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E-29382 (page 1 of 3)

August 26, 2011

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 10 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 U.S. Nuclear Regulatory Commission approval proposed revision 10 to the Transnuclear, Inc. Quality Assurance Program Description Manual for 10CFR71, Subpart H and 10CFR72, Subpart G.

Changes incorporated with this proposed revision 10 include:

1. Addition of a new Transnuclear, Inc office location in the manual Introduction statement identifying the TN Richland, WA office as a location under the scope of the program.
2. Addition to the Introduction statement that the manual scope includes activities subject to the requirements of a DOE Certificate of Compliance and Competent Authority Certifications issued by DOT.
3. Changes to the Transnuclear, Inc organization and corresponding responsibilities for activities under the control of the Manual and a simplified organization chart (see Section 1, Section 20 (Figure 1) and elsewhere in the Manual as appropriate). The following summarizes these changes:
   - The position of President & CEO is changed to Chief Executive Officer (CEO),
   - The position of Chief Operating Officer (COO) is changed to President & COO,
   - Organizational reporting for the Document Control organization was to the Vice President of Engineering and will now be to the Director, Quality Assurance.
4. Responsibility discussion in Section 1 of the Manual was removed for positions below those identified on Figure 1 and additional guidance added in Section 1.0 stating that responsibilities can be delegated but overall responsibility for ensuring compliance is retained by individuals filling positions that have been assigned the responsibility under the program.

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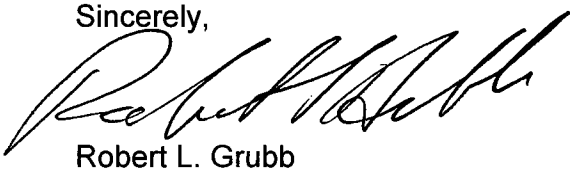
5. Added statements of Manual applicability and identified organizational responsibilities to further clarify that the Manual applies to the lease, maintenance and operation of transportation packages subject to the requirements of 10CFR71. (see Introduction, Statement of Quality Policy, Section 1 and elsewhere in the Manual as appropriate)
6. Clarified that application of the program is done in a graded fashion commensurate with safety significance in accordance with the guidance of USNRC RG 7.10 & NUREG CR 6407 for items and services subject to 10CFR71 and 10CFR72 only.
7. As the program may also be used to provide safety related items and services that are subject to the requirements of 10CFR50 the use of this graded approach for such items and services is not applicable. (see Section 2.0)
8. Reorganized and made editorial corrections to the duties and responsibilities assigned to the QA organization in Section 1 for consistency purposes and clarity without reducing the level of commitment.
9. Added Regulatory Guide 1.28, Revision 4 to Section 19 to better quantify standards utilized in implement program requirements.
10. Reorganized and made editorial corrections to the Introduction and Statement of Quality Policy and Authority for consistency and clarity purposes without reducing the level of commitment.
11. Reorganized and made editorial corrections to Section 4.0 and 5.0 of the Manual for consistency and clarity purposes without reducing the level of commitment.
12. Replaced references to "Transnuclear Implementing Procedures (TIPs)" with the term "procedures" throughout for simplification purposes.
13. Provided a clarifying statement in Section 18.0 that controls for the audit of supplier activities are provided in Section 7.0 of the Manual.
14. Clarified source documents for activities subject to the requirements of Sections 9, 10 and 11of the Manual
15. Other editorial or clarifying corrections were made throughout the Manual. Examples of editorial or clarifying corrections include but are not limited to the reordering of word, use of acronyms, re-organizing sentences within paragraphs, etc.

Please note that prior revisions of the Transnuclear, Inc. QAPDM were approved by the U.S. NRC under QA Program Approval Number 0250 / Docket Number 71-250 for use in accordance with the requirements of 10CFR71.

Please contact Chris Lloyd, Director, Quality Assurance if you require additional information regarding this submittal.

