



Tennessee Valley Authority, 1101 Market Street, Chattanooga, Tennessee 37402-2801

October 16, 2009

10 CFR 71.38

Document Control Desk
Director, Spent Fuel Project Office
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Tennessee Valley Authority
Docket No. 071-0227
Quality Assurance Program Approval No. 0227

Subject: **Request for Renewal of Quality Assurance Program Approval for Radioactive Material Shipping Packages Licensed Under 10 CFR Part 71 and Revision 11 of the Quality Assurance Program Description for Radioactive Material Shipping Packages Licensed Under 10 CFR Part 71**

Reference: Letter from NRC to TVA dated November 16, 2004, "Quality Assurance Program Approval for Radioactive Material Packages No. 0227, Revision 14"

In accordance with 10 CFR 71.38, the Tennessee Valley Authority (TVA) requests Nuclear Regulatory Commission (NRC) renewal of the Quality Assurance (QA) Program Approval for Radioactive Shipping Packages, Approval No. 0227. The current approval expires November 30, 2009, as indicated in the Enclosure to the referenced letter. As required by 10 CFR 71.38(b), TVA is applying for renewal not less than 30 days before the expiration date.

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TVA also requests NRC approval of Revision 11 to the enclosed "QA Program Description for Radioactive Material Shipping Packages Licensed Under 10 CFR Part 71." As described in the revision log of the QA Program Description, Section 4.1.6 documents activities involving radiography containers which meet the requirements of 10 CFR 34.31(b), thus satisfying the requirements of 10 CFR Part 71, Subpart H, Paragraphs 71.17(b) and 71.101(b). The remaining changes in Revision 11 are due to organizational changes.

If you have any questions concerning this matter, please contact Kevin Casey at (423) 751-8523.

Respectfully,



R. M. Krich
Vice President
Nuclear Licensing

Enclosure: Quality Assurance Program Description for Radioactive Material
Shipping Packages Licensed Under 10 CFR Part 71, Revision 11

ENCLOSURE

TENNESSEE VALLEY AUTHORITY

QUALITY ASSURANCE PROGRAM
DESCRIPTION FOR RADIOACTIVE MATERIAL
SHIPPING PACKAGES LICENSED UNDER 10 CFR PART 71

TENNESSEE VALLEY AUTHORITY (TVA)
QUALITY ASSURANCE PROGRAM
DESCRIPTION FOR RADIOACTIVE
MATERIAL SHIPPING PACKAGES LICENSED UNDER 10 CFR PART 71

TVA NUCLEAR

REVISION: 11

ISSUE DATE: 12/01/09

EFFECTIVE DATE: 01/04/10

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REVISION LOG

<u>REVISION NUMBER</u>	<u>EFFECTIVE DATE</u>	<u>DESCRIPTION OF REVISION</u>	<u>PAGES AFFECTED</u>
5*	06/27/91	Reformat and revise to describe new organization	All
6**	11/28/94	Revise standard number for TVAN Radiation Protection Plan. Revise organizational references. Differentiate handling of TVA-owned and vendor packages by TVAN users not at nuclear plants.	All
7a***	06/11/97	Change program description from "User/fabricator" to "User" by removing design, fabrication assembly and modification actions. Revise organizational references.	All
8	08/20/99	Revise organization references. Revise Figure 1. Revise procedure references.	All
9	07/30/04	Revise organizational references, procedure references and responsibilities.	All
10	01/07/08	Revise organizational references, procedure references and responsibilities. Revise Figures 1 and 2.	All
11	01/04/10	Revise organizational references and responsibilities. Revised Section 4.1.6 to remove IS from PQAP applicability. Revise Figure 1 and deleted Figure 2.	All

* Corresponds to NRC approval Revision 8 for Docket 71-0227.

** Corresponds to NRC approval Revision 10 for Docket 71-0227.

PACKAGE QA PROGRAM DESCRIPTION

NRC Docket 71-0227

Revision 11

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*** Corresponds to NRC approval Revision 12 (June 11, 1997) for Docket 71-0227.

