original organizations no longer exist or are no longer responsible.

6.2 DOCUMENT CONTROL SYSTEM

The control and distribution of the document types identified in Section 6.1 is as prescribed in written procedures. They are distributed by authorized personnel to individuals and locations requiring the documents in the execution of their assigned responsibilities.

Written procedures provide for the preparation of master lists identifying the current revision numbers of approved and released documents. These lists are updated by the controlling organizations and distributed to user organizations on an as needed basis.

The use of obsolete or superseded documents is controlled by requiring personnel to refer to the document master lists to determine the current revisions of documents applicable to their work.

Section	Subject	Revision
7	**CONTROL OF PURCHASED ITEMS & SERVICES**	1

7.1 GENERAL

As a function of the overall Quality Audit Program, Quality evaluates the capability of suppliers of items and services critical to safety (refer to Appendix C) and maintains a list of approved suppliers (Supplier Status List). The list is supported by pre-award evaluations and periodic supplier quality program audits.

BWFC exercises control over each supplier by (1) imposing quality program requirements on the supplier through the procurement documents, (2) performing audits of the supplier's quality program, (3) monitoring of the procurement process for compliance with procedures, (4) source inspection or surveillance at the supplier's facility (as appropriate or necessary), and (5) receiving inspection at CNFP.

7.2 SUPPLIER EVALUATION AND SELECTION

When soliciting bids, Purchasing reviews the Supplier Status List (See Section 7.3) for possible suppliers to whom an inquiry will be forwarded, as necessary; taking into consideration the supplier's past performance and quality history. Supplier responses to requests for bids are reviewed to determine overall acceptability of the supplier. Exceptions to quality requirements are reviewed by Quality and exceptions to technical requirements are reviewed by the cognizant engineering organization. In the event an inquiry is sent to a supplier that has not been approved by Quality, Quality will be advised of this and a pre-award survey may be required. Purchasing will not place an order for items/services critical to safety (refer to Appendix C) with a supplier until such supplier has been evaluated by Quality and approved for order placement. The evaluation of suppliers before the award of a contract and during contract performance is accomplished in accordance with Section 18.

The acceptability of suppliers of items and/or services critical to safety (refer to Appendix C) is based on one or more of the following items:

(a) The current ability of the supplier to comply with quality requirements applicable to the type of items and/or services being procured.
(b) A review of previous records and performance of suppliers who have supplied items and/or services similar to the type being procured.
(c) A survey/audit of the supplier's facility and/or an evaluation of their quality program, when no previous quality records are available, to determine the capability to supply items and/or services meeting all procurement document requirements.

In addition, suppliers approved by other companies may be accepted by Quality as a supplier of items and/or services critical to safety. In this case, Quality obtains from the auditing organization a copy of the supplier audit report, audit checklist, and auditor qualifications (if not previously reviewed). These documents are reviewed by Quality to determine if they present sufficient information to make a judgement concerning the supplier's capability to meet the BWFC procurement document requirements. Evidence of an acceptable review is by addition of the supplier to the Supplier Status List.

7.2.1 Dedication of Commercial Grade Items and/or Services

Commercial grade items and/or services for use in critical to safety applications may be procured from suppliers where specific quality controls for nuclear applications cannot be imposed in a practicable manner. In these instances, an evaluation of the suitability of the item or service for nuclear applications is performed by the responsible engineering organization. The critical characteristics of the item or service are also determined and documented as part of this evaluation. Special methods may be needed for verification of these critical characteristics. Such methods may be established by the responsible engineering organization and Quality to provide assurance that the item or service specified is the item or service received. If needed, these special quality verification methods may include inspections, tests, or commercial grade surveys or evaluations of the supplier. Suppliers of commercial grade items and/or services need not appear on the Supplier Status List.

7.3 SUPPLIER STATUS LIST

Suppliers meeting the criteria described in Section 7.2 are included in the Supplier Status List issued by Quality.

Purchasing must select suppliers from this list for placement of orders that impose critical to safety requirements on the suppliers. The particular buyer will assure that the selected supplier is approved for the quality requirements specified in the procurement documents, and for the types of items and/or services to be supplied. If this is not feasible, then an evaluation of procuring a particular item or service as commercial grade with subsequent dedication for critical to safety application may be performed as discussed in Section 7.2.1.

The Supplier Status List is updated periodically to include supplier additions, deletions, or status modifications based upon results of supplier surveys, audits, or evaluations. Interim changes are made by memo or copy of audit reports to appropriate personnel.

7.4 PROCUREMENT PROCESS MONITORING

Procurement documents are reviewed by Quality as described in Section 4. In addition, periodic internal audits of the procurement process are performed as described in Section 18.

7.5 SOURCE INSPECTION OR SURVEILLANCE

Source inspection or surveillance requirements are established by Quality using written criteria during the review of procurement documents. The degree of inspection or surveillance depends upon the importance and complexity of an item, past supplier performance, and practicality of receipt inspection. The source inspection or surveillance requirements for an item may be established in Route Cards, by direct Quality contact with a supplier, and/or by appropriate documents. The inspection/surveillance requirements for an item indicate the BWFC inspection, witness, and/or hold points, as well as any customer designated points.

Visits to the supplier by quality representatives are made to carry out the inspection/surveillance requirements. The results of each inspection/surveillance are documented in Route Cards, appropriate inspection forms, and/or trip reports. Nonconformances detected during an inspection/surveillance visit are described in the inspection documentation. If the supplier elects to disposition a nonconformance by rework or replacement, this is so noted in the inspection documentation, and the supplier documents the nonconformance as prescribed by his quality program. For those nonconformances where the supplier chooses to disposition by repair or use-as-is, this is so noted in the inspection documentation, and the supplier submits a written request to BWFC for approval of such disposition as described in Section 15.

Re-inspection or retest by the supplier may be required when inspection or test results appear questionable or additional data are required. Re-inspection/test may be observed by the quality representative to clear a nonconformance. Re-inspections/tests are conducted in accordance with the original inspection/test requirements.

7.6 RECEIVING INSPECTION

Incoming items received at CNFP for use in critical to safety applications undergo a receiving inspection by inspection personnel prior to the release of such items for further processing. Receiving inspections may be conducted on an individual item or sampling basis. Sampling for receiving inspection operations may be performed in

accordance with MIL-STD-105 or alternate written sampling plans.

Receiving inspections are conducted as specified in written procedures or instructions which cover the type of test or inspection (i.e., visual, dimensional, chemical, physical) applicable to the item or lot being received. The choice of the type of inspection or test and the data to be generated is made based upon the procurement document requirements and the requirements of applicable drawings and specifications. In addition, received items are inspected for shipping damage, proper identification, and appropriate cleanliness.

Concurrent with the receiving inspection, Quality verifies that all supplier documentation required by the procurement documents to be submitted has been reviewed by the appropriate organizations for completeness and compliance with requirements.

Accepted items are identified as to their inspection status and released by Quality for further processing. Nonconforming items are clearly identified and are segregated or otherwise controlled until proper disposition is made as described in Section 15.

Section	Subject	Revision
8	**IDENTIFICATION & CONTROL OF ITEMS**	1

8.1 GENERAL

Procedures are established by BWFC for the identification and control of items to assure that:

(a) Only correct and accepted items are used. Nonconforming items are identified and segregated from acceptable items.

(b) Identification and traceability of items is maintained from receipt through storage, processing, and assembly to final acceptance of complete items.

(c) Correct identification of items is verified and documented prior to release for fabrication, assembly, or shipment.

(d) Identification of items can be traced to applicable documentation such as drawings, specifications, procurement documents, manufacturing and inspection documents, nonconformance reports, and physical and chemical test reports.

