AREVA
TN Americas LLC

E-45713

October 10, 2016

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

Subject: Submittal for Approval – Revision 15 to the TN Americas LLC Quality Assurance Program Description Manual for 10 CFR Part 71, Subpart H and 10 CFR Part 72, Subpart G (Reference NRC Docket Number 71-0250)

To Whom It May Concern:

This letter is to provide a notification of a change from an operating division of AREVA Inc. to a standalone entity named TN Americas LLC. TN Americas LLC is a wholly owned subsidiary company of AREVA Nuclear Materials LLC.

Additionally, TN Americas LLC is submitting to the U.S. Nuclear Regulatory Commission (USNRC) for approval Revision 15 to the TN Americas LLC Quality Assurance Program Description Manual (QAPDM) for 10 CFR Part 71, Subpart H and 10 CFR Part 72, Subpart G.

TN Americas LLC has reviewed the applicable requirements of 10 CFR Part 71, 10 CFR Part 72 and the guidance provided in USNRC Regulatory Guide 7.10. Based on this review, we have concluded that the change being made to the program with this Revision 15 is a reduction in program commitment as defined in 10 CFR Part 71.106.

Specifically, this revision removes all discussion and reference to the TN Americas LLC ASME Section III Quality Assurance Program Description as TN Americas LLC has made a business decision not to renew its ASME "N" and "N3" Certificates of Authorization. The basis for this decision was twofold:

1. Compliance with the provisions of ASME Section III, Subsection NCA for Division 1 activities or Subsection WA for Division 3 activities is not a requirement of any of the Safety Analysis Reports and the associated NRC Certificates of Compliance (CoC) for which TN Americas LLC is the Certificate Holder.
2. The ASME certificates were being maintained by TN Americas LLC to satisfy a specific customer who required full compliance with the ASME Code. This requirement was in addition to the requirements of the associated NRC CoC and is no longer needed.

In our evaluation of this change, we have also concluded that the change made to the QAPDM, with this Revision 15, does not impact regulatory compliance and the manual continues to satisfy the provisions of 10 CFR Part 71, Subpart H.

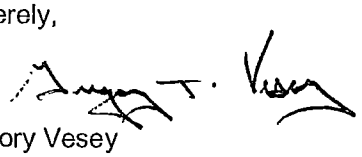
Enclosed for USNRC review and approval is a signed copy of Revision 15, with the above change incorporated.

TN Americas LLC
7135 Minstrel Way, Suite 300
Columbia, Maryland 21045 USA
TEL: (410)-910-6900
www.us.areva.com/AREVATN

NMSS01

If you have any questions or require any additional information regarding this submittal for approval, please contact Paul Oleyar at 410-910-6870.

Sincerely,



Gregory Vesey
President
TN Americas LLC

Enclosures:

1. Revision 15, TN Americas LLC Quality Assurance Program Description Manual (QAPDM) for 10CFR71, Subpart H and 10CFR72, Subpart G (30 pages)

c: (w/o enclosures)

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AREVA

TN Americas LLC

TN Americas LLC
Quality Assurance Program Description Manual

For

10 CFR Part 71, Subpart H

And

10 CFR Part 72, Subpart G

Revision 15

Gregory Vesey:
President,
TN Americas LLC

Date: 10/10/16

Paul Oleyar
Senior Manager, Quality Assurance,
TN Americas LLC

Date: 10/10/16

INTRODUCTION

TN Americas LLC Quality Assurance Program Description Manual (QAPDM) for 10 CFR Part 71, Subpart H, and 10 CFR Part 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 Part 71 and/or 10 CFR Part 72; associated Nuclear Regulatory Commission (NRC) Certificate(s) of Compliance (CoCs), Department of Energy (DOE) CoCs or Department of Transportation (DOT) Competent Authority Certifications. This QAPDM applies to TN Americas LLC associated activities.

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

This QAPDM applies to the following TN Americas LLC locations and at other locations when required by customer contract provisions or the business needs of TN Americas LLC:

TN Americas LLC
7135 Minstrel Way
Columbia, MD 21045

TN Americas LLC
357 & 367 Woodward Drive
Aiken, SC 29803

TN Americas LLC
2101 Horn Rapids Road
Richland, WA 99352

TN Americas LLC
117 Windchaser Way
Moyock, NC 27958

The TN Americas LLC Quality Assurance Program (QAP) is comprised of this QAPDM and associated implementing procedures that are designed and administered to meet the applicable requirements of 10 CFR Part 71, Subpart H; 10 CFR Part 72, Subpart G; 10 CFR Part 50, Appendix B, and ASME NQA-1.