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LIST OF ABBREVIATIONS

The following abbreviations are used in this plan:

ANI/MAELU	- American Nuclear Insurers/Mutual Atomic Energy Liability Underwriters
CFR	- Code of Federal Regulations
DOT	- Department of Transportation
M&TE	- Measuring and Test Equipment
NPG	- TVA Nuclear Power Group
NRC	- Nuclear Regulatory Commission
PQAP	- Package Quality Assurance Program
QA	- Quality Assurance
RMSM	- Radioactive Material Shipment Manual
TVA	- Tennessee Valley Authority

TENNESSEE VALLEY AUTHORITY (TVA) QUALITY ASSURANCE PROGRAM
DESCRIPTION FOR RADIOACTIVE MATERIAL SHIPPING PACKAGES
LICENSED UNDER 10 CFR PART 71

1.0 PURPOSE

TVA Nuclear Power Group (NPG) is the licensee within TVA for radioactive material shipping packages licensed under 10 CFR Part 71. The purpose of this document is to describe the Quality Assurance (QA) Program that satisfies the requirements of subpart H of 10 CFR 71. This program addresses QA for the procurement, use, maintenance, repair, and testing of radioactive material shipping packages licensed by NRC under 10 CFR 71 (herein after referred to as "packages"). NPG is a user of numerous packages licensed to vendors.

2.0 APPLICABILITY

The Package Quality Assurance Program (PQAP) applies to: (a) NPG personnel and organizations performing activities that could affect shipping packages which are licensed by NRC; (b) TVA non-nuclear organizations working either directly under the NPG QA program or under their QA program as required by Intergroup Agreement; and (c) contractor activities that could affect shipping packages which are licensed by NRC, unless NPG has approved alternate administrative controls for those activities.

3.0 GENERAL

This document describes the quality-related functions involved with radioactive material shipping packages. The term "quality-related" encompasses those activities, items, and equipment associated with the performance and support of activities, measurements, and calculations that are required by Federal regulations and license conditions and commitments.

This PQAP description is formatted in such a manner as to describe how procedures and instructions are developed to implement program requirements.

4.0 QUALITY ASSURANCE ORGANIZATION

The organizational structure, functional responsibilities, levels of authority, and lines of internal and external communication for the management, direction, and execution of the PQAP are clearly established for all organizational levels. The organizational chart in Figure 1 show the organizational responsibility for the PQAP for radioactive material shipping packages and its implementation for the procurement, use, maintenance, repair, and testing of shipping packages.

4.1 Functions of Organizations

TVA management, while carrying out their functions, is required to comply fully with the aspects of the PQAP applicable to their organization and ensure proper implementation. This subsection identifies specific QA functional responsibilities that the identified organizations are to develop through NPG documents.

4.1.1 TVA Organizations

In addition to responsibilities delineated in other parts of this document, TVA organizations have the following general functions:

- A. Invoke appropriate QA requirements on TVA organizations that provide services for quality-related programs and features, including the determination of grading indicators with due consideration for importance.
- B. Develop, control, and maintain procedures and instructions as appropriate to implement quality-related activities and processes involving licensed shipping packages.
- C. Ensure appropriate controls for documents and records generated within the organization or received from external sources.
- D. Identify and resolve adverse conditions and perform related corrective action activities including assessing trends for internally and externally identified problems.
- E. Develop certification programs as appropriate and ensure that trained, qualified, and, where required, certified employees are used in the performance of quality-related activities involving licensed shipping packages.
- F. Initiate stop work within their area of responsibilities when warranted.
- G. Ensure personnel performing quality-related activities on licensed packages receive indoctrination and training as necessary to ensure that adequate proficiency is achieved and maintained.
- H. Ensure procedures adequately address interfaces of affected organizations.
- I. Ensure during preparation and review of procedures and procurement documents that appropriate technical and PQAP requirements are included.

4.1.2 Chief Nuclear Officer and Executive Vice President, NPG

The Chief Nuclear Officer and Executive Vice President, NPG ensures that responsibilities for QA are clearly defined and understood and that each organization is adequate to accomplish its task. Significant problems or occurrences relating to QA are brought to his attention, and he participates directly in their resolution as required. The duties of the Chief Nuclear Officer and Executive Vice President, NPG are carried out through the Senior Vice President Nuclear Operations; the Vice President Nuclear Engineering; the Vice President Nuclear Support Services; the Vice President Nuclear Oversight; the Vice President Operation Support; the Vice President New Nuclear Generation Integration; and the Vice President Nuclear Licensing.