Sincerely,



Robert L. Grubb
President & CEO (acting)
Transnuclear, Inc.

Enclosure: Revision 10, Transnuclear, Inc Quality Assurance Program Description Manual (QAPDM) for 10CFR71, Subpart H and 10CFR72, Subpart G (X pages)

c: (w/enclosure)

U.S. Nuclear Regulatory Commission
ATTN: Robert Temps
Senior Safety Inspector, Division of Spent Fuel Storage and Transportation
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c: (w/o enclosure)

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AREVA

TRANSNUCLEAR INC.

TRANSNUCLEAR, Inc.
Quality Assurance Program Description Manual

for

10 CFR 71, Subpart H

and

10 CFR 72, Subpart G

Revision 10

Michael V. McMahon:
Chief Executive Officer _____ **Date:** 8/26/2011

Robert L. Grubb:
President & COO _____ **Date** 8/26/11

Christopher M. Lloyd:
Director, Quality Assurance _____ **Date:** 8/26/11

INTRODUCTION

The Transnuclear, Inc. (TN) Quality Assurance Program Description Manual (QAPDM) for 10 CFR 71, Subpart H, and 10 CFR 72, Subpart G, has been developed as a means to describe the quality assurance requirements that apply to activities affecting quality associated with the design, licensing, procurement, fabrication, handling, shipping, cleaning, assembly, inspection, modification, testing, operation, repair, maintenance and lease of storage and transport systems for spent fuel and radioactive materials that are classified as important to safety and subject to the requirements of 10 CFR 71 and/or 10 CFR 72 and associated Nuclear Regulatory Commission (NRC) Certificate(s) of Compliance (CoCs), Department of Energy (DOE) CoCs and/or Department of Transportation (DOT) Competent Authority Certifications.

This QAPDM also satisfies the provisions of 10 CFR 50, Appendix B and is applicable to activities affecting quality associated with items and services subject to the requirements of 10CFR50 that are classified as safety related.

This QAPDM applies to the following TN locations and other service locations when required by customer contract provisions:

Transnuclear, Inc 7135 Minstrel Way Columbia, MD 21045	Transnuclear, Inc 310 / 357 Woodward Drive Aiken, SC 29803	Transnuclear, Inc 2101 Horn Rapids Road Richland, WA 99352

The TN Quality Assurance Program (QAP) is comprised of this QAPDM; the TN QAPDM for ASME Section III, Division 1 and Division 3 and associated implementing procedures. TN implementing procedures 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) / Division 3 (WA 4000).

Transnuclear maintains appropriate ASME Certificate(s) 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 that are applicable to ASME Code projects only.

STATEMENT OF QUALITY POLICY AND AUTHORITY

Transnuclear, Inc. (TN) is engaged in the business of designing, licensing, certifying, testing, procuring, operating, maintaining and leasing systems for the storage and/or transport 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 TN 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, TN has established this Quality Assurance Description Manual (QAPDM) which complies with 10 CFR 71, Subpart H; 10 CFR 72, Subpart G and 10CFR50, Appendix B and the QAPDM for ASME Section III, Division 1 and Division 3. Collectively, these manuals constitute the TN Quality Assurance Program (QAP). Compliance with this program is mandatory for all personnel performing quality affecting activities associated with items and services classified as important to safety or safety-related.

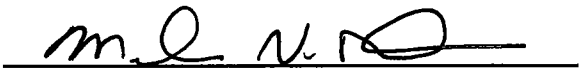
While the ultimate responsibility for implementation of the QAP rests with the Chief Executive Officer (CEO) of TN, every employee is expected to assume personal responsibility for performing their assigned work activities in accordance with the applicable requirements of the QAP and the implementing procedures in effect.

QAP requirements are invoked to the extent applicable upon suppliers to which TN subcontracts quality affecting work classified as important to safety or safety-related.

The President & Chief Operating Officer (President & COO) is assigned the responsibility for implementing the requirements of the TN QAP consistent with this policy.

