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E-27856
March 12, 2009

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

Subject: Proposed Revision 9 to the Transnuclear, Inc. Quality Assurance Program Description Manual for 10CFR71, Subpart H and 10CFR72, Subpart G

To Whom It May Concern:

With this letter, Transnuclear, Inc. submits for approval proposed revision 9 to the Transnuclear, Quality Assurance Program Description Manual for 10CFR71, Subpart H and 10CFR72, Subpart G.

Changes incorporated with this proposed revision 9 include:

1. Changes to the Transnuclear organization and corresponding responsibilities for activities controlled under the Manual (Section 1, Figure 1 and elsewhere in the Manual as appropriate)
2. Added clarifying guidance on implemented the Manual in a graded fashion commensurate with safety significance (Section 2 of the Manual).
3. Added discussion on control of electronic records (Sections 6 and 17 of the Manual).
4. Clarified the distinction between Conditions Adverse to Quality and Significant Conditions Adverse to Quality (Section 16 of the Manual).
5. Clarified that corrective action documents are evaluated for Reportability purposes under the provisions of 10 CFR 21 (Section 16 of the Manual).
6. Updated the reference list (Section 19 of the Manual).
7. Minor editorial corrections were made as necessary.

Please note that previous revisions of the Transnuclear, In. QAPDM were approved under Docket No. 71-0250 for use in accordance with the requirements of 10 CFR 71 and 10 CFR 72. Please do not hesitate to contact me should you require any additional information or have any questions regarding this submittal.

Sincerely,

Christopher M. Lloyd
Director, Corporate Quality Assurance

TRANSNUCLEAR INC.
7135 Minstrel Way • Suite 300 • Columbia, MD 21045
Tel: 410-910-6900 • Fax: 410-910-6902
www.transnuclear.com

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Enclosure: Revision 9, Transnuclear, Inc. QAPDM for 10CFR71, Subpart H and 10CFR72, Subpart G (28 pages)

c: (w/enclosure)

Robert Temps
Senior Safety Inspector, Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety and Safeguards
Mail Stop EBB-3D-02M
11555 Rockville Pike
Rockville, MD 20852

c: (w/o enclosure)

T. Neider (TN)
R. Grubb (TN)
R. Fredericks (TN)
B. Sutherland (TN)

AREVA

Transnuclear, Inc.

TRANSNUCLEAR, Inc.

Quality Assurance Program Description Manual

for

10 CFR 71, Subpart H

and

10 CFR 72, Subpart G

Revision 9

Issue Date: March 12, 2009

Tara J. Neider: Tara Neider **Date:** 3/12/09
President & CEO

Robert L. Grubb: Robert L. Grubb **Date:** 3/12/09
Chief Operating Officer

Christopher M. Lloyd: Christopher M. Lloyd **Date:** 3/12/09
Director, Corporate Quality Assurance

INTRODUCTION

The Transnuclear, Inc. Quality Assurance Program Description Manual for 10 CFR 71, Subpart H, and 10 CFR 72, Subpart G, has been developed as a means to describe the overall measures that control activities governing the design, procurement, fabrication, handling, shipping, cleaning, assembly, inspection, modification, testing, operation, repair, and maintenance of storage and transport systems for spent fuel and radioactive materials in accordance with the regulations pursuant to 10 CFR 71, Subpart H and 10 CFR 72, Subpart G. This Quality Assurance Program Description Manual (QAPDM) is also applicable to activities performed in accordance with the requirements of ASME NQA-1 and 10 CFR 50, Appendix B, as specifically identified in the NRC issued Certificate(s) of Compliance or referenced documents.

This QAPDM applies to the following Transnuclear (TN) locations and other service locations as required by customer contract provisions:

Transnuclear, Inc.
7135 Minstrel Way
Columbia, MD 21045

Transnuclear, Inc.
310 Woodward Drive
Aiken, SC 29803

The TN Quality Assurance Program is comprised of this QAPDM; the Transnuclear, Inc. Quality Assurance Program Description Manual for ASME Section III, Division 1 and Division 3 (ASME QAPDM); and Transnuclear Implementing Procedures (TIPs). The TIPs are designed and administered to meet the applicable requirements of 10 CFR 71, Subpart H; 10 CFR 72, Subpart G; 10 CFR 50, Appendix B and ASME Section III, Division 1 (NCA 4000) and Division 3 (WA 4000).

