TRANSNUCLEAR
AN AREVA COMPANY

TRANSNUCLEAR, INC.

Quality Assurance Program Description Manual for 10 CFR 71, Subpart H and 10 CFR 72, Subpart G

Revision 3
November 9, 2004

Alan S. Hanson
President

Date 11-09-04

Steven C. White
Director, Corporate Quality Assurance

Date 11/9/04

Introduction

The Transnuclear, Inc. Quality Assurance Program Description Manual for 10 CFR 71, Subpart H, and 10 CFR 72, Subpart G, has been developed as a means to describe the overall measures that control activities governing the design, procurement, fabrication, handling, shipping, cleaning, assembly, inspection, modification, testing, operation, repair, and maintenance of storage and transport systems for spent fuel and radioactive materials in accordance with the regulations pursuant to 10CFR71, Subpart H and 10CFR72, Subpart G. This Quality Assurance Program Description Manual (QAPDM) is also applicable to equipment controlled in accordance with the requirements of 10 CFR 50, Appendix B, as specifically identified in the NRC issued Certificate(s) of Compliance or referenced documents. This QAPDM applies to Transnuclear, Inc. and its subsidiary companies (hereafter referred to as Transnuclear) currently located as follows:

Transnuclear, Inc.
Four Skyline Drive
Hawthorne, NY 10532

Transnuclear, Inc.
39300 Civic Center Drive, Suite 280
Fremont, CA 94538

Packaging Technology, Inc. (PacTec)
1102 Broadway Plaza, Suite 300
Tacoma, WA 98424

Transnuclear, Inc.
7135 Minstrel Way
Columbia, MD 21045

Transnuclear, Inc.
310 Woodward Drive
Aiken, S.C 29803

For the purpose of this QAPDM, the entities listed above are considered Transnuclear operating entities. As such, each operating entity is responsible for the implementation of this QAPDM for its respective operations; however, the ultimate overall responsibility is retained by the President of Transnuclear, Inc.

The Transnuclear Quality Assurance Program is comprised of this QAPDM; the Transnuclear, Inc. Quality

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

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

This Introduction constitutes the statement of policy and quality assurance authority, has been issued and signed by the President of Transnuclear, Inc. as part of this manual, and defines Transnuclear's Quality Assurance Program as the Corporation's policy related to all quality affecting activities. This QAPDM contains the policies, assigns responsibilities, and describes and summarizes controls governing the activities described above.

The attainment of quality objectives is the responsibility of all Transnuclear personnel and compliance is mandatory for all Transnuclear personnel whose activities affect quality.

The Director, Corporate Quality Assurance has been delegated the overall responsibility for assuring the adequacy and effectiveness of the Quality Assurance Program. The Quality Assurance Managers are assigned full responsibility for verifying implementation of the TIPs and for ensuring uniform implementation of the QAPDM.

The Quality Assurance Managers have the authority to limit further processing on items of indeterminate quality, initiate management action to resolve any deficiencies, and ensure that satisfactory resolutions are achieved prior to authorizing further processing.

1.0 Organization

1.1 Responsibility for compliance with Transnuclear's Quality Assurance Program resides ultimately with the President of Transnuclear, Inc. Quality Assurance Program activities include Transnuclear actions necessary to comply with the quality criteria of 10 CFR 71, Subpart H; 10 CFR 72, Subpart G; and 10 CFR 50, Appendix B. When outside suppliers are used for performance of quality related activities, Transnuclear qualifies those organizations to ensure compliance with applicable criteria, however Transnuclear retains the overall responsibility for the quality of those activities.

1.2 The President has full authority over all functions of the company, and delegates authority and responsibility for selected functions to other appropriately qualified personnel within the company as outlined in the QAPDM. The entire organization is responsible for implementation of the Quality Assurance Program within their scope of operation and responsibilities.

1.3 The Engineering/Project Departments and personnel assigned to perform licensing activities are responsible for the technical aspects of a project including design, procurement, preparation of licensing documents, and construction and delivery of storage/transport systems, as applicable.

1.4 The Quality Assurance Department is responsible for the development, implementation and administration of the Transnuclear QAPDM and TIPs. The QA Department has sufficient authority and organizational freedom to identify quality problems, implement corrective action and verify corrective action effectiveness and has sufficient independence from cost and schedule considerations when such considerations are opposed to safety considerations.

1.5 Quality Assurance Department personnel are independent from other departments and report directly to a QA Manager or the Supervisor, Supplier Oversight. The QA Managers and the Supervisor, Supplier Oversight report to the Director, Corporate QA who reports directly to the President of Transnuclear, Inc. If a Quality Assurance Manager cannot resolve an issue with the Director, Corporate QA, then they have the authority to bring that issue to the President of Transnuclear, Inc. for resolution. The QA Managers must have sufficient expertise in the field of Nuclear Quality Assurance to enable them to direct the quality functions in accordance with the applicable regulatory criteria invoked by this Quality Assurance Program Description. The Quality Assurance Managers and other quality personnel and/or organizations within, or utilized by Transnuclear, are qualified for their responsibilities. Records supporting QA personnel qualifications are maintained as Quality Assurance records.

1.6 The Quality Assurance Managers are also responsible for delegating the performance of quality-related tasks to persons qualified by virtue of their education, training and experience, and to evaluate the adequacy of performance of those delegated tasks.

1.7 It is delineated in writing, by the President, that designated QA personnel have the authority to prevent the continued processing, fabrication, installation, delivery or use of unsatisfactory work.

1.8 The Organization Chart for Transnuclear, Inc. is included in this QAPDM as Figure 1.

2.0 Quality Assurance Program

2.1 Transnuclear has established and implemented a Quality Assurance Program consistent with the regulations and codes defined in the Introduction for the control of quality in the design, procurement, fabrication, handling, shipping, cleaning, assembly, inspection, modification, testing, operation, repair and maintenance of shipping/storage systems for spent fuel and radioactive materials which are classified as important-to-safety or safety-related. The Transnuclear Quality Assurance Program is comprised of this QAPDM, the ASME QAPDM, and Transnuclear Implementing Procedures (TIPs). The TIPs are designed and administered to meet the requirements of 10 CFR 71, Subpart H; 10 CFR 72, Subpart G; 10 CFR 50, Appendix B; ASME Section III, Division 1 (NCA 4000) and Division 3 (WA 4000). The QA Program identifies the methods utilized to classify components and provide control over activities affecting their quality based upon their importance to safety. The Quality Assurance Program is designed to ensure that quality requirements, engineering specifications, provisions of the ASME Code when applicable, and specific provisions of approved designs are met and complied with at all times.

2.2 Training and/or evaluation of personnel qualifications are required for all QA functions in accordance with written procedures. Transnuclear's training program requires that employees who participate in Quality Assurance Program activities receive training commensurate with their involvement in those activities. Transnuclear personnel performing test and inspection activities are qualified in accordance with written procedures.