4.1.3 Senior Vice President Nuclear Operations

The duties of the SVP Nuclear Operations are carried out by the Vice President, Browns Ferry Nuclear Site; the Vice President, Sequoyah Nuclear Site; and the Vice President, Watts Bar Nuclear Site.

The responsibility and authority for implementing QA requirements for licensed, shipping packages are vested in each plant manager. Through assignments to his site managers, he ensures that NPG instructions pertaining to the procurement, use, maintenance, repair, and testing are prepared in accordance with established QA policies and requirements; that work is performed in accordance with approved documents; and that results are documented and proper records maintained. The plant manager is responsible for the necessary training and qualifications of plant personnel.

4.1.4 Vice President Nuclear Operations Support

The duties of the Vice President, Nuclear Operations Support are carried out through the Corporate Functional Area Manager.

The Corporate Functional Area Manager, has the following responsibilities:

- A. Prepares and coordinates the review of procurement specifications for shipping packages used by NPG.
- B. Works with TVA Procurement to obtain contracts for the rental of shipping packages.
- C. Maintains the PQAP Description and the Radioactive Material Shipment Manual (RMSM) to ensure that the most current NRC and Department of Transportation (DOT) regulations are incorporated into the shipping procedures and instructions.
- D. Analyzes reports of abnormal equipment operation or personnel errors to identify and correct problems.
- E. Ensures that procedures are developed for the implementation of commitments to

NRC concerning the PQAP.

- F. Ensures that QA records generated during the use of radioactive material packages are safely stored in a retrievable manner in accordance with applicable procedures.
- G. Ensures that quality-related requirements are included in or referenced in related procedures and instructions for document control, the Nuclear Procedures System, and records.

4.1.5 Procurement

The duties of the Chief Administrative Officer and Executive Vice President Administrative Services are carried out through the Vice President Procurement. The VP Procurement ensures the control of purchased material, equipment, and services, identification of materials, parts, and components and performs procurement activities for materials and services.

4.1.6 Nuclear Engineering

The duties of the Vice President, Nuclear Engineering are carried out through the Manager, Inspection Services.

The Manager, Inspection Services utilizes radiography containers for shipments of radiography equipment. The Inspection Services Operating and Emergency procedures have been approved by NRC and does meet the requirements of 10 CFR Part 34.31(b) thus satisfying the requirements of 10 CFR Part 71 subpart H, paragraphs 71.17(b) and 71.101(b). Therefore, the Inspection Services radiography containers are no longer included in NPG's PQAP.

4.1.7 Nuclear Licensing

The duties of the Vice President Nuclear Licensing are carried out through the Manager, Corporate Licensing.

The Manager, Corporate Licensing has the following responsibilities:

- A. Establishes an interface between NPG and NRC for nuclear licensing activities.
- B. Reviews and approves submittals and correspondence between NPG and NRC concerning PQAP elements, and
- C. Ensures that commitments to NRC concerning PQAP elements are documented.

4.1.8 Quality Assurance

The duties of the Vice President of Nuclear Oversight are carried out through the General Manager Quality Assurance, who also has an independent reporting relationship to the

Chief Nuclear Officer and Executive Vice President NPG.

The General Manager, Quality Assurance has the following responsibilities:

- A. Ensure compliance with regulations, commitments, and policies related to the quality assurance program.
- B. Provides oversight of PQAP activities by auditing, inspecting, assessing the conduct of activities to ensure they provide the required high degree of safety and reliability.
- C. Manages the quality audit and vendor audit and services QA programs.

5.0 PACKAGE QA PROGRAM

The PQAP provides the appropriate control of quality in relation to the importance of the activity or item commensurate with its safety significance and provides for the graded application and verification of QA requirements to quality-related items and activities involving shipping packages.

The following criteria are to be considered when applying QA requirements:

- The impact on safety of a shipping package malfunction or failure.
- The specification, design, or uniqueness of the package.
- The need for special controls and assessment of shipping packages, processes, and operational activities.
- The degree to which functional compliance can be demonstrated by an inspection or test.
- The quality history of a shipping package or shipping activity and the degree of standardization.
- Requirements of applicable codes and standards.