Transnuclear maintains ASME Certificates of Authorization for the design, fabrication and delivery of products in accordance with the requirements of the ASME QAPDM, which specifies additional ASME Code-related requirements applicable to ASME Code projects only.

STATEMENT OF QUALITY POLICY AND AUTHORITY

Transnuclear is engaged in the business of designing, certifying, testing, procuring, operating and maintaining packages for the transport and/or storage of radioactive materials. This business carries with it the responsibility of protecting the health and safety of the public and workers from the deleterious effects of radiation. Therefore, it is the Policy of Transnuclear that all products and services must be delivered with the highest levels of quality consistent with the expectations of our customers, shareholders and the government agencies which regulate our activities.

In order to carry out this Policy, a Quality Assurance Program has been established that includes this Quality Assurance Program Description Manual which complies with 10 CFR 71, Subpart H, and 10 CFR 72, Subpart G. This QAPDM is reviewed and approved by the U.S. Nuclear Regulatory Commission. Compliance is mandatory for all personnel performing safety-related, quality affecting, or important-to-safety activities subject to the requirements of this QAPDM.

While the ultimate responsibility for implementation of the Quality Assurance Program rests with the President of Transnuclear, each and every employee is expected to assume personal responsibility for performing their assigned work activities in accordance with the applicable requirements of the Quality Assurance Program and implementing procedures in effect.

Quality Assurance Program requirements are invoked to the extent applicable upon suppliers to which Transnuclear subcontracts safety-related, quality affecting, or important-to-safety work.

The Chief Operating Officer is delegated responsibility for implementing the requirements of the Quality Assurance Program consistent with this policy.

The Director, Corporate Quality Assurance is delegated responsibility for developing, maintaining and verifying execution of the Quality Assurance Program consistent with this Policy.

Tara J. Neider: Tara J. Neider
President & CEO

1.0 ORGANIZATION

1.1 Responsibility for compliance with the Transnuclear Quality Assurance (QA) Program resides ultimately with the President of Transnuclear, Inc. (TN). QA Program activities include those actions necessary to comply with the applicable requirements of 10 CFR 71, Subpart H; 10 CFR 72, Subpart G; 10 CFR 50, Appendix B; ASME Section III, Division 1 (NCA 4000) / Division 3 (WA 4000) and ASME NQA-1. When suppliers are used for performance of activities subject to the requirements delineated in this QAPDM, TN qualifies those organizations to ensure compliance with applicable requirements; however, TN retains the overall responsibility for the quality of those activities.

1.2 The President has full authority over all functions of the company, and is responsible for overall company policy and providing executive direction and guidance to senior management staff. Responsibility for implementing the QA Program is delegated to the Chief Operating Officer and authority for developing, maintaining and verifying execution of the program is delegated to the Director, Corporate Quality Assurance. Each organization within TN is responsible for implementation of the program for their respective scope of operation and responsibilities.

1.3 The Chief Operating Officer (COO) reports to the President and has overall responsibility for the implementation of the QA Program. This responsibility includes setting priorities, objectives and policies to ensure that activities under the purview of the QA Program are performed in accordance with the requirements of the QA Program.

1.4 The Vice President of Engineering reports to the COO and is responsible for Engineering, Licensing, Project Engineering and Fabrication, Project Management and Fuel Loading Services associated with storage and transportation systems. This position is also responsible for the support functions of document control (except as provided for elsewhere in this Manual) and records storage.

1.5 The Vice President of Purchasing and Contract Administration reports to the COO and is responsible for negotiating contracts and issuing procurement documents in support of engineering, fabrication and other activities associated with storage and transportation systems. This position is also responsible for issuing procurement documents for transportation management services subject to the requirements of the QA Program.

1.6 The Director of Transportation Logistics reports to the COO and is responsible for transportation management, regulatory assistance, and specialized support services related to the nuclear fuel cycle.

1.7 The Director, Corporate Quality Assurance (DCQA) reports to the COO and is responsible for developing, maintaining and verifying execution of the QA Program. This responsibility includes, document control activities associated with this Manual and associated Transnuclear Implementing Procedures (TIPs), ensuring that QA staff is appropriately qualified, conducting audits and inspections to verify that activities are conducted in accordance with QA Program requirements, initiating corrective action requests when conditions or significant conditions adverse to quality are identified by QA staff and periodically reporting to the COO and the President on the status and effectiveness of the program. If disagreements arise between the DCQA and COO on quality assurance matters, then the disagreement is provided to the President for final resolution.