2.3 The President requires that the Quality Assurance Program be implemented and enforced on applicable quality and Code related activities at Transnuclear, Inc. locations, as well as at approved supplier facilities. The Director, Corporate Quality Assurance regularly evaluates the Quality Assurance Program for adherence to the baseline commitments in scope, implementation and effectiveness.

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

3.0 Design Control

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

3.1.1 Design activities are planned, controlled and documented.

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

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

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, Transnuclear's Quality Assurance Program provides for ensuring that licensing considerations have been reviewed and are complied with or otherwise reconciled by amending licenses for Transport Applications or evaluated in accordance with the requirements of 10 CFR 72.48 for Storage Applications.

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

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

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

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

4.0 Procurement Document Control

4.1 Transnuclear Implementing Procedures have been established to assure that procurement documents are

prepared to clearly define applicable technical and quality assurance requirements including codes, standards, regulatory requirements and commitments, and contractual requirements. These documents serve as the principal documents for the procurement of structures, systems and components, and related services for use in the design, fabrication, maintenance and operation, inspection and testing of storage and/or transportation systems. The Quality Assurance Program ensures that purchased material, components, equipment and services adhere to the applicable requirements.

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

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

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

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

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

4.7 Transnuclear maintains the rights of access to supplier facilities and performance of source surveillance and/or audit activities, as applicable. A statement to this effect is included in procurement documents.

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

5.0 Instructions, Procedures and Drawings

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

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

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

5.4 Compliance with these approved instructions, procedures and drawings is mandatory for Transnuclear personnel while performing activities affecting quality.

6.0 Document Control

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

6.1.1 Design specifications

6.1.2 Design and fabrication drawings

6.1.3 Special process specifications and procedures

6.1.4 QA Program Description Manuals and TIPs

6.1.5 Test procedures

6.1.6 Operational test procedures and data.

6.2 Changes to documents, which prescribe activities affecting quality, 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 activities affecting quality 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 activities affecting quality are performed prior to commencing the work.

7.0 Control of Purchased Materials, Parts and Components

7.1 Transnuclear Implementing Procedures have been established to assure 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 item/activity being purchased.

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

7.3.1 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, or ASME Section III that are applicable to the scope of work to be performed.

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

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

7.5 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 Transnuclear for review and approval. These conditions are reviewed by technical and quality personnel to assure that they have not compromised the quality of the item or service.

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

7.7 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 10 CFR 71, 10 CFR 72, 10 CFR 50 criteria, procurement document requirements, or contract specifications is performed in accordance with approved TIPs.

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

8.0 Identification and Control of Materials, Parts and Components

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

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

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

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

9.0 Control of Special Processes

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

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

9.3 Personnel who perform special processes are trained and qualified in accordance with applicable codes, standards, specifications, or and other special requirements. Records of qualified procedures and personnel are filed and kept current by the organization that performs the special processes.

10.0 Inspection

10.1 Transnuclear Implementing Procedures have been established to assure that inspection or surveillance is performed to verify that materials, parts, processes or other activities affecting quality conform to documented instructions, procedures, specifications, drawings, or procurement documents.

10.2 Personnel performing inspection and surveillance activities shall be trained and qualified in accordance with written 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 safety-related and important-to-safety structures, systems and components are inspected in accordance with the original design and inspection requirements or acceptable alternatives.

10.6 Mandatory hold points, inspection equipment requirements, acceptance criteria, personnel qualification requirements, performance characteristics, variable and/or attribute recording instructions, reference documents, and other requirements are considered and included, as applicable, during inspection and surveillance planning.

11.0 Test Control

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

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

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

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

11.3.2 Instructions for performance of tests, including environmental conditions;

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

11.3.4 Provisions for data recording and records retention.

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

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

12.0 Control of Measuring and Test Equipment

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

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

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

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

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

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

13.0 Handling, Storage and Shipping

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

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

14.0 Inspection, Test and Operating Status

14.1 Transnuclear Implementing Procedures have been established to assure that the inspection and test status

of materials, items, structures, systems and components throughout fabrication, installation, operation and test are clearly indicated by suitable means, (e.g., tags, labels, cards, form sheets, check lists, etc.).

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

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

14.4 Any nonconforming items are identified and controlled in accordance with Section 15 of this QAPDM.

15.0 Nonconforming Material, Parts or Components

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

15.2 Nonconforming items include those items that do not meet specification or drawing requirements. Additionally, nonconforming items include items not fabricated or tested (1) in accordance with approved written procedures, (2) by qualified processes, or (3) by qualified personnel; where use of such procedures, processes or personnel is required by the fabrication, test, inspection or 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 shall be 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. The nonconformance report includes 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 nonconformance reports and approved following completion of the disposition.

15.6 Acceptability of rework or repair of nonconforming materials, parts, and components is verified by re-inspecting and/or re-testing the item to the original

requirements or equivalent inspection/testing methods. Inspection, testing, rework, and repair methods are documented and controlled.

15.7 The disposition of nonconforming items as ***use-as-is*** or ***repair*** shall include technical justification and independent verification to assure 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 made part of the inspection records and are periodically reviewed to identify quality trends. Unsatisfactory quality trends are documented on a Corrective Action Report as detailed in Section 16 of this QAPDM. The results of these reviews are reported to management.

15.11 Nonconformance reports related to activities internal to Transnuclear are issued to the management of the affected organization. The appropriate Quality Assurance Manager approves their disposition and performs follow-up activities to assure proper closure.

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

16.0 Corrective Action

16.1 Transnuclear Implementing Procedures have been established to identify significant conditions adverse to quality. Significant and/or repetitive failures, malfunctions and deficiencies in material, components, equipment and operations are promptly identified and documented on a Corrective Action Reports (CARs) and reported to appropriate management. The cause of the condition and corrective action necessary to prevent recurrence are identified, implemented and followed up to verify corrective action is completed and effective.

16.2 The Director, Corporate Quality (DCA) is responsible for ensuring implementation of the corrective action program, including follow up and close-out actions. The DCA may delegate certain activities in the Corrective Action process to others.

17.0 Quality Assurance Records

17.1 Transnuclear Implementing Procedures have been established to assure the control of quality records. The purpose of the Quality Assurance Records system is to

assure that documented evidence pertaining to quality related activities is maintained and available for use by Transnuclear, 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 Transnuclear 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 regulations to furnish evidence of activities affecting the quality of structures, systems and components that are safety-related or important-to-safety. These records include records of design, procurement, fabrication, assembly and erection.

17.4 When Transnuclear performs maintenance, these records include the use of operating logs; results of reviews, inspections, tests, and audits; results from monitoring of work performance and material analyses; results of maintenance, modification, and repair activities; qualification of personnel, procedures and equipment; records of calibration of measuring and test equipment; and related instructions, procedures, and drawings.