The Director, Quality Assurance (DQA) is assigned the responsibility for developing, maintaining and verifying execution of the QAP consistent with this Policy.

Michael V. McMahon:
Chief Executive Officer



1.0 ORGANIZATION

1.1 Responsibility for compliance with the QAP resides ultimately with the CEO of TN. QAP 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 of this QAPDM, TN qualifies those organizations to ensure their capability to comply with applicable requirements; however, TN retains the overall responsibility for the quality of those activities.

1.2 The CEO 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 QAP is assigned to the President & COO and authority for developing, maintaining and verifying execution of the program is assigned to the DQA. Each organization within TN is responsible for implementation of the program for their respective scope of responsibility.

1.3 The President & COO reports to the CEO 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 QAP are performed in accordance with the requirements of the QAP.

1.4 The Vice President of Engineering reports to the President & COO and is responsible for Engineering (Design), Licensing, Project Management, Site Services and Project Engineering and Fabrication activities associated with storage and transportation systems.

1.5 The Vice President of Purchasing and Contract Administration reports to the President & 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.

1.6 The Director of Transportation reports to the President & COO and is responsible for management, maintenance, operations and lease of transportation packages. The Director is also responsible for specialized support services related to the transportation of radioactive materials.

1.7 The Director, Quality Assurance (DQA) reports to the President & COO and is responsible for developing, maintaining and verifying execution of the QAP. The responsibilities assigned to this position include; document control and records storage activities, ensuring that QA staff is appropriately qualified, conducting audits and inspections to verify that activities are conducted in accordance with QAP requirements, initiating corrective action requests when conditions or significant conditions adverse to quality are identified by QA staff and periodically reporting to the CEO and the President & COO on the status and effectiveness of the program. The DQA and the Quality Assurance organization have:

1.7.1 Sufficient authority and organizational freedom to identify quality problems, require that corrective action be taken and verify corrective action effectiveness.

1.7.2 Sufficient independence from cost and schedule considerations when such considerations are opposed to safety.

1.7.3 The authority to stop unsatisfactory work and prevent its further processing, installation, use or delivery.

1.7.4 Access to all levels of management and records necessary to perform their assigned responsibilities.

1.75 The responsibility and authority to bring an issue to the President and COO or the CEO for resolution if resolution of the issue cannot be achieved at a lower level of management.

1.7.5 Sufficient expertise and training in the field of Nuclear Quality Assurance to enable them to assess the quality functions in accordance with the applicable regulatory criteria, codes and standards invoked by this QAPDM. These members or organizations utilized by TN are qualified for their responsibilities. Documentation supporting QA personnel qualifications are maintained as Quality Assurance Records.

1.8 Individual's assigned QAP responsibilities under this QAPDM may delegate those responsibilities to others but retain the overall responsibly for ensuring compliance with the requirements of this QAPDM.

1.9 The TN organization for QAP Activities is included as Figure 1 in Section 20.0 of this QAPDM.

2.0 QUALITY ASSURANCE PROGRAM

2.1 General

2.1.1 TN has established a QAP consistent with the regulations and codes defined in the **Introduction** to this manual for the control of activities affecting quality in the areas of design, licensing, procurement, fabrication, handling, shipping, cleaning, assembly, inspection, modification, testing, operation, repair, lease and maintenance of storage and transportation systems for spent fuel and radioactive materials which are classified as important to safety or safety-related. 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 QAP is comprised of this QAPDM, the QAPDM for ASME Section III related activities and associated implementing procedures, 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 QAP utilizes the guidance provided in Regulatory Guide 7.10 and NUREG/CR-6407 for implementing program requirements for activities subject to the requirements of 10 CFR 71 and 10 CFR 72 in a graded fashion commensurate with safety significance. This grade approach is not utilized for items and services classified as safety related and subject to the requirements of 10 CFR 50.