1.8 QA management and staff have sufficient authority and organizational freedom to identify quality problems, implement corrective action and verify corrective action effectiveness. The QA organization has sufficient independence from cost and schedule considerations when such considerations are opposed to safety.

1.9 QA staff is independent from other departments and report directly to a QA Manager (QAM) who reports to the DCQA. If a QAM cannot resolve an issue with the DCQA, then the QAM has the authority and the responsibility to bring that issue to the COO or President for resolution. The QAMs must have sufficient expertise in the field of Nuclear Quality Assurance to enable them to direct the quality functions in accordance with the applicable regulatory criteria invoked by this QAPDM. The QAMs, QA staff and/or organizations within, or utilized by TN, are qualified for their responsibilities. Documentation supporting QA personnel qualifications are maintained as Quality Assurance Records.

1.10 The QAMs are also responsible for delegating the performance of quality-related tasks to QA staff qualified by virtue of their education, training and experience, and to evaluate the adequacy of performance of those delegated tasks.

1.11 QA management and staff positions have the authority to prevent the continued processing, fabrication, installation, delivery or use of unsatisfactory work.

1.12 The TN Functional Organization for QA Program Activities is included as Figure 1 in Section 20.0.

2.0 QUALITY ASSURANCE PROGRAM

2.1 General

2.1.1 TN has established a QA Program consistent with the regulations and codes defined in the **Introduction** for the control of quality in the design, procurement, fabrication, handling, shipping, cleaning, assembly, inspection, modification, testing, operation, repair, and maintenance of shipping/storage systems for spent fuel and radioactive materials that are classified as safety-related, quality affecting, or important-to-safety. The program ensures that activities affecting quality are accomplished under suitable controlled conditions and that prerequisites for given activities are satisfied.

2.1.2 The TN QA Program is comprised of this QAPDM, the TN ASME Section III QAPDM, and Transnuclear Implementing Procedures (TIPs), all of which are designed and administered to meet the applicable requirements of 10 CFR 71, Subpart H; 10 CFR 72, Subpart G; 10 CFR 50, Appendix B; ASME Section III, Division 1 (NCA 4000) / Division 3 (WA 4000) and ASME NQA-1.

2.1.3 The TN QA Program utilizes the guidance provided in Regulatory Guide 7.10 and NUREG/CR-6407 for implementing program requirements in a graded fashion commensurate with safety significance.

2.1.4 The **Statement of Quality Policy and Authority** directs all employees working on safety-related, quality affecting, or important-to-safety activities to comply with the provisions of the QA Program.

2.1.5 The **Statement of Quality Policy and Authority** directs that the applicable provisions of the QA Program be applied at approved supplier locations for safety-related, quality affecting, or important-to-safety work subcontracted by TN.

2.1.6 TN commits to complying with the provisions of 10 CFR 21, including internal posting and dissemination via procurement documents to suppliers.

2.1.7 More specific details or methods of implementing QAPDM requirements are defined in the TIPs. Applicability of other quality standards, unique customer or project requirements, or other contract considerations may dictate the need to address unique project requirements that are not specifically covered by the TIPs. These other requirements or considerations are defined in the Project Plan or in Project Instructions. Requirements for the review, approval, and control of Project Plans, TIPs, and Project Instructions are defined in the applicable TIPs.

2.2 Preparation and Control of the Transnuclear, Inc. Quality Assurance Program Description Manual for 10 CFR 71, Subpart H and 10 CFR 72, Subpart G

2.2.1 This QAPDM provides for the planning and accomplishment of safety-related, quality affecting, or important-to-safety activities in a controlled manner.

2.2.2 This QAPDM and revisions thereof are prepared by the DCQA or designee and approved by the President, COO and the DCQA.

2.2.3 The QAPDM and revisions thereof are subject to review and approval by the U.S. Nuclear Regulatory Commission (NRC). The effective date for implementation is the **Issue Date** noted on the cover of the QAPDM, following approval by the NRC.

2.2.4 Revisions to the QAPDM shall be indicated by a vertical line in the appropriate margin except for minor editorial corrections. Extensive revisions that constitute a complete rewrite do not require the application of revision bars.

2.2.5 Controlled copies of the QAPDM are issued in accordance with the applicable TIPs to identified controlled copy holders. The controlled copy holder is responsible for keeping their manuals up-to-date.