(e) Items are identified by heat number, part number, serial number, lot number, or other means either on the item or on records traceable to the item.

(f) Identification methods used are not detrimental to the item.

(g) Physical identification is used whenever possible. Where physical identification is either impractical or insufficient, physical separation, procedural controls or other means is employed.

Identification numbers such as part or task numbers are assigned by the responsible BWFC organizations to all items supplied by BWFC. These numbers are used to identify the items and for the association of documents to the items for which they are applicable.

8.2 IMPLEMENTATION

The identification of items manufactured by CNFP is established using the identification requirements contained in drawings, specifications, and/or in internal procedures. Control and traceability are maintained by means of documentation covering the manufacturing and inspection operations in accordance with the requirements of Section 8.1.

Section	Subject	Revision
8	**IDENTIFICATION & CONTROL OF ITEMS**	**1**

CNFP operates under a Release Point System that provides a continuous audit of the various materials and components from their initial receipt, processing through the plant, and finally through release for packaging and storage. Each release point is in effect a Quality hold and requires a release document from Quality prior to continuation of processing or shipment. Test items need not follow the Release Point System but rather be controlled by the responsible engineer as defined in written procedures.

Suppliers may use the BWFC assigned identification numbers in conjunction with their own identification system during design, procurement, fabrication and shipping. If the supplier uses his identification and control system, he must be able to demonstrate traceability of his number to the BWFC assigned identification number.

Section	Subject	Revision
9	**CONTROL OF PROCESSES**	1

9.1 GENERAL

Written procedures establish the requirements for the control of special processes used in the manufacture or inspection of radioactive material shipping containers. Special processes as defined in Appendix B include welding, heat treating, and nondestructive examination. Cleaning is considered to be a special process when exceptional and unusual care in cleaning is necessary as defined in the applicable drawings and specifications.

Special processes are controlled to ensure the following:

(a) Special process procedures (including changes) are approved by the responsible engineering and quality organizations when required by the applicable procedures, drawings, specifications, and procurement documents.

(b) Special process procedures incorporate applicable codes, standards, and other regulatory requirements.

(c) Special processes are performed in accordance with qualified, approved procedures using approved methods and materials, utilizing personnel and equipment qualified in accordance with applicable codes or standards.

(d) Records of procedure, process, operator, and equipment qualification and approval are maintained and available for review.

(e) Special processes are accomplished with written process sheets, shop procedures, checklists, travelers, or equivalent that provide adequate space for recording evidence of verification.

9.2 IMPLEMENTATION

Quality and Manufacturing Engineering are responsible for the preparation of special process procedures and their related qualification procedures including the qualification of personnel and equipment. Qualification is performed when it is required by the applicable drawings and specifications or when deemed necessary by Quality or Manufacturing Engineering.

Special process procedures and their related qualification procedures encompass the requirements of Section 9.1 and they are prepared/reviewed/approved, as applicable, by the responsible engineering, manufacturing, and quality organizations as stipulated

in written procedures/instructions. They are controlled, distributed for use, and maintained current by the issuing organization. In addition, they are released for specific BWFC manufacturing applications by reference in Route Cards described in Section 5.5.

BWFC manufacturing personnel performing NDE are qualified, as appropriate, to written practices established in accordance with SNT-TC-1A by the appropriate Level III individual. In some cases, personnel from suppliers may qualify BWFC NDE personnel or perform NDE under the direction of BWFC. When this is the case, the NDE personnel supplier is evaluated and approved by Quality as described in Section 7.

Section	Subject	Revision
10	**INSPECTION**	**1**

10.1 GENERAL

Inspections of items for acceptability are performed. The inspection functions operate in accordance with written procedures and utilize personnel trained and qualified in accordance with applicable standards. Program procedures provide criteria for determining the accuracy requirements of inspection equipment and criteria for determining when inspections are required or define how and when inspections are performed. In addition, the inspection programs provide for the following:

(a) The cognizant quality organization participates in the establishment and implementation of inspection programs for specific items.

(b) Product Quality (inspection) personnel are independent from the individual or group performing the activity being inspected and have no conflict of interest with cost and schedule.

(c) Inspection procedures or instructions are available for use, along with necessary drawings and specifications, prior to each inspection operation. In addition, inspection equipment is within calibration prior to an inspection operation.

(d) Reworked, repaired, and replacement items are inspected in accordance with the original inspection requirements or acceptable alternatives. Items reworked, repaired, or replaced in the field are inspected as required by the field procedures.

(e) Inspection results are documented, evaluated, and their acceptability determined by the cognizant quality organization.

(f) Mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector are identified in pertinent documents.

(g) Indirect control (by monitoring processing methods, equipment, and personnel) is provided when inspection of processed items is impractical or disadvantageous. Both inspection and process monitoring are provided when control is inadequate without both.

Inspection procedures, instructions, and/or checklists are provided and contain or reference the following items:

(a) Identification of characteristics and activities to be inspected including

acceptance and rejection criteria along with data/measurements to be recorded.

(b) A description of the method of inspection along with any sequential operations such as operational checks or preliminary calibration of setup to be performed by the inspector.

(c) Identification of the organization/individual responsible for performing the inspection and identification of the required procedures, drawings, and specifications including revisions.

(d) Conditions to be maintained during the inspection.

(e) Provisions for evidence of comparison and acceptability of each inspection operation including provisions for a record of the results of each inspection operation along with inspector identification and date of inspection.

10.2 IMPLEMENTATION

The CNFP Inspection Program utilizes personnel trained and qualified in accordance with applicable standards and is conducted in accordance with documented procedures which incorporate the quality requirements defined in applicable specifications and drawings. The procedures and inspection forms encompass receiving, in-process and final inspection of items. These procedures and forms include the requirements of Section 10.1.

Section	Subject	Revision
11	**TEST CONTROL**	**1**

11.1 GENERAL

When engineering judgment, codes, standards, regulations, or specifications indicate that testing is required, a written test program is established via test requirements documents by the responsible engineering organization to ensure conformance with those requirements. In those cases where design is the responsibility of BWFC suppliers, the requirements for written test programs are imposed on those suppliers through procurement documents.

The test programs describe all required tests, such as prototype qualification tests or design verification tests, to demonstrate that the items will perform satisfactorily in service. Whenever engineering judgment leads to the conclusion that design analysis or previous experience cannot substantiate a design or design feature, design verification testing is conducted as described in this section and Section 3.4.4.

11.2 IMPLEMENTATION

Tests may be conducted at CNFP or by BWFC suppliers. The requirements for such tests are included in test requirements documents prepared by the responsible engineering organization. These test requirements documents include, as appropriate, the requirements of this section, scope of the test effort, technical requirements, and quality requirements.

The test requirements documents require testing to be performed in accordance with written test plans and/or procedures that incorporate or reference the design requirements and acceptance limits contained in the applicable design documents. The test plans and/or procedures for tests performed at CNFP are prepared by the responsible engineering or test organization and those for tests at suppliers are prepared by the supplier and approved by the responsible engineering organization. Nonconformances to test requirements documents are processed by the responsible engineer as defined in written procedures.

These plans or procedures provide instructions for performing the test and include provisions for ensuring that prerequisites for the given test are complied with; that testing methods are provided; that adequate instrumentation is available and used; that testing is performed under suitable environmental conditions; and that necessary monitoring is performed.