The following factors are to be considered in the degree of QA verification required to ensure implementation of QA requirements:

- New activities not previously performed or implemented.
- Trend or previous histories of quality problems.
- Activities critical to package safety or having the most potential to impact safety.
- Revisions to procedures which have recently been implemented.
- Activities that have not been assessed in the recent past or are performed infrequently.
- Activities that are performed by new personnel, contractors, or technicians.
- The requirements of applicable codes and standards that are mandated for the shipping package or shipping activity.

The PQAP includes procedural controls for ensuring that the use of packages does not result in undue risk to the health and safety of the public or employees. These procedural controls are established in the RMSM, implementing facility instructions, and cask handling procedures. The requirements of the certificate of compliance for each package are included in these procedural controls. Revisions to PQAP documents are made in accordance with established procedures and instructions.

Work affecting the characteristics of the shipping package which are important to safety is controlled by properly approved procedures and instructions. Maintenance and repair work on shipping packages by NPG personnel are also performed in accordance with approved procedures and instructions.

NPG personnel who are involved in the procurement, use, maintenance, repair, and testing of shipping packages are trained as specified in the RMSM and facility instructions. This training includes familiarization with the PQAP. Non-TVA personnel who transport or use shipping packages at NPG facility sites receive training and/or orientation from NPG as specified in the RMSM.

PQAP description revisions are reviewed and concurred with by the Manager, Corporate Licensing or his designee. This concurrence is documented on the concurrence sheet attached to the outgoing correspondence to the NRC. The General Manager, Quality Assurance provides independent audits of the effectiveness of implementation of the PQAP.

Contractors providing equipment or services under the PQAP are required to have a QA Program that meets the requirements of subpart H of 10 CFR 71. The adequacy of the contractor's program is evaluated by Quality Assurance.

6.0 CONTROL OF DOCUMENTS AND RECORDS

6.1 Procedures and Instructions

Instructions, procedures, and drawings are developed using a graded approach to prescribe those activities that affect the quality-related functions of shipping packages. Compliance with these documents is mandatory. Requirements for suppliers and contractors to develop and implement procedures, instructions, and drawings to meet the pertinent requirements of the PQAP are included under the section entitled "Procurement Document Control." Vendor packages are controlled by vendor procedures, which may be contained in controlled vendor manuals, referenced, or contained in NPG procedures and instructions. NPG users ensure that they have the most recent revision of procedures before package use.

Procedures are written to provide a controlled method for preparing, reviewing, changing, and approving procedures and instructions. Procedures and instructions prescribing operational activities that affect the quality-related functions of shipping packages identify special equipment and environmental conditions required to perform the activity, provide applicable quantitative and qualitative acceptance criteria, and include provisions for documenting that activities were accomplished in accordance with these documents.

NPG instructions for administration, operation, and maintenance of shipping packages at each facility are issued, approved, and controlled by standard practices or procedures. NPG instructions for the use of vendor packages may reference or contain vendor package instructions, which can also be implemented directly from the Controlled Vendor Manual.

NPG instructions that implement QA requirements are reviewed by line organizations, and program implementation is periodically audited by QA using a graded approach to verify that such QA requirements are adequately defined.

NPG procedures or instructions are prepared, reviewed, and approved within the organization responsible for the activities involved. Whenever the procedure or instruction specifies actions for another organization, the affected organization concurs with the proposed procedure or instruction before approval, unless concurrence has been made in a higher-level document.

Procedures, instructions, and drawings that affect the quality-related functions of shipping packages are controlled in accordance with the following section.

6.2 Document Control

Activities such as the procurement, use, maintenance, repair, and testing of shipping packages are performed using approved procedures prepared in accordance with the NPG Procedures System and the RMSM. PQAP implementing procedures and associated revisions are prepared, revised by qualified individuals, and approved for issuance by authorized personnel before release or issuance in accordance with approved written procedures. These procedures identify the organization responsible for these actions and ensure that changes to these documents are reviewed and approved by the originating group. Manuals, procedures, and drawings for vendor packages are controlled by the vendor through his document control system. NPG users ensure that they have the latest revision of documents before package use.

6.3 Records

The RMSM establishes the requirements for preparation and storage of records generated during the procurement, use, maintenance, repair, and testing of shipping packages used by NPG. These records are maintained and retained as specified in the RMSM. Records are identifiable, retrievable, and maintained in designated storage locations in accordance with established procedures.