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

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

18.0 Audits

18.1 Transnuclear Implementing Procedures have been established to assure that periodic audits to verify compliance with all aspects of the Quality Assurance Program and determine its effectiveness are performed. 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 Transnuclear audits supplier Quality Assurance Programs, procedures and implementation activities to

evaluate and verify that procedures and activities are adequate and comply with applicable requirements.

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

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

18.5 Responsible management shall undertake corrective actions as a follow-up to audit reports when appropriate. The Director, Corporate Quality Assurance shall evaluate audit results for indications of adverse trends that could affect quality. When results of such assessments so indicate, appropriate corrective action will be implemented.

18.6 The Director, Corporate Quality Assurance shall follow up on audit findings to assure that appropriate corrective actions have been implemented and directs the performance of re-audits when deemed necessary.

19.0 References

19.1 Title 10, Code of Federal Regulations, Part 21 - ***Reporting of Defects and Noncompliances***

19.2 Title 10, Code of Federal Regulations, Part 50, Appendix B – ***Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants***

19.3 Title 10, Code of Federal Regulations, Part 71, Subpart H – ***Packaging and Transportation of Radioactive Material, Quality Assurance***

19.4 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***

19.5 ASME Section III, Division 1 ***(NCA 4000 Quality Assurance)***

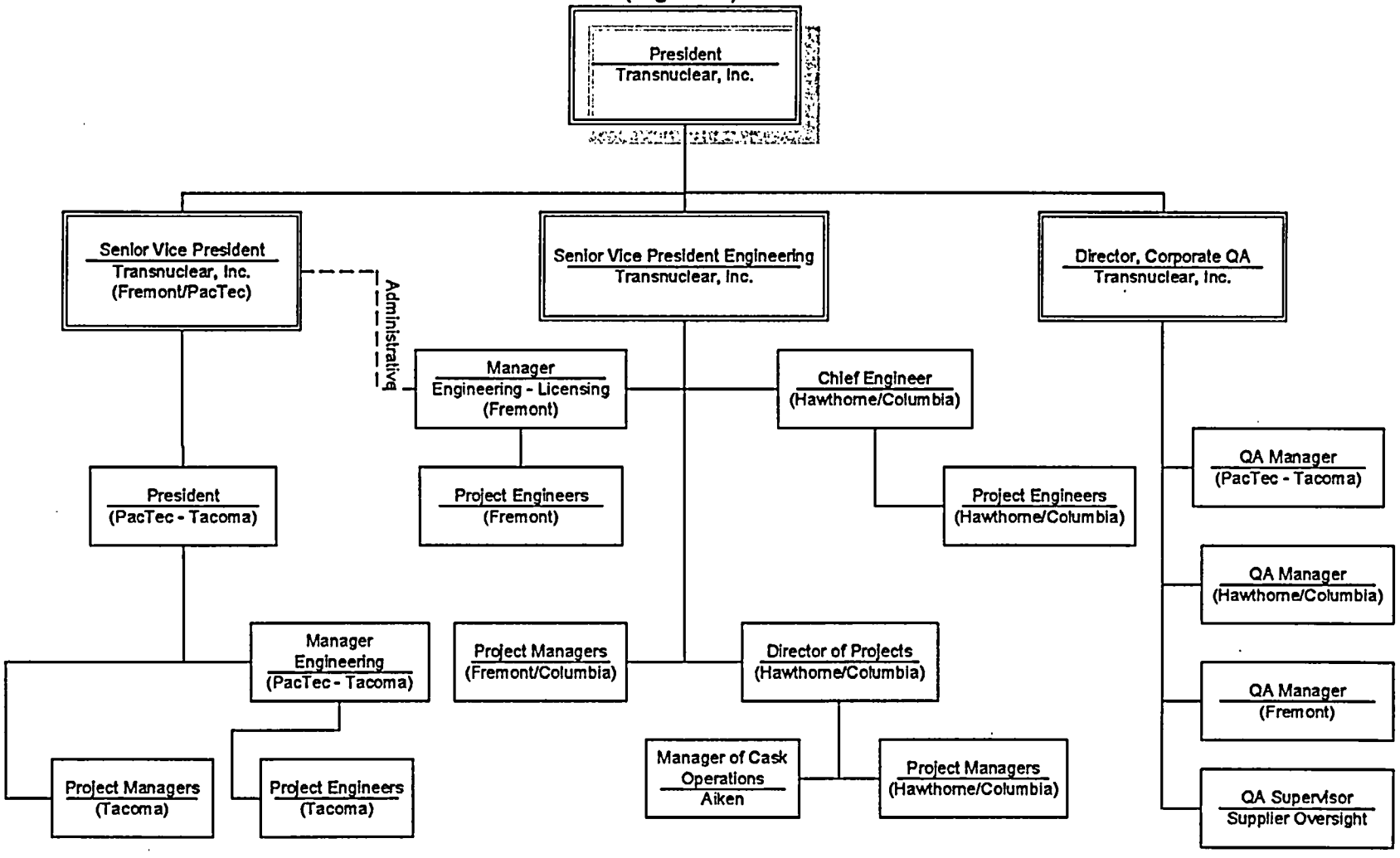
19.6 ASME Section III, Division 3 (***WA 4000 Quality Assurance***)

20.0 Attachments

Figure 1 - Transnuclear Organization Chart

Transnuclear, Inc. Organization

(Figure 1)



CURRENT REVISION 2 CONTENT WITH NO FORMATTING – PARAGRAPH NUMBERED & MARKED-UP

10 CFR 71, Subpart H/10 CFR 72, Subpart G Quality Assurance Program Description For Design, Fabrication, Inspection, Modification, Testing, Use and Maintenance of Storage and Transport Systems for Spent Fuel and Radioactive Material

Revision 2

March 15, 2001

FOR INFORMATION

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Introduction

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The Transnuclear Quality Assurance Program is comprised of this ~~Quality Program Description~~QAPDM; ~~the~~ Transnuclear, Inc. Quality Assurance Program Description Manual for ASME Section III, Division 1 and Division 3 (ASME QAPDM); and Transnuclear Implementing ~~implementing Quality~~ Procedures (TIPs). The TIPs are designed and administered to meet the ~~eighteen (18) criteria~~ requirements of 10 CFR 71, Subpart H~~,~~; 10 CFR 72, Subpart G~~,~~; ~~and~~ 10 CFR 50, Appendix B~~,~~ and ASME Section III, Division 1 (NCA 4000) and Division 3 (WA 4000).

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

This Introduction constitutes the ~~A~~ statement of policy and quality assurance authority, has been issued and signed by the President of Transnuclear, Inc. as part of this manual, and defines Transnuclear's Quality~~uality~~ Assurance~~ssurance~~ Program as the Corporation's policy related to all quality affecting activities. ~~The~~ This QAPDM ~~Program~~ contains the policies, assigns responsibilities, and describes and summarizes controls governing the activities described above.