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

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

2.1.6 TN commits to complying with the provisions of 10 CFR 21.

2.1.7 More specific details or methods of implementing QAPDM requirements are defined in implementing procedures. 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 implementing procedures. These other requirements or considerations are defined during the project planning process and implemented with project specific procedures, instructions or drawings. Requirements for the review, approval, and control of implementing procedures, project plans and

project specific procedures, instructions or drawings are defined in these implementing procedures.

2.2 Preparation and Control of the QAPDM for 10 CFR 71, Subpart H and 10 CFR 72, Subpart G

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

2.2.2 This QAPDM and revisions thereof are approved by the Chief Executive Officer (CEO), the President & COO and the DQA.

2.2.3 This QAPDM and all revisions thereof are subject to review and approval by the U.S. Nuclear Regulatory Commission (NRC). Following NRC approval, the implementation date is identified as the **Effective Date** on the cover of the QAPDM.

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 implementing procedures 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 DQA regularly evaluates the QAP for adherence to baseline commitments in scope, implementation and effectiveness. The DQA informs the CEO, the President & COO, and other senior management personnel annually of the status and adequacy of the QAP.

2.3.2 Annually, a Management Audit of the QA organization is conducted by an organization independent of the TN QA organization. An audit team appointed by the President & COO performs the audit. The purpose of this audit is to assess the adequacy and effectiveness of those parts of the QAP 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 Procedures have been established to ensure that QAP indoctrination training is provided for employees who perform quality affecting activities related to items and services classified as important to safety or safety-relate. 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 or other individuals knowledgeable in the subject matter. This training is conducted in accordance with approved procedures.

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

2.4.4 Proficiency of personnel who participate in QAP activities is maintained by continuing execution of their assigned responsibilities, retraining, reexamining, and/or recertifying, as appropriate. If it is determined by the DQA 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 that the individual has been retrained and has demonstrated adequate capability for performing that activity.

2.4.5 Records of training, qualification and certification are maintained in accordance with the approved procedures to demonstrate compliance with training requirements.

2.4.6 Personnel performing audit activities are qualified in accordance with approved procedures. Personnel who are designated as Lead Auditors are certified by the DQA after confirmation that they meet applicable requirements for qualification. All records of personnel training, 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 Procedures have been established to control design and licensing activities to ensure that:

3.1.1 Design and licensing 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 or safety related are selected and reviewed for suitability of application.

3.3 Computer programs used for design analysis or verification are controlled in accordance with approved procedures. 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 Procedures have been established to ensure that procurement documents are prepared to clearly define applicable technical and quality requirements including codes, standards, regulatory requirements, 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, testing and leasing of storage and/or transportation systems. The Quality Assurance Program ensures that purchased material, components, equipment and services comply with applicable requirements.

4.2 Procurement activities are performed in accordance with procedures that establish requirements for preparation, review, approval and control of procurement documents. Revisions to procurement documents that involve changes to technical and quality requirements receive the same level of approval as originally required.

4.3 The assignment of quality requirements to procurement documents for safety-related or important-to-safety items and services is administered and controlled in accordance with procedures. These procedure require consideration of the applicable provisions of 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 for the scope of the procurement.

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

4.5 TN procurement documents include provisions that suppliers either maintain or supply those QA records that 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.

4.6 TN procurement documents include requirements for the right of access to supplier facilities for the purposes of audit, surveillance or inspections as determined necessary by TN.

4.7 When applicable, TN procurement documents include the reporting requirements of 10 CFR 21 for the Reporting of Defects and Noncompliances.

5.0 INSTRUCTIONS, PROCEDURES AND DRAWINGS

5.1 Procedures have been established to ensure that activities affecting quality are controlled in accordance with appropriate instructions, procedures and drawings necessary for complying with the applicable criteria of 10 CFR 71, Subpart H; 10 CFR 72, Subpart G; 10 CFR 50, Appendix B, or ASME Section III, for items and services classified as safety-related or important-to-safety.