7.0 PROCUREMENT AND MATERIAL CONTROL

7.1 Procurement Document Control

Procurement document control applies to documents used to obtain packages, parts, and services required to maintain, repair, test, inspect, or use shipping packages. The quality of purchased replacement materials, components, and spare parts is required to be equal to or better than the original item.

Control of package procurements is accomplished primarily through procurement documents. The originating organization is responsible for including or referencing regulations, codes, standards, design bases, or other provisions necessary to assure adequate QA requirements in the documents for procurement of packages, spare parts, and services. Procurement documents include the following, as applicable:

- A. Basic technical requirements, including drawings, test and specification requirements, special instructions, applicable regulations, codes, and industrial standards.
- B. QA program requirements including requirements for supplier audits, surveillance, inspection, and provisions for NPG's access to the supplier's facility and records.
- C. Requirements that the cask supplier provide a description of his QA Program which meets the requirements of subpart H of 10 CFR 71.
- D. Documentation requirements, including records to be prepared, maintained, submitted, or

made available for review, such as drawings, specifications, procedures, procurement documents, inspection and test records, qualifications, chemical and physical test results, and instructions for ultimate disposition of the records.

NPG utilizes recognized standards or internal specifications for the purchase of standardized items. Other items are purchased by part number or recommendations supplied by the vendor.

The line organization reviews procurement documents for shipping packages, spare parts, and services to assure they have been prepared, reviewed, and approved in accordance with applicable QA requirements. Procurement documents for licensed packages are reviewed and approved by individuals having responsibility to ensure that appropriate QA and technical requirements have been included.

For "off-the-shelf" items, where it is impractical to impose appropriate QA controls on the supplier, the line organization specifies quality verification requirements sufficient to ensure the adequacy of such items for use.

Package procurement documents include quality-related requirements which are not changed without the review and approval of the organizations responsible for originally reviewing the procurement document. Changes to procurement documents such as typos, changes in quantities, and monetary changes need not be routed to the originating organization provided that the procurement document change does not affect QA requirements and a copy of the change is sent to affected organizations.

7.2 Control of Purchased Materials, Equipment, and Services

7.2.1 General

Shipping packages, spare parts, and services, whether purchased directly or through others, conform to procurement document specifications described in "Procurement Document Control." Provisions are made, as appropriate, for source evaluation and selection, review for objective evidence of quality, inspection at source, and examination upon delivery.

Quality control measures of package suppliers are assessed by the line organization commensurate with the importance, quantity, and complexity of the packages or services being procured. This assessment verifies that documentation such as certificates of compliance are valid. Proposals (bids or quotations) by suppliers are reviewed to ensure that no exceptions are taken which would violate quality requirements.

7.2.2 Source Evaluation and Selection

The selection of package suppliers is based on Quality Assurance review and qualification of the supplier's facilities and the QA Program to verify the supplier's capability to comply with the required elements of subpart H of 10 CFR 71, and/or other specific codes or standards which are applicable to the package, type of material, equipment, or service being procured.

Suppliers who meet these requirements are added to an "Acceptable Suppliers List" which is maintained by the General Manager, Quality Assurance. Suppliers on this list are periodically reevaluated and re-qualified or purged from the list based on results of these reevaluations.

7.2.3 Surveillance at Supplier Facilities

Surveillance of suppliers of licensed shipping packages is accomplished consistent with the importance to quality in accordance with written instructions. The originating organizations for each purchase request are responsible for delineating QA requirements.

7.2.4 Receiving Inspection

Examination of shipping packages upon delivery is performed in accordance with general written instructions which contain measures to assure:

- A. The shipping package, or related item, is properly identified and corresponds with the receiving documentation.
- B. Inspection of the shipping packages and acceptance records is performed and judged acceptable in accordance with predetermined inspection instructions, before the first use of the shipping package.
- C. Documentation, such as the package certificate of compliance, required drawings, operating procedures, and other items required for use of the package, is available before package use. In special circumstances, and with appropriate management approval, packages may be used before receipt of associated documentation. In these cases, the shipping packages are tagged as nonconforming, and additional administrative controls are used to provide assurance that the package is not used for radioactive material shipment before disposition of a nonconformance.
- D. Nonconforming items are segregated where practical, controlled, and clearly identified until proper disposition is made.