Test prerequisites include such items as provisions for hold and notification points for witness by the responsible engineering or quality organizations, the customer, or

authorized agents; calibrated instrumentation; adequate and appropriate test equipment; acceptance and rejection criteria; use of trained and qualified personnel; the condition of test equipment and preparation, condition and completeness of the item to be tested; suitable environmental conditions; and provisions for data acquisition, collection, and storage. The methods of documenting or recording the test data is indicated.

Test results are documented, evaluated, and their acceptability determined by the responsible engineering organization to ensure that the design requirements have been met.

Section	Subject	Revision
12	**CONTROL OF MEASURING & TEST EQUIPMENT**	1

12.1 GENERAL

Effective and operational systems for the control, selection, calibration, and maintenance of measuring and test equipment (M&TE) are provided. Internal procedures and procurement document requirements ensure inclusion of the following in these systems, as appropriate:

(a) Methods of selection, calibration and control of M&TE.

(b) Calibration schedules and intervals.

(c) Availability of procedures and instructions describing the calibration techniques, calibration frequency, maintenance and control of M&TE, tools, gages, fixtures, reference standards, transfer standards, and nondestructive test equipment.

(d) M&TE in the system is processed through a mechanical, electrical, or optical calibration facility.

(e) Reference standards used are calibrated by equipment traceable to the National Institute of Standards and Technology (formerly the National Bureau of Standards) where such standards exist or, where non-existent, provisions are established to document the basis for calibration.

(f) Standards have an accuracy adequate to verify that the M&TE being calibrated are accurate within the tolerance requirements for which they are being used. M&TE are calibrated against reference standards having an accuracy at least four (4) times greater than the required accuracy of the M&TE. Greater uncertainty is acceptable when limited by the accuracy of commercially available standards, provided the standards have an accuracy that assures the equipment being calibrated will be within required tolerance and that the basis of acceptance is documented and authorized by responsible management.

(g) Working standards are either marked with calibration labels to indicate the next due date for calibration or the calibration information is contained in records traceable to the working standard.

(h) M&TE instruments are uniquely identified and traceable to calibration records. Records are maintained indicating the last calibration date and the due date. The calibration due date is displayed on or attached to each item or on records traceable to each item.

(i) Provisions for ensuring and documenting the validity of previously performed inspections or tests and the acceptability of items inspected or tested since the last calibration when M&TE is found to be out of calibration, including identification of M&TE used.

12.2 IMPLEMENTATION

The CNFP system for the control of M&TE encompasses the above requirements. It is the responsibility of Quality to assure that M&TE used in activities affecting quality are properly controlled, calibrated, and adjusted to maintain accuracy within necessary limits. It is also their responsibility to assure that proper procedures are followed for active gages, measuring devices and inspection fixtures used to verify and certify item conformance with specified requirements. If production tooling or fixtures are used as an accessory inspection medium, such items are also subject to the control program for M&TE.

Suppliers of M&TE and of calibration services for M&TE or reference standards are required by the procurement documents to have an effective system for the calibration of M&TE. Manufacturers of M&TE or calibration service suppliers utilized to calibrate M&TE or reference standards are audited and approved by Quality to appropriate standards such as MIL-STD-45662A, "Calibration System Requirements." State and federal agencies such as the National Institute of Standards and Technology are exempted from this requirement.

Alternatively, the acceptability of calibration services performed by an unaudited supplier may be confirmed/verified by having the same item, prior to use, calibrated by another independent supplier. If the other supplier finds the item to be within calibration, then the item is acceptable for use. This comparison of calibrations is documented by Quality and neither supplier need be audited and approved by Quality. If the item is found to be out of calibration by the independent supplier, then it is unacceptable for use until the disparity in calibrations is resolved.

Section	Subject	Revision
13	**HANDLING, STORAGE, & SHIPPING**	**1**

13.1 GENERAL

Methods are established for the control of handling, cleanliness, preservation, packaging, storage and shipping of radioactive material shipping containers as specified in applicable drawings, specifications, and procedures.

13.2 CLEANLINESS & PRESERVATION

Final assembly operations are carried out in areas which are adequate to permit the attachment of the final cleanliness level specified in applicable drawings and specifications. After completion of final inspections, the cleanliness of accepted items is maintained by suitable means to ensure compliance with the applicable cleanliness requirements.

13.3 STORAGE

After the completion of final assembly, acceptable radioactive material shipping containers are tagged with tags which contain container identity, initials of inspector, and final inspection date. They are then placed in appropriate storage areas. Measures are taken during storage to preclude damage, loss, or deterioration by environmental conditions.

13.4 HANDLING

Handling devices such as cranes, slings, and other devices used for the purpose of lifting and transporting major components are periodically inspected in accordance with written procedures.

13.5 PACKAGING & SHIPMENT

Prior to each use, radioactive material shipping containers are inspected to the criteria specified in written procedures which incorporate the requirements of applicable regulatory controls including Certificates of Compliance and the Code of Federal Regulations.

Radioactive material is packaged as specified in written procedures. All necessary shipping papers are prepared and processed as required. Shipment and receipt of a radioactive material shipping container is monitored as specified in 10CFR71.

Section	Subject	Revision
14	INSPECTION, TEST, & OPERATING STATUS	1

14.1 GENERAL

Systems for the control of inspection, test, and operating status of items are established and implemented. The systems contain provisions for:

(a) Documenting and identifying items that have satisfactorily passed required inspections and tests.

(b) Precluding inadvertent bypassing of inspection and test requirements.

(c) Providing inspection and test status using positive means such as stamps, tags, labels, route cards, and shop travelers.

(d) Controlling the application and removal of status indicators and identifying the source of authority required for such actions.

(e) Controlling and documenting the bypassing of required inspections, tests, or other critical operations when dictated by circumstances.

(f) Ensuring that personnel concerned with production or cost control will not exercise control over the application or removal of status indicators.

14.2 IMPLEMENTATION

14.2.1 Route Cards

The status of manufacturing and inspection operations for items fabricated and assembled by BWFC are indicated in Route Cards. Route Cards define the chronological sequence of manufacturing and inspection operations and list the appropriate drawings, specifications, or procedures applicable for each operation.

Route Cards are prepared by Manufacturing Engineering and reviewed by Quality to verify that the appropriate inspection operations, sequences of such operations, and procedures for performance of the inspection operations are properly noted.

Each performer of a manufacturing or inspection operation signifies completion of that operation by initials and date on the Route Card. Inspectors verify that operations subsequent to the last inspection operation have been properly initialed as completed.

As defined in written procedures, the status of manufacturing, inspection, and test

operations for test items may be indicated by documents other than Route Cards.

14.2.2 Status Indication by Tags

Suitable tags are attached by the inspector to items or their containers to indicate their successful completion of receiving or final inspection operations. Items found to be acceptable during in-process inspection are so noted on the Route Card and tags are not used.

Any item found to be nonconforming during inspection operations, will have a "Hold" tag attached to it by the Inspector indicating a deviation which may require a repair or rework, reject, or use-as-is disposition. Once the nonconformance is dispositioned as described in Section 15, the "Hold" tag is removed by the inspector and a "Rework", "Reject", or "Accepted" tag is attached depending upon the disposition of the nonconformance. Any item with a "Reject" tag is separated from conforming items.

Section	Subject	Revision
15	**CONTROL OF NONCONFORMING ITEMS**	1

15.1 GENERAL

Measures are established to control the quality of documentation and items that do not conform to specified requirements. These measures address deficiencies of characteristics, documentation, or procedures that render an item or activity unacceptable or indeterminate. They include procedures for controlling the identification, documentation, and segregation of nonconforming items pending notification of affected individuals and/or organizations, review of the nonconformance, and approval of disposition.