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

5.3 Changes to instructions, procedures and drawings, receive the same level of review and approval as originally required.

5.4 Compliance with these approved instructions, procedures and drawings is mandatory for all personnel performing activities subject to the requirements of this QAPDM.

6.0 DOCUMENT CONTROL

6.1 Procedures have been established to control the issuance of documents that prescribe requirements for quality affecting activities associated with items or services classified as important to safety or safety-related 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 implementing procedures

6.1.5 Test procedures

6.1.6 Operational test procedures and data.

6.2 Changes to documents, which prescribe requirements for important to safety or safety-related 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 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 important to safety or safety related activities are being performed. These measures include controls for electronic records when appropriate.

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

7.1 Procedures have been established to ensure that purchased material, equipment 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 Approved Suppliers List (ASL) for the items and/or services they provide. The ASL is controlled in accordance with approved procedures.

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, 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 procedures. 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 procedures.

7.9 For commercial "off-the-shelf" items or services, 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 or service is required for use in an important to safety or a safety-related application, such dedication is performed in accordance with approved procedures.

8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

8.1 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 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 Procedures have been established to control special processes used in the fabrication, maintenance and inspection of storage and transportation systems. These processes may include welding, non-destructive examination, or other special processes as identified in design, licensing or procurement documents.

9.2 Special processes are performed in accordance with 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 Procedures have been established to ensure that inspection or surveillance is performed to verify that material, parts, processes classified as important to safety or safety-related and associated quality affecting activities conform to documented instructions, procedures, specifications, drawings, procurement documents and regulatory requirements, as applicable.

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

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 important to safety or safety related structures, systems and components and related quality affecting activities 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 Procedures have been established to ensure that proof, acceptance and/or operational tests required by specifications, drawings, procurement documents and regulatory requirements 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 instructions or procedures.

11.3 Tests are performed by qualified personnel in accordance with approved instructions, procedures and/or checklists that 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 important to safety or safety related 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 Procedures have been established to ensure that tools, gages, instruments and other measuring and testing devices (M&TE) used in important to safety or safety related activities are properly controlled, calibrated and adjusted to maintain accuracy within required limits.

12.2 M&TE is 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 procedures. Inspection, measuring and test equipment are marked to indicate calibration status.

12.4 M&TE is labeled or tagged indicating the next required calibration due date and identified in a fashion that ensures traceability to associated calibration records.

12.5 If M&TE is 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. If M&TE is consistently found to be out of calibration, it is repaired, replaced and the calibration frequency adjusted if necessary.

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 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 Procedures have been established to ensure that the inspection, test and operating status of materials, items, structures, systems and components throughout fabrication, installation, operation and 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 (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 Nonconforming items are identified and controlled in accordance with approved procedures.

15.0 NONCONFORMING MATERIAL, PARTS OR COMPONENTS

15.1 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 fabrication, test, inspection or other quality assurance 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 includes a documented 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 Nonconformance reports 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 Nonconformance reports related to activities internal to TN are issued to the management of the affected organization. Engineering approval of the disposition is obtained and follow-up activities are performed to ensure that the requirements of the disposition have been satisfied prior to closure of the report.

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

16.0 CORRECTIVE ACTION

16.1 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 DQA is responsible for ensuring implementation of the Corrective Action Program, including follow up and closeout actions. The DQA 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 procedures.

17.0 QUALITY ASSURANCE RECORDS

17.1 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 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 for safety-related 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 procedures. 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/or until the Nuclear Regulatory Commission terminates the Certificate of Compliance for 10 CFR 72 related records.

18.0 AUDITS

18.1 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 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.

18.3 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 the appropriate level of 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.

18.4 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.

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

18.6 Requirements for audit of supplier activities are provided in Section 7.0 of this QAPDM.

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 1.28, Revision 4, June 2010 – *Quality Assurance Program Criteria (Design and Construction)*
- 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