The site Radiation Protection Manager at each nuclear power plant (or equivalent at other NPG facilities) is responsible for the receipt inspection of licensed shipping packages. The Nuclear Material Manager in Procurement Materials Management at each nuclear power plant (or equivalent at other facilities) is responsible for the receipt of spare parts in accordance with applicable procedures and instructions. Each item is receipt-inspected by appropriately trained and qualified personnel. Personnel performing receipt inspections utilize written instructions to verify conformance to procurement documents. Each item is stored in accordance with its related technical and/or QA requirements.

Deficiencies, such as damage, shortage, or missing items, are resolved before packages or spare parts are released for use or installation and before declaring

shipping packages to be ready for use. Resolution is achieved according to the requirements of "Nonconforming Materials, Parts, or Components."

7.3 Identification and Control of Materials, Parts, and Components

As required, materials, parts, and components are identified by heat number, lot number, unique serial number, or other means appropriate to their application. Item identification is used to maintain traceability between items in storage and the documentation which attests to the acceptability of these items, as applicable. When required by applicable codes and standards, traceability is maintained to the point of installation.

Where size and accessibility permit, the identification is on the item but such as not to interfere with the performance characteristics of the item. In other cases, the identification is maintained on records traceable to the item. Regardless of the extent of traceability required, the acceptability of parts installed on a shipping package is ensured by control systems which permit only acceptable items to be released from storage.

8.0 CONTROL OF ACTIVITIES

8.1 Inspection and Line Verification

Inspection is performed using a graded approach during maintenance, material receiving, and storage activities affecting the quality of shipping packages and related items at NPG facilities to verify conformance with applicable requirements. Instructions covering these activities contain appropriate inspection requirements, including mandatory hold points, which are in accordance with the original package design and inspection source requirements or acceptable alternatives. Alternatives to original inspection requirements are in accordance with the requirements of applicable codes, standards, and regulations.

8.2 Assessments

Quality Assurance performs assessment activities in accordance with Section 9.2 of the Nuclear Quality Assurance Plan (NQAP). NPG organizations responsible for implementing the PQAP may also perform assessments of program elements.

8.3 Test Control

Testing is performed to demonstrate that shipping packages perform satisfactorily in service and to ensure that malfunctions are identified in a timely manner. Tests required by the NRC Certificate of Compliance and other tests required to ensure the qualification of the shipping package for use are conducted by the responsible onsite organization in accordance with the controls of the PQAP.

Testing is accomplished in accordance with written and approved procedures or instructions which include the requirements of NRC Certificate of Compliance, drawings, specifications, codes, standards, and regulatory requirements.

Written test instructions and/or checklists include as necessary: test equipment and calibration requirements, material requirements, prerequisite conditions, environmental conditions, limiting conditions, precautions, detailed performance instructions for the testing, inspection hold points, acceptance or rejection criteria, and data collection, reporting, and approval requirements.

The facility managers implement the test programs and are responsible for oversight of the test control program (i.e., test performance, test results, and acceptability of tests). Results of tests performed on shipping packages are documented, evaluated, and their acceptability determined by qualified individuals.

8.4 Control of Measuring and Test Equipment (M&TE)

M&TE utilized in or related to the use, maintenance, or testing of shipping packages is controlled in accordance with written procedures or instructions. Procedures and instructions for calibrating and controlling M&TE include identification of the test equipment, calibration techniques, calibration frequencies, maintenance control, and storage requirements.

Control of M&TE requires:

- A. That each item of M&TE be assigned a specific interval for calibration.
- B. Unique identification of each item of test equipment.
- C. Traceability to calibration test data and tagging (when practical) to show the due date of calibration.
- D. Traceability of reference standards to national standards and periodic revalidation of reference standards.
- E. Records to be maintained which indicate the complete status of each item of test equipment, including its maintenance history, calibration results, abnormalities, and last and future calibration dates.
- F. Control of the purchase requirements and acceptance tests for new or replacement test equipment.
- G. M&TE are calibrated against a working standard having tolerances within appropriate limits for the type of measurement being taken or test being performed.
- H. The reference standards used to calibrate the working standards have a closer tolerance

than that of the working standard and are calibrated against higher level reference standards of closer tolerance.