STATEMENT OF QUALITY POLICY AND AUTHORITY

TN Americas LLC is engaged in the business of designing, licensing, certifying, testing, procuring, operating, shipping, testing, 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 Americas LLC 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.

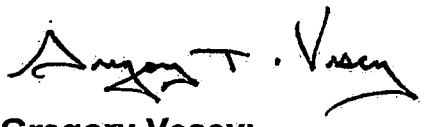
In order to carry out this Policy, TN Americas LLC has established this Quality Assurance Program Description Manual (QAPDM) and associated implementing procedures that are based on the requirements provided in 10 CFR Part 71, Subpart H; 10 CFR Part 72, Subpart G; 10 CFR Part 50, Appendix B and ASME NQA-1. Collectively, these documents constitute the TN Americas LLC 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 compliance with the QAP rests with the President, TN Americas LLC, 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 Americas LLC subcontracts quality affecting work classified as important-to-safety or safety-related.

The Senior Management staff of TN Americas LLC are assigned the responsibility for implementing the requirements of the TN Americas LLC QAP consistent with this policy.

The Senior Manager, Quality Assurance of TN Americas LLC is assigned the responsibility for developing, maintaining and verifying execution of the QAP consistent with this Policy.



Gregory Vesey:
President,
TN Americas LLC

ORGANIZATION

1.1 Responsibility for compliance with the QAP resides ultimately with the President, TN Americas LLC. QAP activities include those actions necessary to comply with the applicable requirements of 10 CFR Part 71, Subpart H; 10 CFR Part 72, Subpart G; 10 CFR Part 50, Appendix B and ASME NQA-1. When suppliers are used for performance of activities subject to the requirements of the QAP, TN Americas LLC qualifies those organizations to ensure their capability to comply with applicable requirements; however, TN Americas LLC 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 regarding QAP activities which include setting objectives, priorities, performance improvement initiatives and providing executive direction and guidance to senior management staff.

1.3 The President has assigned responsibility for implementing the requirements of the QAP within their respective scope of responsibilities to the senior management staff of TN Americas LLC (see Section 20.0, Figure 1).

1.3.1 These managers also retain the responsibility for ensuring that staff within their respective organizations are properly indoctrinated, trained and qualified (when required) in a fashion that is commensurate with the scope, complexity and importance of their assigned responsibilities.

1.4 The President has assigned responsibility and authority for developing, maintaining and verifying execution of the QAP to the Senior Manager, Quality Assurance (see Section 20.0, Figure 1).

1.5 The Chief Technical Officer reports directly to the President and is responsible for research & development activities as well as advising senior management on design and licensing matters.

1.6 The Senior Managers for the Business Lines report directly to the President and serve as the primary interface with the customer and are responsible for the implementation of QAP requirements associated with project planning, procurement and execution to ensure that customer and other requirements are met. The Business Lines are divided into the following three functional areas:

- Fuel Cycle Services – Material Packaging & Transportation Logistics
- Services – Field Services and Operations
- Back-End – Supply of Used Nuclear Fuel (UNF) Dry Storage and Material Storage and Transportation Systems with associated Ancillary Items

1.7 The Senior Manager, Business Operations reports to the President and is responsible for implementing QAP requirements associated with work control, document control, records and other operations support systems and functions.

1.8 The Senior Manager, Design & Licensing reports to the President and is responsible for implementing QAP requirements associated with design & licensing activities.

1.9 The Senior Manager, Fabrication Engineering reports to the President and is responsible for implementing QAP requirements necessary for ensuring that fabricated equipment and other procured items meet design, licensing and other requirements.

1.10 Senior Manager, Manufacturing reports to the President and serves as the primary interface with suppliers and is responsible for QAP requirements associated with supply chain and purchasing.