2.3 Management Review of Quality Assurance Program

2.3.1 The DCQA regularly evaluates the QA Program for adherence to baseline commitments in scope, implementation and effectiveness. The DCQA informs the President, the COO, and other senior management personnel annually of the status and adequacy of the TN QA Program.

2.3.2 A Management Audit of the QA organization is conducted annually by an organization independent of TN QA. An audit team appointed by the COO performs the audit. The purpose of this audit is to assess the adequacy and effectiveness of that part of the TN QA Program for which the QA organization is responsible. The audit report is transmitted to management for correction of any observed deficiencies.

2.4 Indoctrination and Training

2.4.1 Transnuclear Implementing Procedures have been established to ensure that QA Program indoctrination training is provided for employees who perform safety-related, quality affecting, or important-to-safety activities. Measures have been established to:

a. Identify personnel performing activities affecting quality

b. Define indoctrination and training requirements

c. Define documentation requirements.

2.4.2 When necessary, training in project unique quality requirements is provided by the appropriate Project Manager in accordance approved TIPs.

2.4.3 When required by applicable codes and standards, qualified personnel are appropriately certified in accordance with approved TIPs.

2.4.4 Proficiency of personnel who participate in QA Program activities is maintained by continuing execution of their assigned responsibilities, retraining, reexamining, and/or recertifying, as appropriate. If it is determined by the DCQA, a QAM or responsible management staff that an individual's capabilities are not in accordance with specified requirements, that individual is removed from that capacity until such time as that person has been retrained and has demonstrated adequate capability for performing that activity.

2.4.5 Records of training and certification are maintained in accordance with the applicable approved TIPs to demonstrate compliance with training requirements.

2.4.6 Personnel performing audit activities are qualified in accordance with the applicable approved TIPs. Personnel who are designated as Lead Auditors are certified by the DCQA after confirmation that they meet applicable requirements for qualification. All records of personnel qualification and certification, including previous certifications used in support of current qualifications, are retained as QA Records. Capability demonstrations (tests) of Lead Auditors shall be written.

3.0 DESIGN CONTROL

3.1 Transnuclear Implementing Procedures have been established to control design activities to ensure that the following occur:

3.1.1 Design activities are planned, controlled and documented.

3.1.2 Regulatory requirements, design requirements and appropriate quality standards are correctly translated into specifications, drawings and procedures.

3.1.3 Competent engineering personnel, independent of design activities, perform design verification. Verification may include design reviews, alternate calculations or qualification testing. Qualification tests are conducted in accordance with approved test programs or procedures under the most adverse design conditions.

3.1.4 Design interface controls are established and adequate.

3.1.5 Design, specification and procedure changes are reviewed and approved in the same manner as the original issue. In a case where a proposed design change potentially impacts licensed conditions, the QA Program ensures that licensing considerations are reviewed and complied with or otherwise reconciled by amending licenses for Transport Applications or evaluated in accordance with the requirements of 10 CFR 72.48 for Storage Applications.

3.1.6 Design errors and deficiencies are documented, corrected and corrective action to prevent recurrence is taken.

3.1.7 Design organization(s) and their responsibilities and authorities are delineated and controlled through written procedures.

3.2 Materials, parts, equipment, and processes essential to the function of items that are important to safety are selected and reviewed for suitability of application.

3.3 Computer programs used for design analysis or verification are controlled in accordance with approved TIPs. These procedures provide for verification of the accuracy of computer results and for the assessment and resolution of reported computer program errors.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 Transnuclear Implementing Procedures have been established to ensure that procurement documents are prepared to clearly define applicable technical and QA requirements including codes, standards, regulatory requirements and commitments, and contractual requirements. These documents serve as the principal documents for the procurement of structures, systems and components, and related services for use in the design, fabrication, maintenance and operation, inspection and testing of storage and/or transportation systems. The Quality Assurance Program ensures that purchased material, components, equipment and services comply with applicable requirements.

4.2 The assignment of quality requirements through procurement documents is administered and controlled in accordance with approved TIPs.

4.3 Procurement activities are performed in accordance with approved TIPs delineating requirements for preparation, review, approval and control of procurement documents. Revisions to procurement documents are reviewed and approved by the same cognizant groups as the original.

4.4 Quality requirements are included in safety-related, quality affecting, or important-to-safety purchase orders. TN personnel assign quality requirements within procurement documents, as applicable to the scope of the procurement referencing 10 CFR 71, Subpart H; 10 CFR 72, Subpart G; 10 CFR 50, Appendix B, ASME Section III, or other regulations, codes or standards as appropriate.