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The ~~statement of policy and authority includes a statement that~~ attainment of quality objectives is the responsibility of all Transnuclear personnel. ~~It also states that~~ and compliance ~~with the Transnuclear Quality Assurance Program~~ is mandatory for all Transnuclear personnel whose activities affect quality.

The Director, Corporate Quality Assurance has been delegated the overall responsibility for assuring the adequacy and effectiveness of the Quality Assurance Program. The Quality Assurance Managers ~~for the respective operating entity is~~are assigned~~given~~ full responsibility for verifying implementation of the TIPs~~Quality Assurance Procedures~~ and for ensuring uniform implementation of the QAPDM~~uality Assurance Program~~.

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The ~~respective~~ Quality Assurance Manager~~s~~ ~~has~~ have the authority to limit further processing on items of indeterminate quality, initiate management action to resolve any deficiencies, and ensure that satisfactory resolutions are achieved prior to authorizing further processing.

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~~DESCRIPTION OF THE TRANSNUCLEAR 10 CFR 71/10 CFR 72 QUALITY PROGRAM~~

1.0 ~~Criterion 1 –~~ Organization

1.1 Responsibility for compliance with Transnuclear's Quality Assurance Program resides ultimately with the President of Transnuclear, Inc. Quality Assurance Program activities include Transnuclear actions necessary to comply with the quality criteria of ~~as contained in~~ 10 CFR 71, Subpart H; 10 CFR 72, Subpart G; and 10 CFR 50, Appendix B. When outside suppliers are used for performance of quality related activities, Transnuclear qualifies those organizations to ensure compliance with ~~the~~ applicable ~~eighteen (18)~~ criteria; however, Transnuclear retains the overall responsibility for the quality of those activities.

1.2 The President has full authority over all functions of the company, and delegates authority and responsibility for selected functions to other appropriately qualified personnel within the company as outlined ~~by~~ in the ~~Quality Assurance Program~~QAPDM. The entire ~~Each~~ organization is responsible for implementation of the Quality Assurance Program within their scope of operation and responsibilities.

1.3 The Engineering/Project Departments and personnel assigned to perform licensing activities ~~of the respective operating entity~~ are responsible for the technical aspects of a project including design, procurement, preparation of licensing documents, construction and delivery of storage/transport systems, as applicable.

1.4 The Quality Assurance Department is responsible for the development, implementation and administration of the Transnuclear QAPDM and TIPs. The QA Department ~~of the respective operating entity~~ has sufficient authority and organizational freedom to identify quality problems, implement corrective action and verify corrective action effectiveness and has. ~~The Quality Assurance Departments have~~ sufficient independence from cost and schedule considerations when such considerations are opposed to safety considerations.

1.5 ~~The~~ Quality Assurance Departments personnel are ~~are~~ independent from other departments ~~within their respective operating entity~~ and report directly to a ~~the~~ QA Manager ~~Director, Corporate QA~~ or the Supervisor, Supplier Oversight. The QA Managers and the Supplier Oversight Supervisor report to the ~~The~~ Director, Corporate QA who reports directly to the President of Transnuclear, Inc. ~~The Quality Assurance Departments are headed by Quality Assurance Managers who, by delegation from the President, are responsible for the development, verification of implementation and administration of the Transnuclear Quality Assurance Program within that organization.~~ If a Quality Assurance Manager cannot resolve an issue with the Director, Corporate QA, then they ~~QA Manager has~~ have the authority to bring that issue to the President of Transnuclear, Inc. for resolution. The QA Managers must have sufficient expertise in the field of Nuclear Quality Assurance to enable them to direct the quality functions in accordance with the applicable regulatory criteria invoked by this Quality Assurance Program Description. The Quality Assurance Managers and other quality personnel and/or organizations within, or utilized by Transnuclear, are qualified for their responsibilities. Records sSupporting QA personnel qualifications ~~records~~ are maintained as ~~in~~ Quality Assurance records. ~~Record files~~.

1.6 The Quality Assurance Managers are also responsible for ~~assurance that quality acceptance requirements have been developed for inspections and Non-Destructive Examination activities.~~

~~It is also their responsibility to delegate~~ delegating the performance of quality-related tasks to persons qualified by virtue of their education, training and experience, and to evaluate the adequacy of performance of those delegated tasks.

1.7 It is delineated in writing, by the President, that designated QA personnel have the authority to prevent the continued processing, fabrication, installation, delivery or use of unsatisfactory work.

1.8 The ~~Functional~~ Organization Chart for Transnuclear, Inc. is ~~shown at the end~~ included in~~of~~ this ~~program description~~ QAPDM as ~~Attachment~~ Figure 1.

2.0 ~~Criterion 2—~~Quality Assurance Program

2.1 Transnuclear has established and implemented a Quality Assurance Program consistent with the regulations and c~~C~~odes defined in the ~~I~~introduction for the control of quality in the design, procurement, fabrication, handling, shipping, cleaning, assembly, inspection, modification, testing, operation, repair and maintenance of shipping/storage systems for spent fuel and radioactive materials which are classified as important-to-safety or safety-related. ~~The Transnuclear Quality Assurance Program is comprised of this QA Program Description containing corporate quality policy, supplemented by a series of written approved Quality Procedures containing detailed implementation instructions.~~ The Transnuclear Quality Assurance Program is comprised of this QAPDM, the ASME QAPDM, and Transnuclear Implementing Procedures (TIPs). The TIPs are designed and administered to meet the requirements of 10CFR71, Subpart H; 10CFR72, Subpart G; 10CFR50, Appendix B; ASME Section III, Division 1 (NCA 4000) and Division 3 (WA 4000). The QA Program identifies the methods utilized to classify components and provide control over activities affecting their quality based upon their importance to safety. The Quality Assurance Program is designed to ensure that quality requirements, engineering specifications, provisions of the ASME Code when applicable, and specific provisions of ~~the~~ approved designs are met and complied with at all times.

2.2 Training and/or evaluation of personnel qualifications are required for all QA functions in accordance with written procedures. Transnuclear's training program requires that employees who participate in ~~the~~ Quality Assurance Program activities receive training commensurate with their involvement in those activities. Transnuclear personnel performing test and inspection activities are qualified in accordance with written procedures.

2.3 The President requires that the Quality Assurance Program be implemented and enforced on applicable quality and Code related activities at Transnuclear, Inc. locations, as well as ~~and their~~ at approved supplier facilities. The ~~QA Manager~~ Director, Corporate Quality Assurance ~~for each Transnuclear operating entity~~ regularly evaluates the Quality Assurance Program for adherence to the ~~eighteen (18) criteria~~ baseline commitments in scope, implementation and effectiveness, ~~within that entity.~~

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

3.0 ~~Criterion 3—~~Design Control

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

~~(a)~~3.1.1 Design activities are~~y~~ ~~is~~ planned, controlled and documented.

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

(c)3.1.3 Competent engineering personnel, independent of the design activityies, 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.

3.1.4(d) Design interface controls are established and adequate.