1.11 The Senior Manager, Quality Assurance reports directly to the President and is responsible for developing, maintaining and verifying execution of the QAP. The responsibilities and authorities assigned to this position include:

1.11.1 Periodically reporting to the President on the status and effectiveness of the program,

1.11.2 Administering the corrective action program,

1.11.3 Ensuring that Quality Assurance staff is appropriately indoctrinated and trained in oversight methods (audits, assessments, surveillances, inspections or other) used to verify that activities are being conducted in accordance with QAP requirements. Indoctrination and training methods for Quality Assurance staff are geared towards ensuring sufficient expertise is developed in the field of Nuclear Quality Assurance to enable the staff to properly assess the quality functions in accordance with applicable regulatory criteria, codes and standards and other documents invoked by the QAP. When required, members of the Quality Assurance staff are qualified for their responsibilities with supporting documentation maintained as Quality Assurance Records.

1.11.4 With full support of the President, ensuring that the Quality Assurance organization have:

- Sufficient authority and organizational freedom to identify quality problems and when necessary require that corrective action be taken when conditions or significant conditions adverse to quality are identified and verify the effectiveness of corrective action taken,

- Sufficient independence from cost and schedule considerations when such considerations are opposed to safety,
- The authority to stop unsatisfactory work and prevent its further processing, installation, use or delivery,
- Access to all levels of management and records necessary to perform their assigned responsibilities,
- The responsibility and authority to bring an issue to the President for resolution if resolution cannot be achieved at a lower level of management.

1.12 Individual's assigned responsibilities under the QAP may delegate those responsibilities to others but retain the overall responsibility for ensuring compliance with the requirements of the QAP.

1.13 When used in this QAPDM, the position title of "Senior Manager" is used to generically describe a management position responsible for a specific function. Other terms such as "Manager", "Director" or "Vice President" may be used in implementing procedures to identify these positions.

1.14 The TN Americas LLC 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 Americas LLC 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 and associated implementing procedures, all of which are designed and administered to meet the applicable requirements of 10 CFR Part 71, Subpart H; 10 CFR Part 72, Subpart G; 10 CFR Part 50, Appendix B and ASME NQA-1.

2.1.3 The QAP utilizes the guidance provided in United States Nuclear Regulatory Commission (NRC) Regulatory Guide 7.10 and NRC NUREG/CR-6407 for implementing program requirements for activities subject to the requirements of 10 CFR Part 71 and 10 CFR Part 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 Part 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 QAP 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 Americas LLC.

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

2.1.7 More specific details or methods of implementing QAP 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.

2.1.8 Requirements for the review, approval, and control of implementing procedures, project plans and project specific procedures, instructions or drawings are defined in implementing procedures.

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

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

2.2.2 This QAPDM and revisions thereof are approved by the President and the Senior Manager, Quality Assurance.

2.2.3 All revisions to this QAPDM are subject to screening under the applicable provisions of 10 CFR 71, Subpart H prior to implementation to determine if the change(s) requires review and approval by the NRC. The following addition controls are applied to QAPDM revisions:

- The screening to determine if a change requires NRC approval prior to implementation is documented and maintained as a record.
- The implementation date for revisions to the QAPDM is identified as the **Effective Date** on the cover of the QAPDM. In the case of changes that require NRC prior approval, the effective date is after the date that NRC approval is received.
- A listing of changes made to the QAPDM that were determined not to require prior NRC approval shall be submitted to the NRC every 24 months. If no changes were made during the 24 month period, then the report to the NRC shall identify no changes made. The 24 month periodicity is based on the approval date identified on the NRC Quality Assurance Approval Form for the QAPDM.

2.2.4 Revisions to this 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 this QAPDM are issued in accordance with the implementing procedures to identified controlled copyholders. The controlled copyholder is responsible for keeping their assigned manuals up-to-date.

2.3 Management Review of Quality Assurance Program

2.3.1 The Senior Manager, Quality Assurance regularly evaluates the QAP for adherence to baseline commitments in scope, implementation and effectiveness. The Senior Manager informs the President and other senior management personnel annually of the status and adequacy of the QAP.

2.3.2 Annually, a Management Audit of the Quality Assurance organization is conducted by an organization independent of the TN Americas LLC Quality Assurance organization. An audit team appointed by the President performs the audit. The purpose of this audit is to assess the adequacy and effectiveness of those parts of the QAP for which the Quality Assurance 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 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 continued execution of their assigned responsibilities, retraining, reexamining, and/or recertifying, as appropriate. If it is determined by 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 the 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 Senior Manager, Quality Assurance 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 Quality Assurance Records. Capability demonstrations (tests) of Lead Auditors are documented.