M&TE found out of calibration is conspicuously tagged, segregated, and an investigation is initiated to determine the validity of previous measurements and the corrective action to be taken.

Tools, gauges, and instruments necessary for maintenance, inspections, and tests are calibrated and controlled in accordance with written instructions. Test instrumentation is maintained by various organizations within NPG and is used at the nuclear facilities as required to perform shipping package tests or other special operations. Each organization is responsible for assuring that test equipment used by that organization has been properly calibrated and documented.

8.5 Handling, Storage, and Shipping Control

The RMSM requires approved procedures for handling, storing, and shipping operations; establishes safety restrictions concerning handling, storage, and shipping of packages; and ensures that tests, certifications, acceptances, and final inspections have been completed before shipment. Packages are handled, stored, cleaned, and shipped in a manner to minimize deterioration, contamination, or damage.

Package-handling equipment such as cranes, forklifts, and cables which are used on radioactive material packages are tested in accordance with established procedures before use. The facility manager designates those persons responsible for handling, storage, and shipping operations that are quality-related.

8.6 Inspection, Test, and Operating Status

The RMSM establishes procedures for determining inspection, test, and operating status of shipping packages. Certificate of compliance test and inspection results are recorded using site or vendor instructions or procedures. A "hold" on package use is established when inspection or test criteria are not satisfied. Only authorized personnel are allowed to remove a "hold." The facility manager designates those persons responsible for implementing the requirements of this section.

9.0 ADVERSE CONDITIONS

9.1 Nonconforming Materials, Parts, or Components

Nonconforming materials, parts, or components discovered during receipt inspection or package repair or maintenance are controlled to prevent their inadvertent use or installation. Control of nonconforming items include:

- A. Conspicuous markings to identify the items as nonconforming.
- B. Reporting of nonconformance to responsible supervision and the package vendor as appropriate.
- C. Segregation of nonconforming items from acceptable material, when practical.

- D. Review and disposition of nonconforming items by designated supervision. Disposition action for nonconforming materials, spare parts, and components is taken by designated personnel in accordance with applicable procedures.

The package vendor independently reviews and approves any nonconforming items before package use. Decisions to reduce engineering requirements to permit the use of nonconforming parts, materials, or components for shipping packages are also made by the package vendor with concurrence by appropriate site management.

9.2 Corrective Action

NPG organizations and onsite non-NPG service organizations performing quality-related activities promptly identify and resolve adverse conditions. Adverse conditions are dispositioned and corrected by organizations with defined responsibility and authority for the adverse condition. Actions are documented in corrective action plans.

The cause of significant adverse conditions is determined, and corrective action is taken to preclude recurrence. Significant adverse conditions are reported to appropriate levels of management. The satisfactory completion of corrective actions is verified and documented by the appropriate organization.

Commensurate with their importance to quality and safety, adverse conditions which are not being effectively or timely resolved are escalated to appropriate levels of management in a timely manner. Procedures describing the corrective action program establish the requirements for those adverse conditions which are tracked.

Trend analysis is performed on adverse conditions and quality indicators by line organizations. Trend results are used to advise management of the quality status, identify adverse trends that need increased management attention, and compare quality of performance among organizations and, where applicable, with industry standards. The trend analysis program is described in procedures and instructions.

Work is stopped under any of the following conditions:

- A. Work is proceeding in violation of approved and controlling documents.
- B. A condition which clearly indicates that cessation of an activity is the only means available to protect the health and safety of the public and/or TVA personnel.
- C. An activity which, if continued, will require extensive rework or repair for corrective action.
- D. An activity which, if continued, may jeopardize package safety.
- E. A condition that represents continual failure to comply with technical or administrative

controls.

The General Manager, Quality Assurance is responsible for the development of the Corrective Action Program. Line managers are responsible to stop any work within their areas of responsibility when a continuation of activities could meet the above criteria for work stoppage. Quality Assurance is responsible to issue a formal Stop Work Order, as required, if a line manager fails to act on a stop work condition. Stop Work Orders remain in effect until proper evaluation can be made and adequate corrective action can be applied.