15.2 INTERNAL NONCONFORMANCES

Nonconformances may be generated within BWFC as a result of internal audits, customer audits, customer problems, or other deficiencies. These nonconformances are documented and resolved as follows:

15.2.1 Quality Action Reports

Quality Action Reports are used to document and determine the resolution of significant quality concerns that occur within BWFC that are not otherwise documented. Quality Action Reports may be originated, as appropriate, by Quality or other BWFC personnel to identify significant concerns. In general Quality Action Reports will be used as follows:

- to document an audit finding, recommendation or other concern expressed by the customer for which the customer requires a written response,
- to document findings (refer to Appendix B for definition) generated during an internal audit,
- to document nonconformance item corrective action evaluations,
- and to document concerns raised by any employee within BWFC that are considered by Quality management to be of significance and warranting formal documentation and follow up of corrective action.

Quality Action Reports will request a response from the organization involved. The response must address root cause and corrective action to preclude recurrence. Quality will review and approve the response and follow up on implementation of the corrective action.

15.2.2 Safety Concerns

Nonconformances which may constitute potential significant deficiencies or substantial safety hazards are processed in accordance with written procedures. Safety concerns are processed to the requirements of 10CFR21.

15.2.3 Design Deficiency Report (DDR)

DDRs are initiated by BWFC personnel with the concurrence of the cognizant manager to report an error discovered in any issued BWFC prepared design document. DDRs define the cause of the error, the action to correct the error and any subsequent corrective action.

15.3 MANUFACTURING NONCONFORMANCES

Nonconforming items detected during receiving, in-process, or final inspections are tagged as described in Section 14 and documented. For those manufacturing operations where the nonconformance condition can be corrected by a continuation of the original manufacturing process or where it is suitable to define the rework (or repair allowed in the design specification) and subsequent reinspection between release points on the Route Card, the in-process nonconformance is noted on the inspection report and the rework and reinspection are documented on the Route Card or other appropriate documentation.

Nonconformances, which cannot be corrected as described above, are documented by Product Quality and submitted to Manufacturing Engineering for review and determination of cause; need for corrective action evaluation and safety concern evaluation; and a recommended disposition. Disposition of nonconformances are concurred with by the Manager of Quality Verification.

Disposition of a nonconformance by Manufacturing Engineering may be: scrap, rework, repair, use-as-is, restricted use, return to supplier, or acceptable. Definitions of these dispositions are in Appendix B. Rework is performed in accordance with methods or procedures specified by Manufacturing Engineering and approved by Quality. Repair procedures or instructions are prepared by Manufacturing Engineering and approved by Quality. Reworked items are reinspected to the original requirements and repaired items are reinspected to criteria established for the acceptability of the repair. Manufacturing Engineering must provide engineering justification for all use-as-is or restricted use dispositions.

Test item nonconformances may be processed as described above or they may be processed by the responsible engineer as described in written procedures.

15.4 SUPPLIER NONCONFORMANCES

Supplier nonconformances enter the BWFC system in one of three ways:

(a) By the submittal of a written request by a supplier for approval of nonconformances that violate requirements of BWFC procurement documents or BWFC approved supplier drawings, specifications, or procedures and the supplier wishes to repair the nonconforming item or use-as-is. The nonconformance is prepared by the supplier and includes his determination of cause, corrective action, and recommended disposition, i.e., repair or use-as-is. Repair disposition must be accompanied with a repair procedure or indicate the repair will be performed in accordance with a BWFC approved repair procedure. A supplier nonconformance is processed in the same manner as a manufacturing nonconformance (Section 15.3).

(b) By audit findings initiated by Quality to identify nonconformances found during supplier audits as described in Section 18.

(c) By nonconformance reports issued by Quality to document nonconformances detected during source or receiving inspections or surveillances as described in Section 7.

Resolution of (b) and (c) may result in the submittal of supplier requests for approval of the nonconformances as described in (a) above.

Section	Subject	Revision
16	**CORRECTIVE ACTION**	**1**

16.1 GENERAL

Procedures are established by BWFC to ensure prompt identification and correction of conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances during the design, procurement, fabrication, inspection, and testing of items. These procedures require assurance that:

(a) Nonconformances and failures are evaluated to determine the need for corrective action, and that such action is taken as necessary.

(b) The cause of the nonconformance or failure is determined and action is taken to preclude recurrence.

(c) Appropriate levels of management are informed of significant conditions adverse to quality, the cause of the conditions, the action taken, and the corrective action taken to preclude recurrence.

(d) Follow-up is conducted to verify proper implementation of both corrective and preventive actions and to close out the corrective action documentation.

16.2 IMPLEMENTATION

Reports of nonconformances are generated/received by BWFC as described in Section 15. They are analyzed by Quality to determine whether more extensive actions are required in addition to any corrective action applied to the specific nonconformance. The stated cause of the nonconformance is reviewed by Quality to determine the following:

(a) Whether there may have been previous occurrences.

(b) Whether the root cause may result in subsequent nonconformances if not corrected.

(c) Whether the cause indicates a defect or a correctable trend in design, fabrication, processing, personnel training, etc.

Potential problems identified by the Quality review are reported to the responsible organization for further corrective action. Subsequent review and follow-up is accomplished by Quality to determine the effectiveness of the corrective action taken.

Section	Subject	Revision
17	**QUALITY ASSURANCE RECORDS**	1

17.1 GENERAL

Procedures are established by BWFC to collect and retain records which provide evidence that design, procurement, fabrication, inspection, and testing activities are in accordance with quality requirements. Requirements and responsibilities for record generation, identification, accumulation, transmittal, retention, and maintenance are contained in these procedures.

Quality records include such documentation as design analyses and calculations; design reviews; drawings; specifications; procurement documents; results of inspections, tests, audits, and material analyses; monitoring of work performance; qualification of personnel, procedures, and equipment; calibration procedures and reports; nonconformance reports; corrective action reports; inspection and test records; and other documentation required by applicable codes and regulations. These records are classified either as lifetime or nonpermanent (refer to Appendix B for definitions).

17.2 IMPLEMENTATION

Records are collected during design, procurement, fabrication, inspection, and test activities to provide documentary evidence of the quality of items and of the activities affecting quality. These records are identifiable, retrievable, and maintained to minimize deterioration or damage and to prevent loss. For records classified as lifetime, original documents are microfilmed and copies are maintained in separate locations.

Quality is responsible for the collection, filing, maintenance, and retrieval of records generated during the manufacture of radioactive material shipping containers and for other lifetime quality records mandated by the QA Program. Likewise, Manufacturing Engineering has the same responsibility for radioactive material shipping container design records. Safety & Licensing has similar responsibilities for records related to the licensing and use of radioactive material shipping containers. These records are retained for the life time of the radioactive shipping container that they represent.

Section	Subject	Revision
18	**AUDITS**	**1**

18.1 GENERAL

BWFC Quality conducts an audit program defined by written procedures providing program definition as well as direction and guidance for audits and the supporting activities concerned. These procedures establish the scheduling, preparation, execution, reporting, and follow-up methods to be used in implementing the audit program. The audits conducted under the Quality audit program include an objective evaluation of quality-related practices, procedures, and instructions; the effectiveness of implementation; conformance with policy directives; work areas, activities, processes, and items; indoctrination and training programs; interfaces within BWFC and with the customer; corrective action, calibration, and nonconformance control systems; calculations and associated computer codes; and the review of documents and records.

Audits are regularly scheduled based upon the status and safety importance of the activities being performed and are initiated early enough to assure effective control during design, procurement, fabrication, inspection, and testing. The audits are performed in accordance with pre-established written procedures or checklists and conducted by trained personnel having no direct responsibilities in the areas being audited.