3.1.5(e) 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, Transnuclear's Quality Assurance Program provides for ensuring that licensing considerations have been reviewed and are complied with or otherwise reconciled by amending licenses licensing amendment for Ttransport Aapplications or evaluated in accordance with the requirements of 10 CFR-72.48 for Sstorage Applications.

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

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

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

3.3 Computer programs used for design analysis or verification are controlled in accordance with approved TIPsQuality 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 Criterion 4 – Procurement Document Control

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

4.2 Supplier evaluation and selection, objective evidence of supplier quality, The assignment of quality requirements through to procurement documents, source surveillance, and receipt inspection are is administered and controlled in accordance with written approved TIPsQuality Procedures.

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

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4.4 Quality requirements are included inwith quality-related purchase orders. Quality TransnuclearAssurance personnel assign quality requirements within the procurement documents, as applicable to the scope of the procurement referencing 10-CFR-71, Subpart H; 10-CFR-72, Subpart G; or 10-CFR-50, Appendix B, or ASME Section III, as appropriate.

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

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

4.7 Transnuclear Quality Assurance personnel maintains the rights of access to supplier's facilities and documentationperformance of for source surveillance and/or audit activities, as applicable. A statement to this effect is included in procurement documentsation.

4.8 Procurement documents also address the applicability of the provisions of 10 CCFR-21 for the Reporting of Defects and Noncompliances.

5.0 Criterion 5—Instructions, Procedures and Drawings

5.1 Transnuclear Implementing Procedures have been established to assure that mMethods for complying with each of the applicable eighteen (18) criteria of 10-CFR-71, Subpart H; 10-CFR-72, Subpart G; or 10-CFR-50, Appendix B, or ASME Section III, as applicable, for activities affecting quality during design, fabrication, inspection, testing, use and maintenance are specified in instructions, procedures, and/or drawings.

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

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

5.4 Compliance with these approved instructions, procedures and drawings is mandatory for Transnuclear personnel while performing activities affecting quality.

6.0 Criterion 6—Document Control

6.1 Transnuclear Implementing Procedures Measures have been established and are implemented to control the issuance of documents that prescribe activities affecting quality and to assure. Quality Procedures define document control measures to ensure adequate review, approval, release release, and distribution, and use of documents and their revisions. Controlled documents may include, but are not limited to:

(a)6.1.1 Design specifications

6.1.2(b) Design and fabrication drawings

(c)6.1.3 Special process specifications and procedures

(d)6.1.4 QA Program Description Manuals and TIPsProcedures

~~(e)~~6.1.5 Test pProcedures

~~(f)~~6.1.6 Operational test procedures and data.

6.2 Changes to documents, which prescribe activities affecting quality, are reviewed and approved by the same organization that performed the initial review and approval, or by ~~equally~~ qualified responsible organizations.

6.3 Documents that prescribe activities affecting quality 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 activities affecting quality are performed prior to commencing the work.

7.0 ~~Criterion 7 –~~ Control of Purchased Materials, Parts and Components

7.1 Transnuclear Implementing ~~Quality~~ Procedures have been established ~~and are implemented~~ to assure ~~ensure~~ that purchased material, equipment and services conform to procurement documents.

7.2 Procurement documents are reviewed and approved by authorized ~~QA~~ personnel for acceptability of proposed ~~suggested~~ suppliers based on the quality requirements of the item/activity being purchased. ~~and the Approved Suppliers List.~~

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

~~(a)~~7.3.1 The supplier's capability to comply with the requirements of 10-CFR-71, Subpart H; 10-CFR-72, Subpart G; ~~or~~ 10-CFR-50, Appendix B, or ASME Section III that are applicable to the scope of work to be performed.

~~(b)~~7.3.2 A review of previous records to establish the past performance of the supplier.

~~(c)~~7.3.3 A survey of the supplier's facilities and review of the supplier's QA Program to assess the adequacy and verify implementation of ~~a Quality Program~~ quality controls consistent with the requirements ~~regulations to be~~ being invoked.

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

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

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7.6 ~~The Quality Assurance Program provides for~~ Periodic surveillance of supplier in-process activities is performed as necessary, to verify suppliers' compliance with the procurement documents. When deemed necessary, the need for surveillance is noted in approved quality or project planning documents, and surveillances are ~~conduct~~performed and documented in accordance with approved TIPs~~Quality Procedures~~. Personnel performing surveillance of supplier activities are trained and qualified in accordance with approved procedures.

7.7 Quality planning ~~is prepared and approved by authorized QA personnel~~ for the performance of source surveillance, test, shipping and/or receiving inspections ~~and surveillance~~ activities to verify compliance with ~~in accordance with~~ approved design and licensing requirements, applicable 10-CFR-71/10-CFR-72/10-CFR-50 criteria, procurement document requirements, ~~or and~~ contract specifications is performed in accordance with approved TIPs.

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

8.0 ~~Criterion 8—~~Identification and Control of Materials, Parts and Components

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

8.2 R~~The r~~equirements for identification are established during the preparation of procedures and specifications.

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

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

9.0 ~~Criterion 9—~~Control of Special Processes

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

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

9.3 Personnel who perform special processes are ~~formally~~ trained and qualified in accordance with applicable codes, standards, ~~or~~ specifications, ~~or criteria~~ and other special requirements. Records of qualified ~~Qualified records of~~ procedures and personnel are filed and kept current by the organization that performs the special processes.

10.0 ~~Criterion 10—~~Inspection

10.1 Transnuclear Implementing ~~Quality~~ Procedures have been established ~~and are implemented~~ to assure that ~~for the~~ inspection or surveillance is performed to verify that ~~of~~ materials, parts, processes or other activities affecting quality ~~to verify~~ conformance with documented instructions, procedures, specifications, drawings, or ~~other~~ procurement documents, ~~and for Transnuclear surveillance of supplier activities.~~

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10.2 Personnel performing inspection and surveillance activities shall be trained and qualified in accordance with written approved procedures.

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

10.~~2~~4 Inspection or surveillance and process monitoring are both required where either one by itself will not provide assurance ~~adequate~~ of quality. ~~control.~~

10.~~3~~5 Modifications and/or repairs to and replacements of safety-related and important-to-safety structures, systems and components are inspected in accordance with the original design and inspection requirements or acceptable alternatives.

10.64 Mandatory hold points, inspection equipment requirements, acceptance ~~accept-reject~~ criteria, personnel qualification requirements, performance characteristics ~~to inspect~~, variable and/or attribute recording instructions, reference ~~documentation~~ documents, and other requirements are considered and included, as applicable, during inspection and surveillance planning.

11.0 ~~Criterion 11—~~Test Control

11.1 Transnuclear Implementing ~~Quality~~ Procedures have been ~~are~~ established ~~and implemented~~ to assure that ~~perform r~~required proof, acceptance and operational tests, as identified in design or procurement document~~sation~~, are performed and appropriately controlled.