The General Manager, Quality Assurance is responsible to establish and maintain trend analysis guidelines for adverse conditions and the quality indicators generated by Quality Assurance verification activities such as audits, assessments, inspections, and vendor audits and surveillances.

10.0 INDOCTRINATION, TRAINING, QUALIFICATION, AND CERTIFICATION

Personnel involved in the use, maintenance, repair, and testing of shipping packages receive training and periodic retraining of the type applicable to their responsibilities and at the frequency specified in the RMSM. The Corporate Functional Area Manager delineates training requirements in the RMSM. The facility managers develop a program of training and indoctrination for quality-related employees which includes instruction, testing, and documentation of training, as appropriate.

11.0 AUDITING

11.1 General

The General Manager, Quality Assurance is responsible for the audit program. Measures are established to implement a comprehensive audit program which consists of internal audits including NPG and other TVA organizations which support the Radioactive Material Shipment Program and contractor/supplier audits to determine and assess the adequacy and effectiveness of the QA program.

11.2 Internal Audits

The scope of an audit is determined by considering such factors as work areas, activities, processes, or items and the specific organizations involved. Auditing organizations ensure that audit procedures and instructions adequately cover applicable elements of the PQAP. Audits are scheduled in accordance with site license requirements and regulatory requirements and, to the extent possible, based upon the status and importance to quality of the activities being performed.

11.3 Contractor/Supplier Audits

Audits of selected suppliers are conducted to verify implementation and adequacy of specified QA requirements. Contractors/suppliers to be audited are selected on the basis of importance of their products to package quality, status of contract activity, historical performance of the supplier, and potential QA program problems that may be discovered during source surveillance activities or earlier audits. Audit schedules are prepared, and audits are conducted in accordance with the schedules. Audit reports are prepared and reviewed by the audit team, approved by management, and transmitted to the supplier and appropriate management within NPG.

12.0 COMPUTER SOFTWARE AND DATA

The development, procurement, maintenance, and use of computer software involved with shipping packages are controlled as a quality-related activity in accordance with the NPG Standard Programs and Processes 5.9, "Radiological Control and Radioactive Material Shipment Augmented Quality Assurance Program."

13.0 REFERENCES

13.1 Regulations

10 CFR 20, "Standards for Protection Against Radiation"

10 CFR 21, "Reporting of Defects and Noncompliance"

10 CFR 71, "Packaging and Transportation of Radioactive Material"

NRC Certificates of Compliance for shipping packages

49 CFR 171, 172, 173, 175, 177, and 178 (DOT regulations)

13.2 Regulatory Guidance

NRC Regulatory Guide 7.4, "Leakage Tests on Packages for Shipment of Radioactive Materials"

NRC Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material"

NRC Draft Regulatory Guide DG-7004, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material"

NRC IE Bulletin 79-19, "Packaging of Low-level Radioactive Waste for Transport and Burial"

NRC Bulletin 79-21, "Transportation and Commercial Burial of Radioactive Material"

NRC IE Bulletin 83-10, "Clarification of Several Aspects Relating to use of NRC-Certified Transport Packages"

NRC IN 2002-35, "Changes To 10 CFR 71 and 72 Quality Assurance Programs"

13.3 NPG Licensing Submittal Documents

Browns Ferry Updated Final Safety Analysis Report

Sequoyah Updated Final Safety Analysis Report

Watts Bar Updated Final Safety Analysis Report

13.4 QA Manuals

TVA NQAP, TVA-NQA-PLN89-A

TVA Topical Report Organizational Description, TVA-NPOD89-A

13.5 Other

NPG Standard Programs and Processes 5.9, "Radiological Control And Radioactive Material Shipment Augmented Quality Assurance Program"

ANI/MAELU Engineering Inspection Criteria, Section 4.1, Low-Level Radioactive Waste Packaging and Transportation

ANI/MAELU Engineering Inspection Criteria, Section 4.2, Radioactive Waste Management

14.0 DEFINITIONS

Unless redefined in this document, the terms used in this document are those defined in: (1) the NPG Radioactive Material Shipment Manual, (2) the NPG SPP 5.9, Radiological Control and Radioactive Material Shipment Augmented Quality Assurance Program, or (3) section 15.0 of the NQAP (TVA-NQA-PLN89-A) in order of priority.

Figure 1 Organizational Chart TVA