4.5 TN procurement documents require suppliers to pass on appropriate quality assurance program requirements to subtier suppliers.

4.6 TN procurement documents include provisions that suppliers either maintain or supply those QA records which provide evidence of conformance to the procurement documents. Additionally, procurement documents designate those supplier documents required for submittal to TN for review and/or approval.

4.7 TN maintains right of access to supplier facilities and performance of source surveillances and/or audit activities, as applicable. A statement to this effect is included in procurement documents.

4.8 Procurement documents also address the applicability of the provisions of 10CFR21 for the Reporting of Defects and Noncompliances.

5.0 INSTRUCTIONS, PROCEDURES AND DRAWINGS

5.1 Transnuclear Implementing Procedures have been established to ensure that methods for complying with each of the criteria of 10 CFR 71, Subpart H; 10 CFR 72, Subpart G; 10 CFR 50, Appendix B, or ASME Section III, as applicable, for safety-related, quality affecting, or important-to-safety activities during design, fabrication, inspection, testing, use, maintenance, and operations are specified in instructions, procedures, and/or drawings.

5.2 Instructions, procedures and drawings are developed, reviewed, approved, utilized and controlled in accordance with the requirements of approved TIPs. These instructions, procedures and drawings include appropriate quantitative and qualitative acceptance criteria.

5.3 Changes to instructions, procedures and drawings, are developed, reviewed, approved, utilized and controlled using the same requirements and controls as applied to the original documents.

5.4 Compliance with these approved instructions, procedures and drawings is mandatory for all personnel performing safety-related, quality affecting, or important-to-safety activities.

6.0 DOCUMENT CONTROL

6.1 Transnuclear Implementing Procedures have been established to control the issuance of documents that prescribe requirements for safety-related, quality affecting, or important-to-safety activities, and to ensure adequate review, approval, release, distribution, and use of documents and their revisions. Controlled documents may include, but are not limited to:

6.1.1 Design specifications

6.1.2 Design and fabrication drawings

6.1.3 Special process specifications and procedures

6.1.4 QA Program Description Manuals and TIPs

6.1.5 Test procedures

6.1.6 Operational test procedures and data.

6.2 Changes to documents, which prescribe requirements for safety-related, quality affecting, or important-to-safety activities, are reviewed and approved by the same organization that performed the initial review and approval, or by qualified responsible organizations.

6.3 Documents that prescribe requirements for safety-related, quality affecting, or important-to-safety activities, are reviewed and approved for technical adequacy and inclusion of appropriate quality requirements prior to approval and issuance.

6.4 Measures are taken to ensure that only current documents are available at the locations where safety-related, quality affecting, or important-to-safety activities are being performed. These measures include controls for electronic records when appropriate.

7.0 CONTROL OF PURCHASED MATERIALS, PARTS AND COMPONENTS

7.1 Transnuclear Implementing Procedures have been established to ensure that purchased materials, parts, components, and services conform to procurement documents.

7.2 Procurement documents are reviewed and approved by authorized personnel for acceptability of proposed suppliers based on the quality requirements of the items/services being purchased.

7.3 Approved suppliers are listed on the TN Approved Suppliers List (ASL) for the items and/or services they provide. The ASL is controlled in accordance with approved TIPs.

7.4 As required, audits and/or surveys are conducted to determine supplier approval. These audits/surveys are based on one or all of the following criteria:

7.4.1 The supplier's capability to comply with the requirements of 10 CFR 71, Subpart H; 10 CFR 72, Subpart G; 10 CFR 50, Appendix B, ASME Section III, and other regulations, codes or standards that are applicable to the scope of work to be performed.

7.4.2 A review of previous records to establish the past performance of the supplier.

7.4.3 A survey of the supplier's facilities and review of the supplier's QA Program to assess the adequacy and verify implementation of quality controls consistent with the requirements being invoked.

7.5 Qualified personnel conduct audits and surveys. Audit/survey results are documented and retained as Quality Assurance Records. Suppliers are re-audited and/or re-evaluated at planned intervals to verify that they continue to comply with quality requirements and to assess the continued effectiveness of their QA Program. Additionally, interim periodic evaluations are performed of supplier quality activities to verify implementation of their QA Program.