The BWFC Quality audit program is in compliance with Regulatory Guides 1.28 (Rev. 3) and 1.144 (Rev. 1) as set forth in Appendix A. Quality audit personnel are trained and qualified in accordance with the requirements of Regulatory Guides 1.28 (Rev. 3) and 1.146 (Rev. 0) as described in Appendix A.

18.2 INTERNAL AUDITS

Internal audits of BWFC activities are used to evaluate compliance with and the effectiveness of the QAP. These audits are scheduled to cover the quality program elements once each calendar year. The Quality organization is audited by qualified auditors who have no direct responsibility for the performance of the activities being audited. Audits of other BWFC organizations' activities are conducted by qualified auditors having no responsibilities in the areas audited.

Reports from the audits of BWFC activities are provided to the managers of the areas audited and to the President of BWFC for review, analysis, and direction. Managers of the audited areas investigate audit findings; determine cause, schedule corrective action, including measures to prevent recurrence; and provide written responses to the findings of the audit. Follow-up is conducted by Quality to ensure implementation of

appropriate corrective and preventative actions. When necessary, follow-up will include reaudit of deficient areas.

18.3 SUPPLIER AUDITS

Suppliers of safety related items and services are evaluated or audited by Quality to determine compliance with procurement document requirements and the effectiveness of their quality programs.

Audit frequency is based upon written criteria that incorporate the safety classification, importance, complexity, and quality requirements of the items or services being procured. Reports of findings from these audits are provided to the audited supplier, and responses (which address cause and corrective action) to the findings are required. The findings are closed when the supplier can demonstrate effective corrective actions in the areas of the findings. The audit reports, supplier responses, and their evaluation provide input for the maintenance of the Supplier Status List (Refer to Section 7).

18.4 SITE AUDITS

Site audits of BWFC field operations will be performed in accordance with customer requirements. When performed, they will be conducted in the same manner as internal audits and as early in the life of the activity as practical. In addition, they will be conducted on intervals consistent with the schedule for accomplishing the activity and commensurate with the status and importance of the activity.

18.5 AUDIT RECORDS

Audit records are maintained as nonpermanent (refer to Appendix C for definition) records. These records include audit plans, audit reports, audit findings, audit responses, follow-up actions, and audit personnel qualification records.

B&W FUEL COMPANY
RADIOACTIVE MATERIAL SHIPPING CONTAINER QAP

Section	Subject	Revision
APP A	**QAP PROCEDURES (TYPICAL LISTING)**	**1**

NUMBER	SUBJECT	QAP SECTION
BWNT-0310-05	PRODUCT NUMBERING	8
BWNT-0310-38	HISTORICAL DOCUMENT LIST (HDL)	6
BWNT-0310-48	CONTROLLING MANUFACTURING RISK OPERATIONS AT CNFP	5
BWNT-0402-01	PREPARING & PROCESSING BWNT CALCULATIONS	3,6
BWNT-0403-11	TECHNICAL DOCUMENT SIGNATURES	3
BWNT-0405-22	DESIGN REVIEW BOARDS	3
BWNT-0405-30	DESIGN VERIFICATION	3-6,11
BWNT-0408-08	MATERIALS REVIEW AND CONSULTATION	3
BWNT-0412-57	PREPARING BWNT DETAIL DESIGN DOCUMENTS	3-6,11,13
BWNT-0412-58	PROCESSING BWNT PREPARED DETAIL DESIGN DOCUMENTS	3-6,11,13
BWNT-0412-59	ENGINEERING INFORMATION RECORD/TECHNICAL DATA RECORD	3,5,6,11
BWNT-0412-63	BWNT TECHNICAL DOCUMENT FORMAT	3,5,6
BWNT-0412-66	RELEASE OF PRODUCT DOCUMENTATION	3-6
BWNT-0414-12	PREPARATION OF LICENSING DOCS AND B&W OWNERS GROUP RPTS	3,6
BWNT-0414-13	PROCESSING LICENSING DOCS AND B&W OWNERS GROUP RPTS	3,6
BWNT-0902-06	SOFTWARE CERTIFICATION	3,6
BWNT-0902-10	SOFTWARE DEVELOPMENT	3,6
BWNT-0902-12	ACCESS CTRL SYS FOR COMPUTERS USING A UNIX-BASED OPR SYS	3,6
BWNT-0902-13	PRODUCTION SYSTEM SOFTWARE AND HARDWARE CHANGES	3,6
BWNT-0903-03	DEVELOPMENT AND CONTROL OF SOFTWARE DOCUMENTATION	3,6
BWNT-1212-12	PROCUREMENT DOCUMENTS	4,6
BWNT-1303-07	PREPARING & PROCESSING ADMINISTRATIVE PROCEDURES	5,6
BWNT-1303-15	CONTROL OF MANUALS	5,6
BWNT-1406-10	VERIFICATION OF PREVIOUS EMPLOYMENT AND EDUCATION	2
BWNT-1702-22	EMPLOYEE TRAINING	2
BWNT-1702-25	ASSIGNMENT OF NUCLEAR SAFETY CLASS TO PRODUCTS & SVCS.	2
BWNT-1703-71	BWFC QUALITY ACTION REPORTS	15,16

Section	Subject	Revision
APP A	**QAP PROCEDURES (TYPICAL LISTING)**	**1**

NUMBER	SUBJECT	QAP SECTION
BWNT-1703-73	NONCONFORMING MATERIALS, PARTS OR COMPONENTS	15,16
BWNT-1705-16	QA REVIEW OF PROCUREMENT PACKS.	4
BWNT-1706-01	OPERATIVE & TEMPORARY PROCEDURES	5,6
BWNT-1707-03	REPORTING OF DEFECTS & FAILURE TO COMPLY (10CFR21)	15,16
BWNT-1717-02	INTERNALLY IDENTIFIED DESIGN DEFICIENCIES	15,16
BWNT-1717-03	CORRECTIVE ACTION	16
BWNT-1719-23	QUALIFICATION OF QUALITY ASSURANCE AUDIT PERSONNEL	2,18
BWNT-1719-24	INTERNAL AUDITS OF BWFC QUALITY ASSURANCE PROGRAMS	18
BWNT-1719-25	QUALITY SYSTEM SURVEYS & QUALITY AUDITS OF BWFC SUPPLIERS	7,18
BWNT-1719-27	AUDITS, SURVS, OR INSPS OF BWFC BY OUTSIDE ORGANIZATIONS	18
AS-1112	FORK LIFT AND CRANE OPERATIONS	13
AS-1117	CRANE, SLING, & LIFTING FIXTURE INSPECTION AND TESTING	13
AS-1124	OCCUPATIONAL PROCEDURES	5,6
MA-132	FUEL ASSY CONTAINER UNPACKING & LOADING & PREP FOR RETURN	13
MA-292	MKBW FUEL ASSY PACKAGING/SHIPPING & CONTAINER STORAGE	13
MA-332	SNM SCRAP SHIPPING	13
MA-425	UNLOADING OF MKBW FUEL ASSY SHIPPING CONTAINER	13
MA-439	MAINTENANCE/REFURBISHMENT OF DHTF SHIPPING CONTAINER	13
MA-470	MKB FUEL ASSY PACKAGING/SHIPPING & CONTAINER STORAGE	13
MA-512	UNLOADING OF SHIPPING CONTAINERS AT CNFP	13
MA-533	MAINTENANCE OF MODEL B FUEL ASSY SHIPPING CONTAINER	13
MA-561	MODEL 51032-2 SHIPPING CONT. PACKING, SHIPPING, & STORAGE	13
MA-562	MODEL 51032-2 SHIPPING CONT. UNLOAD. & PREP. FOR RETURN	13
MA-1200	DISTRIBUTION OF MANUFACTURING ENGINEERING DOCUMENTS	5,6
MA-1201	PREPARATION & APPROVAL OF ENGINEERING REQUIREMENTS	4-6
MA-1202	QUALIFICATION OF MANUFACTURING PROCESS OPERATIONS	9
MA-1203	PREPARATION & APPROVAL OF BILL OF MATERIALS	4-6