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

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

~~(a)~~11.3.1 Acceptance criteria ~~The requirements and acceptance limits~~ contained in the applicable test specifications, or design and procurement documents;

~~(b)~~11.3.2 Instructions for performance of ~~the~~ tests, including environmental conditions;

~~(c)~~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

~~(d)~~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 ~~perform~~conducted after modifications, repairs or replacements of safety-related and important-to-safety structures, systems or components are performed in accordance with the original design and testing requirements or acceptable alternatives.

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12.0 ~~Criterion 12—~~Control of Measuring and Test Equipment

12.1 Transnuclear Implementing ~~Quality~~ Procedures are established ~~and implemented~~ to ~~ensure~~ assure ~~that~~ tools, gages, instruments and other measuring and testing devices (M&TE) used in activities affecting quality are properly controlled, calibrated and adjusted to maintain accuracy within required limits.

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

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

12.~~2~~4 M&TE ~~Measuring and test equipment~~ are ~~is~~ identified, labeled or tagged indicating the next required calibration due date, and traceable to calibration records~~,~~;
~~and are is labeled or tagged indicating the next required calibration due date.~~

12.~~3~~5 ~~If When measuring and test equipment~~M&TE are ~~is~~ found to be out of calibration, an evaluation is performed~~made~~ and documented regarding ~~of~~ the validity of inspections or tests ~~results~~ performed and ~~of~~ the acceptability of items inspected or tested since the previous acceptable calibration. The current status of M&TE~~measuring and test equipment under the calibration system~~, is recorded and maintained. ~~A If~~ any M&TE that are~~inspection, measuring or test equipment is~~ consistently found to be out of calibration~~;~~ shall be ~~it is~~ repaired or replaced.

12.~~6~~4 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 ~~Criterion 13—~~Handling, Storage and Shipping

13.1 Transnuclear Implementing ~~Quality~~ Procedures have been established ~~and are implemented~~ to ~~ensure~~ assure 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 ~~Criterion 14—~~Inspection, Test and Operating Status

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

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

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

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14.4 Any~~The status of~~ nonconforming items are~~is are documented,~~ identified and controlled ~~, and segregated to prevent inadvertent use,~~ in accordance with Section~~Criterion~~ 15 of this QAPDM.

15.0 ~~Criterion 15—~~Nonconforming Material, Parts or Components

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

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

15.3 Nonconforming items are identified and 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 shall be ~~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.

~~Nonconforming items are be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions are employed to preclude inadvertent use of the item.~~

15.4 Nonconforming conditions are documented on nonconformance reports (NCRs) and ~~the~~ affected organizations are notified. The nonconformance report includes a description of the nonconforming condition. ~~As a minimum,~~ Nnonconforming 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 nonconformance reports and ~~,~~ approved ~~and signed~~ following completion of the disposition.

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

15.7 The disposition of n~~N~~onconforming items as ~~dispositioned~~ "***use-as-is***" or "***repair***" shall include technical justification and independent verification ~~requirements to indicate and~~ to assure ~~ensure continued~~ 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.

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

15.11 Nonconformance reports are made part of the inspection records and are periodically reviewed to identify quality trends. Unsatisfactory quality trends are documented on a Corrective Action Report as detailed in Section ~~Criterion~~ 16 of this QAPDM. The results of these reviews are reported to management ~~for their assessment~~.

15.12 Nonconformance reports relate~~ding~~ to activities internal to Transnuclear are issued to the management of the affected organization. The appropriate Quality Assurance Manager approves their disposition and performs follow-up activities to ~~ensure~~ assure proper closure.

15.13 Compliance with the evaluation and reporting ~~Established procedures ensure the implementation of the~~ requirements of 10-CFR-21 related to ~~for the reporting of~~ defects and noncompliances is controlled by approved TIPs.

16.0 ~~Criterion 16 – Corrective Action~~

16.1 Transnuclear Implementing ~~Quality~~ Procedures have been established ~~and are implemented~~ to identify significant conditions adverse to quality. Significant and/or repetitive failures, malfunctions and deficiencies in material, components, equipment and operations are promptly identified and documented on a Corrective Action Reports (CARs) and reported to ~~the~~ appropriate management. The cause of the condition and corrective action necessary to prevent recurrence are identified, implemented and ~~then~~ followed-up to verify corrective action is completed and effective. ~~Detailed requirements for this activity are delineated in Quality Procedures.~~

16.2 The Director, Corporate Quality ~~Assurance Manager~~ (DCA) is responsible for ensuring implementation of the corrective action program, including follow up and close-out actions. The DCA may delegate certain activities in the Corrective Action process to others.

17.0 ~~Criterion 17 – Quality Assurance Records~~

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

17.2 Approved ~~Quality P~~ procedures identify the types of documents to be retained as Quality Assurance ~~R~~records, as well as those to be retained by the originating organization. *"Lifetime"* and *"Non-Permanent"* records are retained by Transnuclear or its ~~'~~ customers ~~the Transnuclear client~~, as appropriate. Records ~~The records~~ are identified, indexed and stored in accessible locations.

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

17.4 ~~Where~~ When Transnuclear performs maintenance, these records include the use ~~of~~ of operating logs~~,~~ ~~and the~~ results of reviews, inspections, tests, and audits; results from monitoring of work performance and material analyses; results of maintenance, modification, and repair activities; qualification of personnel, procedures and equipment; records of calibration of measuring and test equipment; and related instructions, procedures, and drawings.

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

17.6 ~~Maintenance of records at Transnuclear is in accordance with written approved procedures. These procedures address duration of storage, responsibilities for safekeeping, preservation, and disposition of nonpermanent records. Maintenance of Quality Records is in accordance with the approved Quality Procedure.~~ Transnuclear shall retain ~~these~~ required records for at least three (3) years beyond the date of last engagement in the activities under the scope of this ~~Quality Assurance Program~~QAPDM for 10-CFR-71 related records and until the Nuclear Regulatory Commission terminates the Certificate of Compliance for 10-CFR-72 related records.

18.0 ~~Criteria 18 –~~ Audits

18.1 Transnuclear ~~Quality~~ Implementing Procedures have been established ~~and implemented~~ to assure that ~~plan and perform~~ periodic audits to verify compliance with all aspects of the Quality Assurance Program and determine its effectiveness are performed. Those a~~The audit program identifies ar~~eas and activities to be audited, such as design ~~activities,~~ procurement, fabrication, inspection, and testing of storage/transportation systems, s are identified in audit planning.~~.~~

18.2 ~~The audit program includes audits by~~ Transnuclear audits ~~of~~ supplier Quality Assurance Programs, procedures and implementation activities to evaluate and verify that procedures and activities are adequate and comply with applicable requirements~~the overall Quality Assurance Program. Suppliers of safety-related or important-to-safety equipment, material or services are required to implement programs to verify compliance with all applicable aspects of their Quality Assurance Program and to determine its effectiveness.~~

18.3 Audits are planned and scheduled in a manner to provide coverage and coordination with ongoing Quality Assurance Program activities commensurate with the~~ir~~ status and importance of the activity~~ies~~.