7.6 Suppliers are required to provide objective evidence that items or services provided meet the requirements specified in procurement documents. Items are properly identified to appropriate records that are available to permit verification of conformance with procurement documents. Any procurement requirements not met by suppliers are reported to TN for review and approval. These conditions are reviewed by technical and quality personnel to ensure that they have not compromised the quality of the item or service.

7.7 Periodic surveillance of supplier in-process activities is performed as necessary, to verify supplier compliance with the procurement documents. When deemed necessary, the need for surveillance is noted in approved quality or project planning documents, and surveillances are performed and documented in accordance with approved TIPs. Personnel performing surveillance of supplier activities are trained and qualified in accordance with approved procedures.

7.8 Quality planning for the performance of source surveillance, test, shipping and/or receiving inspection activities to verify compliance with approved design and licensing requirements, applicable regulatory criteria, procurement document requirements, or contract specifications is performed in accordance with approved TIPs.

7.9 For commercial "off-the-shelf" items, where specific quality controls appropriate for nuclear applications cannot be imposed in a practical manner, additional quality verification is performed to the extent necessary to verify the acceptability and conformance of the items to procurement document requirements. When dedication of a commercial grade item is required for use in a safety-related, quality affecting, or important-to-safety application, such dedication is performed in accordance with approved TIPs.

8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

8.1 Transnuclear Implementing Procedures have been established to identify and control materials, parts and components. These procedures ensure identification of items by appropriate means during fabrication, installation and use of the items and prevent the inadvertent use of incorrect or defective items.

8.2 Requirements for identification are established during the preparation of procedures and specifications.

8.3 Methods and location of identification are selected so as to not adversely affect the fit, function or quality of the items being identified.

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

9.0 CONTROL OF SPECIAL PROCESSES

9.1 Transnuclear Implementing Procedures have been established to control special processes used in the fabrication and inspection of storage/transport systems. These processes may include welding, non-destructive examination, or other special processes as identified in procurement documents.

9.2 Special processes are performed in accordance with written approved procedures.

9.3 Personnel who perform special processes are trained and qualified in accordance with applicable codes, standards, specifications, or and other special requirements.

9.4 Records of procedure and personnel qualifications are filed and kept current by the organization that performs the special processes.

10.0 INSPECTION

10.1 Transnuclear Implementing Procedures have been established to ensure that inspection or surveillance is performed to verify that material, parts, processes or other safety-related, quality affecting, or important-to-safety activities conform to documented instructions, procedures, specifications, drawings, or procurement documents.

10.2 Personnel performing inspection and surveillance activities are trained and qualified in accordance with approved TIPs.

10.3 Inspections and surveillances are performed by individuals other than those who performed or supervised the subject activities.

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

10.5 Modifications and/or repairs to and replacements of safety-related, quality affecting, or important-to-safety structures, systems and components are inspected in accordance with the original design and inspection requirements or acceptable alternatives.

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

10.7 Inspection and surveillance activities are performed in accordance with written instructions and the results are documented.

11.0 TEST CONTROL

11.1 Transnuclear Implementing Procedures have been established to ensure that required proof, acceptance and operational tests, as identified in design or procurement documents, are performed and appropriately controlled.

11.2 Test personnel have appropriate training and are qualified for the level of testing which they are performing. Personnel are qualified in accordance with approved, written instructions, procedures and/or checklists.

11.3 Tests are performed by qualified personnel in accordance with approved, written instructions, procedures and/or checklists. Test procedures contain or reference the following information, as applicable:

11.3.1 Acceptance criteria contained in the applicable test specifications, or design and procurement documents;

11.3.2 Instructions for performance of tests, including environmental conditions;

11.3.3 Test prerequisites such as test equipment and instrumentation requirements, personnel qualification requirements, fabrication or operational status of the items to be tested; and

11.3.4 Provisions for data recording and records retention.

11.4 Test results are documented and evaluated to ensure that acceptance criteria have been met.

11.5 Tests to be conducted after modifications, repairs or replacements of safety-related, quality affecting, or important-to-safety structures, systems or components are performed in accordance with the original design and testing requirements or acceptable alternatives.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 Transnuclear Implementing Procedures have been established to ensure that tools, gages, instruments and other measuring and testing devices (M&TE) used in safety-related, quality affecting, or important-to-safety activities are properly controlled, calibrated and adjusted to maintain accuracy within required limits.