Section	Subject	Revision
APP A	QAP PROCEDURES (TYPICAL LISTING)	1

NUMBER	SUBJECT	QAP SECTION
MA-1205	PREPARATION & APPROVAL OF PURCHASED MATERIALS LIST	4-6
MA-1206	PREPARATION & APPROVAL OF MFG. PROCESS PROCEDURES	5,6
MA-1207	PREPARATION, APPROVAL, & RELEASE OF ROUTE CARDS	5,6,14
MA-1210	PREPARATION & APPROVAL OF MFG. PROCESS TEMP PROCEDURES	5,6
MA-1221	ABNORMAL EVENT REPORT (AER)	15,16
MA-1222	PREPARATION & APPROVAL OF DESIGN MATERIALS LISTS	4-6,
MA-1223	MANUFACTURING ENGINEERING RECYCLE/SCRAP REPORT (MERSR)	15,16
MM-1208	MATERIALS MANAGEMENT ADMINISTRATIVE PROCEDURES	5,6
MM-1301	PREPARATION & APPROVAL OF PROCUREMENT REQUIREMENTS (PR)	4-6
MM-1302	DISTRIBUTION OF MATERIALS MANAGEMENT DOCUMENTS	5,6
MM-1305	PREPARATION OF MATERIAL REQUISITION	4
MM-1306	PREPARATION OF MATERIAL REQUISITION CHANGE NOTICES	4
MM-1307	INTERIM CHANGE SYSTEM (IC)	4
MM-1309	MATERIAL & PART DEVIATION & CERTIFICATION HISTORY	15,16
MM-1310	DR CORRECTIVE ACTION SYSTEM	16
MM-1312	SUBCONTRACTOR RATING SYSTEM	7
MM-1315	COMMERCIAL DEDICATION ROUTE CARDS	5,6,14
MM-1503	PO/CO FOR INVENTORY	4
MM-1504	PO/CO FOR NON INVENTORY	4
PC-1315	PREPARATION OF DOCUMENTATION FOR FUEL SHIPMENTS	7,13,17
PC-1317	TRANSFER OF CONTRACT MATERIAL	8
PC-1319	SMALL CONTRACTS WITHIN THE CNFP	5,6
PC-1321	ISSUING CONTRACT MATERIAL (EXCEPT SNM)	8
PC-1322	CONTRACT MATERIAL - RELEASING (EXCEPT SNM)	8
PC-1323	CONTROL OF SHELF LIFE MATERIAL	5,6
PC-1324	CONTRACT MATERIAL RETURN (EXCEPT SNM)	5,6
MC-1725	CONTRACT MATERIAL RECEIVING (EXCEPT SNM)	7,8

Section	Subject	Revision
APP A	**QAP PROCEDURES (TYPICAL LISTING)**	1

NUMBER	SUBJECT	QAP SECTION
RP-001	RADIATION PROTECTION PROCEDURES	5,6
RP-007	SHIPMENT & RECEIPT OF RADIOACTIVE MATERIALS	13
RP-008	CALIB & MAINT OF RADIATION SURVEY INSTRUMENTS	12
QC-509	RECEIVING/INPROCESS/FINAL INSP OF 2901 SHIPPING CONTAINER	13
QC-509 ADDI	RECEIVING/INPROCESS/FINAL INSP OF DHTF SHIPPING CONTAINER	13
QC-629	RECEIVING INSP - MODEL 51032-2 SHIPPING CONTAINER	7
QC-7XX	PROCEDURES FOR NDE PERSONNEL, PROCEDURE, & EQUIP QUAL	9
QC-800(ADD)	VARIOUS PROCEDURES FOR GAGE CONTROL & CALIBRATION	12
QC-815	FUEL ASSY SHIPPING CONTAINER LOADING & SHIPPING INSPECTION	10,13
QC-948	INSP OF CONTAINERS USED FOR SHIPPING SNM FROM CNFP	13
QC-948(ADDI)	INSP OF EMPTY 2901 SHIPPING CONTAINER	10,13
QC-948(ADDII)	INSP OF EMPTY DHTF SHIPPING CONTAINER	10,13
QC-1401	SUPPLIER QUALITY DOCUMENTS	7,18
QC-1402	REVIEW OF PURCHASE ORDERS/CHANGE ORDERS	4
QC-1405	CONTROL OF MEASURING EQUIPMENT	12
QC-1405(ADD I)	PROCUREMENT OF MEASURING AND TEST EQUIPMENT	4
QC-1408	CONTROL OF INSPECTION, TEST, AND OPERATING STATUS	14
QC-1414	RETENTION & STORAGE OF QA RECORDS	17
QC-1415	ANNUAL EYE EXAM	2
QC-1417	QUALITY CONTROL REQUIREMENTS (QCR)	4-6
QC-1426	IDENT & CONTROL OF MATERIALS, PARTS, & COMPONENTS	8
QC-1428	CONTROL OF SPECIAL PROCESSES	9
QC-1431	ESTABLISHMENT & CONTROL OF INSPECTION PROGRAM	10
QC-1434	CONCURRENCE REQUEST (CR)	5,6
QC-1435	CNFP SUPPLIER PRODUCT QUALITY	7
QC-1437	PERFORMING SOURCE INSPECTION AT THE VENDOR'S PLANT	7
QC-1440	QUALIFICATION OF INSPECTION & TEST PERSONNEL	2

Section	Subject	Revision
APP A	**QAP PROCEDURES (TYPICAL LISTING)**	**1**

NUMBER	SUBJECT	QAP SECTION
QC-1446	MATERIAL/COMPONENT RELEASE	8
QC-1450	SOFTWARE DEVELOPMENT FOR BWFC CNFP QUALIFIED SOFTWARE	10
QC-1453	DEDICATION PROCEDURE FOR SAFETY RELATED ITEMS/SERVICES	7
09-1212	QA SPECIFICATION (SUPPLIERS)	4
09-1427	QA SPECIFICATION (R&D)	4
1E1	RECORDS MANAGEMENT PROGRAM	17

Section	Subject	Revision
APP B	ACRONYMS/ABBREVIATIONS/DEFINITIONS	1

ACRONYMS/ABBREVIATIONS

ADL	Applicable Documents List
AER	Abnormal Event Report
AF	Audit Finding
ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
BWFC	B&W Fuel Company
BWNT	B&W Nuclear Technologies
CFR	Code of Federal Regulations
CNFP	Commercial Nuclear Fuel Plant
CO	Change Order
COC	Certificate of Conformance
CR	Concurrence Request
DDR	Design Deficiency Report
DR	Deviation Report
DRB	Design Review Board
DRN	Document Release Notice
ER	Engineering Requirement
HDL	Historical Document List
MERSR	Manufacturing Engineering Recycle/Scrap Report
M&TE	Measuring & Test Equipment
NCR	Nonconformance Report
NDE	Nondestructive Examination
NRC	Nuclear Regulatory Commission
PML	Purchased Material List
PO	Purchase Order
PR	Procurement Requirement
QA	Quality Assurance
QAP	Quality Assurance Program
QAR	Quality Action Report
QC	Quality Control
QCR	Quality Control Requirement
R&D	Research & Development
SNM	Special Nuclear Material