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 drawing changes are reviewed and approved in the same manner as the original issue. In cases where a proposed design change potentially impacts licensed conditions, procedural controls ensure that licensing considerations are reviewed and complied with or otherwise reconciled by obtaining a revision to an existing NRC Certificate of Compliance or Competent Authority Certification for Radioactive Material Packages or evaluating the change in accordance with the requirements of 10 CFR Part 72.48 for Spent Fuel or High Level Waste and Greater than Class C Storage Casks and obtaining an amendment to the NRC Certificate of Compliance for the Storage Casks when determined necessary.

3.1.6 Design errors and deficiencies are documented, corrected and action to prevent recurrence taken when determined necessary.

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 / transportation systems and other items subject to the requirements of the QAP.

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 important- to-safety and safety-related items and services is administered and controlled in accordance with procedures. These procedure require consideration of the applicable provisions of 10 CFR Part 71, Subpart H; 10 CFR Part 72, Subpart G; 10 CFR Part 50, Appendix B; ASME NQA-1 and other regulations, codes or standards as appropriate for the scope of the procurement.

4.4 TN Americas LLC procurement documents require suppliers to pass on appropriate quality assurance program requirements to sub-tier suppliers.

4.5 TN Americas LLC procurement documents include provisions that require suppliers to 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 Americas LLC for review and/or approval.

4.6 TN Americas LLC 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 Americas LLC.

4.7 When purchasing commercial calibration and testing services subject to the requirements for commercial-grade dedication, TN Americas LLC procurement documents include necessary technical and quality requirements based on NRC endorsed industry guidance.

4.8 When applicable, TN Americas LLC procurement documents include the reporting requirements of 10 CFR Part 21 for the Reporting of Defects and Noncompliance.

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 Part 71, Subpart H; 10 CFR Part 72, Subpart G; 10 CFR Part 50, Appendix B or ASME NQA-1, for items and services classified as important-to-safety or safety-related.

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 the QAP.

6.0 DOCUMENT CONTROL

6.1 Procedures have been established to control the issuance of documents that prescribe requirements for activities affecting quality associated with items or services classified as important-to-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 Operations, Maintenance and Test procedures

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 important-to-safety or safety-related 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 Part 71, Subpart H; 10 CFR Part 72, Subpart G; 10 CFR Part 50, Appendix B, ASME NQA- 1 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.

7.4.4 Audit equivalents identified in Section 18.0 maybe used for supplier audits and surveys provided that the conditions of use are also met.

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 Americas LLC 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 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.

7.10 As an alternative to performing a Commercial Grade Survey as part of the commercial grade dedication process, domestic and international commercial calibration and testing service providers may be utilized that have received laboratory accreditation to ISO/IEC 1702:2005 by Accreditation Bodies (Abs) that are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangements (MRA). Requirements for and limitation on the use of this alternative are defined in approved procedures. These controls are based on NRC endorsed industry guidance.

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 to 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 / transportation systems and other items subject to the requirements of the QAP. 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 maintained as QA Records.

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 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. Measuring and test equipment is identified to indicate its 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 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 proper disposition has been determined. 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 dispositions are either 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 re-inspected and retested in accordance with the original inspection and test requirements or acceptable alternatives that comply 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 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 Americas LLC 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 Part 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 (CARs) 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 Compliance with the evaluation and reporting requirements of 10 CFR Part 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 Americas LLC, 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 Americas LLC 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 important-to-safety or safety-related structures, systems and components. These records include design, procurement, fabrication, assembly and erection records.

17.4 When applicable to TN Americas LLC 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 (hardcopy or electronic media) may be maintained at separate locations.

17.6 TN Americas LLC retains required records for at least three (3) years beyond the date of last engagement in the activities under the scope of the QAP for 10 CFR Part 71 related records and/or until the NRC terminates the CoC for 10 CFR Part 72 related records.

18.0 AUDITS

18.1 Procedures have been established to ensure that periodic audits are performed to verify compliance with the QAP 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 QAP activities commensurate with the status and importance of the activities.