12.2 M&TE are calibrated at scheduled intervals against certified standards having known valid relationships to national standards. If no national standards exist, the basis for calibration is documented. Calibration intervals are based on required accuracy, precision, purpose, amount of use, stability characteristics and other conditions that could affect the measurements.

12.3 Calibrations are performed in accordance with approved written procedures. Inspection, measuring and test equipment are marked to indicate calibration status.

12.4 M&TE are identified, labeled or tagged indicating the next required calibration due date, and traceable to calibration records.

12.5 If M&TE are found to be out of calibration, an evaluation is performed and documented regarding the validity of inspections or tests performed and the acceptability of items inspected or tested since the previous acceptable calibration. The current status of M&TE is recorded and maintained. Any M&TE that are consistently found to be out of calibration are repaired or replaced.

12.6 Special calibration and control measures on rules, tape measures, levels and other such devices are not required where normal commercial practices provide adequate accuracy.

13.0 HANDLING, STORAGE AND SHIPPING

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

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

14.0 INSPECTION, TEST AND OPERATING STATUS

14.1 Transnuclear Implementing Procedures have been established to ensure that the inspection and test status of materials, items, structures, systems and components throughout fabrication, installation, operation and test are clearly indicated by suitable means, (e.g., tags, labels, cards, form sheets, check lists, etc.).

14.2 Bypassing of required inspections, tests, or other critical operations is prevented through the use of approved instructions or procedures

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

14.4 Any nonconforming items are identified and controlled in accordance with approved TIPs.

15.0 NONCONFORMING MATERIAL, PARTS OR COMPONENTS

15.1 Transnuclear Implementing Procedures have been established to control materials, parts, and components that do not conform to requirements so as to prevent their inadvertent use in manufacturing operations or during service.

15.2 Nonconforming items include those items that do not meet specification or drawing requirements. Additionally, nonconforming items include items not fabricated or tested (1) in accordance with approved written procedures, (2) by qualified processes, or (3) by qualified personnel, where use of such procedures, processes or personnel is required by the fabrication, test, inspection or QA requirements.

15.3 Nonconforming items are identified and/or segregated to prevent their inadvertent use until properly dispositioned. The identification of nonconforming items is by marking, tagging or other methods that do not adversely affect the end use of the item. The identification is legible and easily recognizable. When identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, is identified.

15.4 Nonconforming conditions are documented on Nonconformance Reports (NCRs) and affected organizations are notified. These reports include a description of the nonconforming condition. Nonconforming items are dispositioned as use-as-is, reject, repair, or rework.

15.5 Inspection or surveillance requirements for nonconforming items following rework, repair or modification are detailed in the NCRs and approved following completion of the disposition.

15.6 Acceptability of rework or repair of nonconforming materials, parts, and components is verified by re-inspecting and/or re-testing the item to the original requirements or equivalent inspection/testing methods. Inspection, testing, rework, and repair methods are documented and controlled.

15.7 The disposition of nonconforming items as use-as-is or repair shall include technical justification and independent verification to ensure compliance with design, regulatory and contractual requirements.

15.8 Items dispositioned as rework or repair are reinspected and retested in accordance with the original inspection and test requirements or acceptable alternatives that are in compliance with the specified acceptance criteria.

15.9 When specified by contract requirements, nonconformances that result in a violation of client contract or specification requirements are submitted for client approval.

15.10 NCRs are made part of the inspection records and are periodically reviewed to identify quality trends. Unsatisfactory quality trends are documented and appropriate corrective actions taken. The results of these reviews are reported to management.

15.11 NCRs related to activities internal to TN are issued to the management of the affected organization. Engineering approval of the disposition is obtained and the QAM or designee performs follow-up activities to ensure that the requirements of the disposition have been satisfied so that the NCR can be closed.

15.12 Compliance with the evaluation and reporting requirements of 10 CFR 21 related to defects and noncompliance is controlled in accordance with approved TIPs.

16.0 CORRECTIVE ACTION

16.1 Transnuclear Implementing Procedures have been established to ensure that conditions adverse to quality such as failures, malfunctions, deficiencies, deviations, defective material and equipment are promptly identified and corrected. In the case of significant conditions adverse to quality, the cause of the condition is determined and corrective actions to prevent recurrence are taken.

16.2 Conditions adverse to quality are documented in Corrective Action Reports and reported to the appropriate level of management. When necessary, follow up is performed to verify that corrective action requirements have been completed and are effective. Periodically, quality trends are evaluated and appropriate corrective actions taken.