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

CURRENT REVISION 2 CONTENT WITH NO FORMATTING – PARAGRAPH NUMBERED & MARKED-UP

18.5 Responsible management shall undertake corrective actions as a follow-up to audit reports when appropriate. The Director, Corporate Quality Assurance ~~Manager~~ shall evaluate audit results for indications of adverse trends that could affect quality. When results of such assessments so indicate, appropriate corrective action will be implemented.

18.6 The Director, Corporate Quality Assurance ~~Manager~~ shall follow up on audit findings to assure that appropriate corrective actions haves been implemented and directs the performance of a ~~performs~~ re-audits ~~where~~ when ~~considered appropriate~~deemed necessary.

~~A qualified lead auditor shall lead audits of project activities for which Transnuclear has direct responsibility.~~

19.0 References

19.1 Title 10, Code of Federal Regulations, Part 21 - *Reporting of Defects and Noncompliances*

19.2 Title 10, Code of Federal Regulations, Part 50, Appendix B – *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*

19.3 Title 10, Code of Federal Regulations, Part 71, Subpart H – *Packaging and Transportation of Radioactive Material, Quality Assurance*

19.4 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*

19.5 ASME Section III, Division 1 (NCA 4000 Quality Assurance)

19.6 ASME Section III, Division 3 (WA 4000 Quality Assurance)

20.0 Attachments

20.1~~1~~) Figure1 - Transnuclear Functional Organization Chart

10 CFR 71, Subpart H/10 CFR 72, Subpart G Quality Assurance Program Description For Design, Fabrication, Inspection, Modification, Testing, Use and Maintenance of Storage and Transport Systems for Spent Fuel and Radioactive Material

Revision 2

March 15, 2001

Transnuclear, Inc.
Four Skyline Drive
Hawthorne, NY 10532

Approvals

Alan S. Hanson, President	Alan S. Hanson	3-15-01
W. R. Sutherland, QA Manager	W. R. Sutherland	3/16/01

Transnuclear West Inc.
39300 Civic Center Drive, Suite 280
Fremont, CA 94538

Approvals

Robert M. Grenier, President	Robert M. Grenier	3/15/2001
T. C. Chen, QA Manager	T. C. Chen	3/15/2001

Packaging Technology, Inc.
4507-D Pacific Highway East
Tacoma, WA 98424

Approvals

Robert A. Johnson, President	Robert A. Johnson	3/15/01
B. C. Counterman, QA Manager	Bernard C. Counterman	3/15/01

Introduction

This Quality Assurance Program Description has been developed as a means to describe the overall measures that control activities governing the design, procurement, fabrication, handling, shipping, cleaning, assembly, inspection, modification, testing, operation, repair, and maintenance of storage and transport systems for spent fuel and radioactive materials in accordance with the regulations pursuant to 10 CFR 71, Subpart H and 10 CFR 72, Subpart G. This Quality Assurance Program Description is also applicable to equipment controlled in accordance with the requirements of 10 CFR 50, Appendix B, as specifically identified in the NRC issued Certificate of Compliance or referenced documents. This Quality Assurance Program Description applies to Transnuclear, Inc. and its' subsidiary companies (hereafter referred to as Transnuclear) currently located as follows:

Transnuclear, Inc.
Four Skyline Drive
Hawthorne, NY 10532

Transnuclear West Inc.
39300 Civic Center Drive, Suite 280
Fremont, CA 94538

Packaging Technology, Inc. (PacTec)
4507-D Pacific Highway East
Tacoma, WA 98424

For the purpose of this Quality Assurance Program Description, the entities listed above are considered Transnuclear operating entities. As such, each operating entity is responsible for the implementation of this Quality Assurance Program Description for its respective operations; however, the ultimate overall responsibility is retained by the President of Transnuclear, Inc.

The Transnuclear Quality Assurance Program is comprised of this Quality Program Description and implementing Quality Procedures designed and administered to meet the eighteen (18) criteria of 10 CFR 71, Subpart H, 10 CFR 72, Subpart G and 10 CFR 50, Appendix B.

A statement of policy and authority has been issued and signed by the President of Transnuclear, Inc. and defines Transnuclear's Quality Assurance Program as the Corporation's policy related to quality. The QA Program contains the policies, assigns responsibilities, and describes and summarizes controls governing the activities described above.

The statement of policy and authority includes a statement that attainment of quality objectives is the responsibility of all Transnuclear personnel. It also states that compliance with the Transnuclear Quality Assurance Program is mandatory for all Transnuclear personnel whose activities affect quality.

The Quality Assurance Manager for the respective operating entity is given full responsibility for verifying implementation of the Quality Assurance Procedures and for ensuring uniform implementation of the Quality Assurance Program.

The respective Quality Assurance Manager has the authority to limit further processing on items of indeterminate quality, initiate management action to resolve any deficiencies, and ensure that satisfactory resolutions are achieved prior to authorizing further processing.

DESCRIPTION OF THE TRANSNUCLEAR 10 CFR 71/10 CFR 72 QUALITY PROGRAM

Criterion 1 - Organization

Responsibility for compliance with Transnuclear's Quality Assurance Program resides ultimately with the President of Transnuclear, Inc. QA Program activities include Transnuclear actions necessary to comply with the quality criteria as contained in 10 CFR 71, Subpart H; 10 CFR 72, Subpart G; and 10 CFR 50, Appendix B. When outside suppliers are used for performance of quality related activities, Transnuclear qualifies those organizations to ensure compliance with the applicable eighteen (18) criteria; however, Transnuclear retains the overall responsibility for the quality of those activities.

The President has full authority over all functions of the company, and delegates authority and responsibility for selected functions to other appropriately qualified personnel within the company as outlined by the Quality Assurance Program. Each organization is responsible for implementation of the Quality Assurance Program within their scope of operation.

The Engineering/Project Department and personnel assigned to perform licensing activities of the respective operating entity are responsible for the technical aspects of a project including design, procurement, preparation of licensing documents, construction and delivery of storage/transport systems, as applicable.

The Quality Assurance Department of the respective operating entity has sufficient authority and organizational freedom to identify quality problems, implement corrective action and verify corrective action effectiveness. The Quality Assurance Departments have sufficient independence from cost and schedule considerations when such considerations are opposed to safety considerations.

The Quality Assurance Departments are independent from other departments within their respective operating entity and report directly to the Director, Corporate QA. The Director, Corporate QA reports directly to the President of Transnuclear, Inc. The Quality Assurance Departments are headed by Quality Assurance Managers who, by delegation from the President, are responsible for the development, verification of implementation and administration of the Transnuclear Quality Assurance Program within that organization. If a Quality Assurance Manager cannot resolve an issue with the Director, Corporate QA, then the QA Manager has the authority to bring that issue to the President of Transnuclear, Inc. for resolution. The QA Managers must have sufficient expertise in the field of Nuclear Quality Assurance to enable them to direct the quality functions in accordance with the applicable regulatory criteria invoked by this Quality Assurance Program Description. The Quality Assurance Managers and other quality personnel and/or organizations within, or utilized by Transnuclear, are qualified for their responsibilities. Supporting qualification records are maintained in Quality Assurance Record files.