18.2.1 Audit Equivalents:

Dependent on the program elements to be audited, TN Americas LLC may utilize equivalent activities such as independent assessments and technical surveillances to satisfy part or all of an audit requirement provided that the audit equivalent meets the following conditions:

- The requirements for a quality assurance audit are met (audit personnel qualification and independence)
- They are reviewed and approved for use as such by the organization responsible for the audit function
- Audit equivalents used to satisfy audits of the QA organization are reviewed and approved by the President

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 are 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 Noncompliance*
- *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 3, June 2015 – 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 NQA-1 – Quality Assurance Requirements for Nuclear Facility Applications*
- *ML14322A535 – Final Safety Evaluation For Technical Report NEI 14-05, "Guidelines For The Use Of Accreditation In Lieu Of Commercial Grade Surveys For Procurement Of Laboratory Calibration And Testing Services," Revision 1*
- *NEI 14-05A, March 2015 – Guidelines For The Use Of Accreditation In Lieu Of Commercial Grade Surveys For Procurement Of Laboratory Calibration And Testing Services*

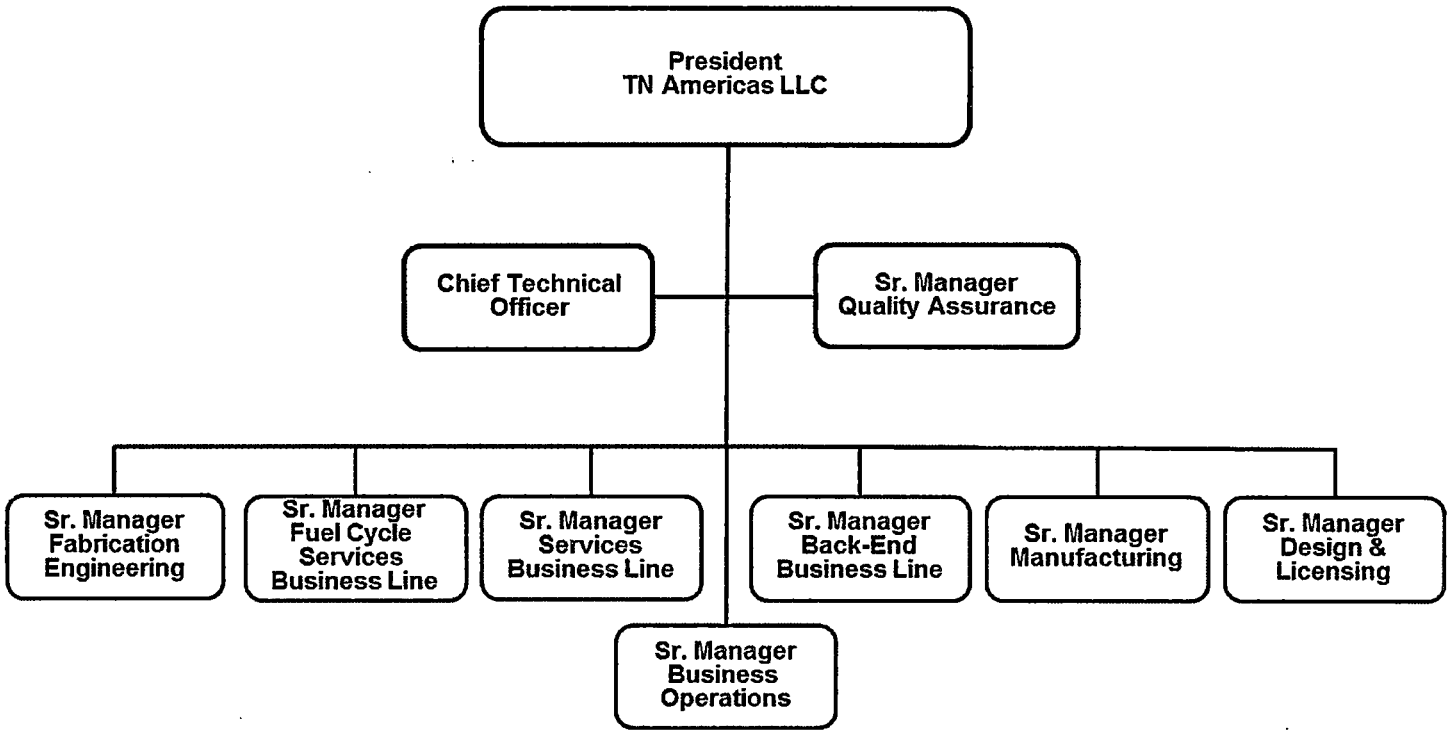


Figure 1 – TN Americas LLC Functional Organization for Quality Assurance Program Activities