Section	Subject	Revision
APP B	**ACRONYMS/ABBREVIATIONS/DEFINITIONS**	**1**

ITEM	DEFINITION
ACCEPTABLE	A disposition permitted on an item designated as nonconforming but determined after evaluation to meet design requirements. This determination must be concurred with by Quality.
ACCEPTANCE CRITERIA	Specified limits placed on characteristics of an item, process, or service defined in codes, standards, or other requirements documents and used to determine whether or not an item, process, or service is satisfactory.
ANNUAL	Defined as occurring within a calendar year, performance of duties shall not be less than 11 months or more than 13 months. Individual procedures may be more restrictive.
APPROVAL	The act of endorsing or assigning positive authorization, or both.
AS-BUILT DATA	Documented data that describe the condition actually achieved in an item.
AUDIT	A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.
AUDIT FINDING	A description of a portion of an audit where a deviation (departure from specified requirements) exists that is adverse, or potentially adverse, to the quality of an item or activity unless corrective action is taken. Each finding requires the issuance of a Quality Action Report (Internal or Customer Audit) or an Audit Finding (Supplier Audit).
AUDIT OBSERVATION	A description of a portion of an audit where a deviation exists that is not adverse, or potentially adverse, to the quality of an item or activity. Most isolated events and administrative errors fall into this category. Observations are brought to the attention of the management of the audited organization. Responses to observations are not normally required.
AUDIT RECOMMENDATION	A suggestion to perform an activity in a better or more acceptable manner. Recommendations are stated in the summary of the audit report. Responses to recommendations are not normally required.

Section	Subject	Revision
APP B	**ACRONYMS/ABBREVIATIONS/DEFINITIONS**	**1**

ITEM	DEFINITION
CERTIFICATE OF CONFORMANCE	A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.
CERTIFICATION	The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.
CHARACTERISTIC	Any property or attribute of an item process, or service that is distinct, describable, and measurable.
CLEANLINESS	A state of being clean in accordance, with predetermined standards, and usually implies freedom from dirt, dust, rust, oil or other contaminating impurities.
CRITICAL CHARACTERISTIC	Those characteristics that are essential for performance of an item's critical to safety function(s). Typical critical characteristics are attributes such as form, fit, dimensions, material including physical and chemical properties, electrical, thermal, or other functional parameters.
CRITICAL TO SAFETY	Refer to Appendix C.
COMMERCIAL GRADE ITEM	An item satisfying (a), (b), and (c) below: (a) not subject to design or specification requirements that are unique to nuclear facilities (b) used in applications other than nuclear facilities (c) is to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, catalog)
COMPUTER PROGRAM (CODE, SOFTWARE)	A sequence of instructions suitable for processing by a computer. Processing may include the use of a assembler, a compiler, an interpreter, or a translator to prepare the program for execution as well as to execute it.
CONDITION ADVERSE TO QUALITY	An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one which, if uncorrected, could have a serious effect on safety or operability.
CORRECTIVE ACTION	Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.
DOCUMENT	Any written or pictorial information describing, defining, specifying, reporting or certifying activities, requirements, procedures or results.

Section	Subject	Revision
APP B	**ACRONYMS/ABBREVIATIONS/DEFINITIONS**	**1**

ITEM	DEFINITION
DOCUMENT MASTER LISTS	Lists of documents to which an individual may refer to determine the current revisions of documents applicable to an activity, project, or contract. Includes such lists as: applicable documents list, contract documents list, historical documents list, procedure manual table of contents or plan list, etc.
DOCUMENTATION	A compilation of those documents concerning a specific function, activity or project.
EXAMINATION	An element of inspection consisting of investigation of materials, components, supplies or services to determine conformance to those specified requirements which can be determined by such investigations. Examination is usually nondestructive and includes visual, simple physical manipulation, gaging, measurement and written documentation.
FINDING (AUDIT)	See Audit Finding
HANDLING	An act of physically moving and/or lifting items by hand or mechanical means.
HOLD	An action by a quality organization wherein an item is withheld and segregated from further processing until a disposition has been defined and imposed.
HOLDPOINT	A point at which witnessing of examinations is required by the quality organization or customer and beyond which point work shall not proceed without the consent of the quality organization or customer representative respectively.
INSPECTION	Examination or measurement to verify whether an item or activity conforms to specified requirements.
INSPECTION & TEST RECORDS	Documents that furnish evidence of the completion of inspections and tests. They contain the following, where applicable, a description of the type of observation; the date and results of the inspection or tests; inspector or data recorder identification; evidence of acceptability of the item inspected; and action taken to resolve any nonconformances noted.
INSPECTOR	A qualified individual whose duties include verification of quality related activities and who is independent of the activity being verified.
ITEM	An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit.

Section	Subject	Revision
APP B	**ACRONYMS/ABBREVIATIONS/DEFINITIONS**	**1**

ITEM	DEFINITION
LIFETIME RECORD	See Quality Record (Lifetime) (Permanent)
MEASURING & TEST EQUIPMENT	Devices or systems used to calibrate, measure, gage, test or inspect in order to control or to acquire data to verify conformance to specified requirements.
MONTHLY	Defined as within a 30-day period. Performance of duties shall not be less than 15 days or more than 45 days. Individual procedures may be more restrictive.
NONCONFORMANCE	A deficiency in characteristic, documentation, performance or procedure which renders the quality of an item unacceptable or indeterminate. Examples of nonconformances include: physical defects, test failures, incorrect or inadequate documentation, or deviation from design standards, prescribed processing, inspection or test procedures and procurement document requirements.
NONDESTRUCTIVE EXAMINATION	A method of detecting indications of discrepancies without destroying the usefulness of the item or material.
NONPERMANENT RECORD	See Quality Record (Nonpermanent)
OBJECTIVE EVIDENCE	Any statement of fact, information, or record; either quantitative or qualitative pertaining to the quality of an item or service which can be verified by records of tests, examinations, inspections, measurements, or observations.
OBSERVATION (AUDIT)	See Audit Observation
PERMANENT RECORD	See Quality Record (Lifetime) (Permanent)
PROCEDURE	A document which specifies instructions for performance of a particular task. It includes methods to be employed, description of equipment or material to be used, sequence of operations, etc.
PROCESS	One or more operations, methods, functions, procedures or other specified actions, which result in the desired end item or result.
PROCUREMENT AUTHORIZATION DOCUMENT	A document used to transmit procurement information/documents to the procurement function for the purpose of obtaining bids, placing orders and change orders, etc.
PROCUREMENT DOCUMENT	A contractually binding document, identifying and defining the requirements which items or services must meet prior to acceptance. Also includes procurement authorizations, purchase requisitions, purchase orders, contracts, drawings, specifications, or instructions.