16.3 The DCQA is responsible for ensuring implementation of the Corrective Action Program, including follow up and closeout actions. The DCQA may delegate responsibilities related to administration, control and coordination of the Corrective Action Program to others.

16.4 Compliance with the evaluation and reporting requirements of 10 CFR 21 related to defects and noncompliance is controlled in accordance with approved TIPs.

17.0 QUALITY ASSURANCE RECORDS

17.1 Transnuclear Implementing Procedures have been established to ensure the control of quality records. The purpose of the Quality Assurance Records system is to ensure that documented evidence pertaining to safety-related, quality affecting, or important-to-safety activities is maintained and available for use by TN, its customers, and/or regulatory agencies, as applicable.

17.2 Approved procedures identify the types of documents to be retained as Quality Assurance Records, as well as those to be retained by the originating organization. Lifetime and Non-Permanent records are retained by TN or its customers, as appropriate. Records are identified, indexed and stored in accessible locations.

17.3 Quality Assurance Records are maintained for periods specified in the applicable regulations to furnish evidence of the quality of safety-related, quality affecting, or important-to-safety structures, systems and components. These records include design, procurement, fabrication, assembly and erection records.

17.4 When applicable to TN activities, Quality Assurance Records include; design records, records of use, results of reviews, inspections, tests, audits, results from monitoring of work performance, material analyses, maintenance activities, modification activities, and repair activities. The records also include closely related data such as; qualification of personnel, procedures and equipment; records of equipment calibration, and related instructions, procedures, and drawings. In the case of inspection and test records; identification of the inspector or data recorder, the type of observation performed, the results of the observation, its acceptability and any actions taken in connection with any noted deficiency are recorded.

17.5 Requirements for legibility, indexing, record retention period(s), storage method(s) and location(s), classification, preservation measures, electronic records, disposition of nonpermanent records, and responsibility for safekeeping are specified in approved TIPs. Record storage facilities have been established to prevent destruction of the records by fire, flood, theft, and deterioration due to environmental conditions (such as temperature, humidity, or vermin). As an alternative, two identical sets of records may be maintained at separate locations.

17.6 TN retains required records for at least three (3) years beyond the date of last engagement in the activities under the scope of this QAPDM for 10 CFR 71 related records and until the Nuclear Regulatory Commission terminates the Certificate of Compliance for 10 CFR 72 related records.

18.0 AUDITS

18.1 Transnuclear Implementing Procedures have been established to ensure that periodic audits are performed to verify compliance with the Quality Assurance Program and determine its effectiveness. Those areas and activities to be audited, such as design, procurement, fabrication, inspection, and testing of storage/transportation systems, are identified in audit planning.

18.2 TN audits supplier QA Programs, procedures and work activities to verify that procedures are adequate, and that activities performed on behalf of TN comply with applicable requirements.

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

18.4 Audits are performed by trained and qualified personnel not having direct responsibilities in the areas being audited and are conducted in accordance with written plans and checklists. Audit results are documented and reviewed with management having responsibility for the area audited. Corrective actions and schedules for implementation are established and recorded. Audit reports include an objective evaluation of the quality-related practices, procedures and instructions for the areas or activities being audited and the effectiveness of implementation.

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

18.6 The QAM follows up on audit findings to ensure that appropriate corrective actions have been implemented and directs the performance of re-audits when deemed necessary.

19.0 REFERENCES

- Title 10, Code of Federal Regulations, Part 21 - *Reporting of Defects and Noncompliances*
- Title 10, Code of Federal Regulations, Part 50, Appendix B – Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
- Title 10, Code of Federal Regulations, Part 71, Subpart H – Packaging and Transportation of Radioactive Material, Quality Assurance
- Title 10, Code of Federal Regulations, Part 72, Subpart G – Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste, Quality Assurance
- Regulatory Guide 7.10, Revision 2, March 2006 – *Establishing Quality Assurance Programs For Packaging Used In Transportation Of Radioactive Material*
- NUREG/CR-6407, February 1996 – *Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety*
- ASME Section III, Division 1 (*NCA 4000 Quality Assurance*)
- ASME Section III, Division 3 (*WA 4000 Quality Assurance*)
- ASME NQA-1 – *Quality Assurance Requirements for Nuclear Facility Applications*

Section 20.0

Figure 1 – Transnuclear Functional Organization for QA Program Activities