Section	Subject	Revision
APP B	**ACRONYMS/ABBREVIATIONS/DEFINITIONS**	**1**

ITEM	DEFINITION
QUALIFICATION (PERSONNEL)	A demonstration of those characteristics or abilities of an individual, gained through training and/or experience, that enable him to perform specific functions.
QUALIFIED EQUIPMENT	Equipment which has been evaluated by sufficient testing to assure performance within specified parameters.
QUALIFIED PROCEDURE	A procedure which incorporates all applicable code and standard requirements, manufacturing parameters and engineering specifications, and which has been proven adequate for the intended purpose.
QUALITY	The properties or characteristics constituting those requisites of specifications, codes, standards, industrial practices, other recognized methods and/or acceptance criteria, by which an item is judged.
QUALITY ASSURANCE	All those planned and systematic actions, including quality administration and quality control, which provide adequate confidence that an item will perform satisfactorily in service.
QUALITY CONTROL	Those quality assurance actions which provide a means to control and measure the characteristics of an item or process to established requirements.
QUALITY RECORD	A completed document that furnishes evidence of the quality of items and/or activities affecting quality. Records must be validated by stamps, initials, or signatures of authorized personnel or otherwise authenticated.
QUALITY RECORD (LIFETIME) (PERMANENT)	Lifetime quality records are those that meet one or more of the following criteria: (a) those which would be of significant value in demonstrating capability for safe operation; (b) those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item; (c) those which would be of significant value in determining the cause of an accident or malfunction of an item; (d) those which provide required baseline data for in-service inspections. BWFC uses the guidelines presented in NQA-1, NRC RG 1.28 (Rev 3), & N45.2.9 in determining the classification of quality records as lifetime or nonpermanent records.

Section	Subject	Revision
APP B	**ACRONYMS/ABBREVIATIONS/DEFINITIONS**	**1**

ITEM	DEFINITION
QUALITY RECORD (NONPERMANENT)	Nonpermanent quality records are those required to show evidence that an activity was performed in accordance with applicable requirements but need not be retained for the life of an item because they do not meet the criteria for lifetime records. It is BWFC's position that the record storage requirements specified in NQA-1 and N45.2.9 do not apply to the storage of nonpermanent records.
QUARTERLY	Defined as occurring 4 times during the calendar year, performance of duties shall not be less than 2 months nor more than 4 months. Individual procedures may be more restrictive.
RADIOACTIVE MATERIAL SHIPPING CONTAINER	As it applies to CNFP, it is those containers used for shipments of unirradiated low enriched fuel assemblies; unirradiated scrap and waste materials such as uranium dioxide powder, pellets, or contaminated material for either burying or recycle; and sealed gamma/beta emitting sources for calibration or analytical purposes.
REJECT	A disposition which may be imposed on a nonconforming item providing for its withdrawal and isolation from further processing.
REPAIR	Any process that does not meet the definition of rework by which an item is restored to an acceptable condition such that the capability of an item to function reliably and safely is unimpaired, even though the items still may not conform to original requirements. Repairs must be made using design organization approved repair procedures.
RESTRICTED USE	A disposition permitted for a nonconforming item when it can be established that the item is satisfactory for use within certain restrictions.
REVIEW/APPROVAL	Acceptance indicated by signature/ initials and date.
REWORK	Any process by which an item is made to conform to original requirements by completion or correction using the same types of operations, and conditions called for in the original processing. Provisions for rework may be included in the original processing. Rework also includes the use of any remedial process (sometimes referred to as repair) allowed in the design documents. For example, if a design document allows a remedial process provided the process is approved by the design organization, then that approved remedial process is considered a rework.
SAFETY RELATED ITEMS	Refer to Appendix C.
SAFETY RELATED SERVICES	Safety related services are those services associated with the determination or verification of one or more characteristics of a safety related item.

Section	Subject	Revision
APP B	**ACRONYMS/ABBREVIATIONS/DEFINITIONS**	**1**

ITEM	DEFINITION
SERVICE	The performance of activities such as engineering; inspection; test; nondestructive examination; destructive examination; qualification of personnel, procedures, and equipment; audits; and calibration of measuring and test equipment.
SCRAP	A disposition which may be imposed upon a nonconforming item when it has been established that the discrepancy renders the item unfit for its intended use and it is not economically or otherwise feasible to repair or rework it. Scrap may also be excess material or damaged material remaining from fabrication.
SOURCE INSPECTION OR SURVEILLANCE	A review, observation or inspection for the purpose of verifying that an action has been accomplished as specified at the location of item procurement or manufacture.
SPECIAL PROCESS	A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.
SPECIFICATION	A concise statement of a set of requirements to be satisfied by a product, material, or process indicating, whenever appropriate, the means by which it may be determined whether the requirements given are satisfied.
SUPPLIER	Any individual or organization who furnishes items or services in accordance with a procurement document. An all inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their subtier levels.
SUPPLIER (SUBCONTRACTOR, SUBTIER, LOWER TIER)	An organization that performs part of a contract for a supplier or contractor who has originally been awarded a contract.
SURVEILLANCE	The act of monitoring or observing to verify whether an item or activity conforms to specified requirements.
TESTING	An element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.
TRACEABILITY	The ability to trace the history, application, or location of an item and like items or activities by means of recorded identification.
USE-AS-IS	A disposition permitted for a nonconforming item when it can be established that the item is satisfactory for its intended use.

Section	Subject	Revision
APP B	**ACRONYMS/ABBREVIATIONS/DEFINITIONS**	**1**

ITEM	DEFINITION
VERIFICATION	The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services or documents conform to specified requirements.
WAIVER	Documented authorization to depart from some specified requirements.
WITNESS	To observe performance.
WITNESS POINT	A step in a process for which the quality organization or customer has requested notification. An organization may proceed past a witness point if the quality organization or customer representative are not present at the appointed time.

Section	Subject	Revision
APP C	CATEGORIZATION OF ITEMS USED IN THE CONSTRUCTION OF RADIOACTIVE MATERIAL SHIPPING CONTAINERS	0

C.1 INTRODUCTION

As outlined in NRC Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material", items used in the construction of radioactive material shipping containers may be categorized as being critical to safe operation or as having a major or minor impact on safe operation. This Appendix presents guidelines for this categorization and for the application of appropriate provisions of this QAP to such items.

C.2 CATEGORIZATION OF ITEMS

The functions or physical characteristics of Items used in the construction of shipping containers may be analyzed by Manufacturing Engineering and categorized as follows:

- **Critical to Safety (Category A):**

  Items that are critical to safety are those items whose failure or malfunction could result directly in a condition adversely affecting public health and safety. This includes such conditions as loss of primary containment with subsequent release of radioactive material, loss of shielding, or unsafe geometry compromising criticality control.

- **Major Impact on Safety (Category B):**

  Items with a major impact on safety are those items whose failure or malfunction could indirectly result in a condition adversely affecting public health or safety. An unsafe condition could result only if the primary event occurs in conjunction with a secondary event or other failure or environmental occurrence.

- **Minor Impact on Safety (Category C):**

  Items with a minor impact on safety are those items whose failure or malfunction would not significantly reduce the effectiveness of the shipping container and would be unlikely to create a condition adversely affecting public health or safety.

The categorization of items and justification for categorization will be performed by Manufacturing Engineering and documented.

Section	Subject	Revision
APP C	CATEGORIZATION OF ITEMS USED IN THE CONSTRUCTION OF RADIOACTIVE MATERIAL SHIPPING CONTAINERS	0

C.3 APPLICABLE QAP PROVISIONS

Depending upon the categorization of an item used in the construction of a shipping container, provisions of this QAP apply as follows:

- **Critical to Safety (Category A):**

  All Sections of this QAP apply to Category A Items.

- **Major Impact on Safety (Category B):**

  All Sections of this QAP apply to Category B Items with the following exceptions:

  - Design verification of such items could be through the use of calculations or computer codes.
  - Procurement of materials need not be from Quality approved suppliers.
  - Traceability of materials need not be required.
  - Only specified welds need be performed by qualified welders.

- **Minor Impact on Safety (Category C):**

  The only quality requirements that apply to Category C items are as follows:

  - Items will be purchased as catalog or off the shelf items.
  - Upon receipt, a visual inspection will be conducted for shipping damage and verification that the item ordered was the item received.

Additional requirements may be imposed as deemed necessary by Manufacturing Engineering.