The Quality Assurance Managers are responsible for assurance that quality acceptance requirements have been developed for inspections and Non-Destructive Examination activities.

It is also their responsibility to delegate the performance of quality-related tasks to persons qualified by virtue of their education, training and experience, and to evaluate the adequacy of performance of those delegated tasks.

It is delineated in writing, by the President, that designated QA personnel have the authority to prevent the continued processing, fabrication, installation, delivery or use of unsatisfactory work.

The Functional Organization Chart for Transnuclear, Inc. is shown at the end of this program description as Attachment 1.

Criterion 2 - Quality Assurance Program

Transnuclear has established and implemented a Quality Assurance Program consistent with the regulations defined in the introduction for the control of quality in the design, procurement, fabrication, handling, shipping, cleaning, assembly, inspection, modification, testing, operation, repair and maintenance of shipping/storage systems for spent fuel and radioactive materials which are classified as important-to-safety or safety-related. The Transnuclear Quality Assurance Program is comprised of this QA Program Description containing corporate quality policy, supplemented by a series of written approved Quality Procedures containing detailed implementation instructions. The QA Program identifies the methods utilized to classify components and provide control over activities affecting their quality based upon their importance to safety. The Quality Assurance Program is designed to ensure that quality requirements, engineering specifications and specific provisions of the approved design are met.

Training and/or evaluation of personnel qualifications are required for all QA functions in accordance with written procedures. Transnuclear's training program requires that employees who participate in the Quality Assurance Program activities receive training commensurate with their involvement in those activities. Transnuclear personnel performing test and inspection activities are qualified in accordance with written procedures.

The President requires that the Quality Assurance Program be implemented and enforced on applicable quality related activities at Transnuclear and their approved suppliers. The QA Manager for each Transnuclear operating entity regularly evaluates the Quality Assurance Program for adherence to the eighteen (18) criteria in scope, implementation and effectiveness within that entity.

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

Criterion 3 - Design Control

Transnuclear Quality Procedures have been developed to control design activities to ensure that the following occur:

(a) Design activity is planned, controlled and documented.

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

(c) Competent engineering personnel, independent of the design activity, 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.

(d) Design interface controls are established and adequate.

(e) 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, Transnuclear's Quality Assurance Program provides for ensuring that licensing considerations have been reviewed and are complied with or otherwise reconciled by licensing amendment for transport applications or evaluated in accordance with the requirements of 10 CFR 72.48 for storage.

(f) Design errors and deficiencies are documented and corrective action to prevent recurrence is taken.

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

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

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

Criterion 4 - Procurement Document Control

Procurement documents are prepared which clearly define applicable technical and quality assurance 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, inspection and testing of storage/transportation systems. The Quality Assurance Program ensures that purchased material, components, equipment and services adhere to the applicable requirements.

Supplier evaluation and selection, objective evidence of supplier quality, assignment of quality requirements to procurement documents, source surveillance, and receipt inspection are administered and controlled in accordance with written approved Quality Procedures.

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

Quality requirements are included with quality-related purchase orders. Quality Assurance personnel assign quality requirements within the procurement documents as applicable to the scope of the procurement referencing 10 CFR 71, Subpart H; 10 CFR 72, Subpart G; or 10 CFR 50, Appendix B, as appropriate.

Transnuclear procurement documents require the supplier to pass on appropriate quality assurance program requirements to subtier suppliers.

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

Transnuclear Quality Assurance personnel maintain the rights of access to supplier facilities and documentation for source surveillance and/or audit activities, as applicable. A statement to this effect is included in procurement documentation.

Procurement documents also address the applicability of the provisions of 10 CFR 21 for the Reporting of Defects and Noncompliance.

Criterion 5 - Instructions, Procedures and Drawings

Methods for complying with each of the applicable eighteen (18) criteria of 10 CFR 71, Subpart H; 10 CFR 72, Subpart G; or 10 CFR 50, Appendix B, as applicable, for activities affecting quality during design, fabrication, inspection, testing, use and maintenance are specified in instructions, procedures, and/or drawings.

Instructions, procedures and drawings are developed, reviewed, approved, utilized and controlled in accordance with the requirements of Quality Procedures. These instructions, procedures and drawings include appropriate quantitative and qualitative acceptance criteria. Changes to instructions, procedures and drawings, are developed, reviewed, approved, utilized and controlled using the same requirements as applied to the original documents. Compliance with these approved instructions, procedures and drawings is mandatory for Transnuclear personnel while performing activities affecting quality.

Criterion 6 - Document Control

Measures have been established and are implemented to control the issuance of documents that prescribe activities affecting quality. Quality Procedures define document control measures to ensure adequate review, approval, release and distribution and use of documents and their revisions. Controlled documents may include, but are not limited to:

(a) Design specifications

(b) Design and fabrication drawings

(c) Special process specifications and procedures

(d) QA Program Description and Procedures

(e) Test Procedures

(f) Operational test procedures and data.

Changes to documents, which prescribe activities affecting quality, are reviewed and approved by the same organization that performed the initial review and approval, or by equally qualified responsible organizations.

Documents that prescribe activities affecting quality are reviewed and approved for technical adequacy and inclusion of appropriate quality requirements prior to approval and issuance.

Measures are taken to ensure that current documents are available at the locations where activities affecting quality are performed prior to commencing the work.

Criterion 7 - Control of Purchased Materials, Parts and Components

Quality Procedures have been established and are implemented to ensure that purchased material, equipment and services conform to procurement documents.

Procurement documents are reviewed by authorized QA personnel for acceptability of suggested suppliers based on the quality requirements of the item/activity and the Approved Suppliers List.

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

(a) The supplier's capability to comply with the requirements of 10 CFR 71, Subpart H; 10 CFR 72, Subpart G; or 10 CFR 50, Appendix B, that are applicable to the scope of work to be performed.

(b) A review of previous records to establish the past performance of the supplier.

(c) A survey of the supplier's facilities and QA Program to assess the adequacy and verify implementation of a Quality Program consistent with the regulations to be invoked.

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

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

The Quality Assurance Program provides for surveillance of supplier in-process activities as necessary, to verify suppliers' compliance with the procurement documents. When deemed necessary, the need for surveillance is noted in approved quality planning documents, conducted and documented in accordance with Quality Procedures. Personnel performing surveillance of supplier activities are trained and qualified in accordance with approved procedures.

Quality planning is prepared and approved by authorized QA personnel for performance of source surveillance, test, shipping and/or receiving inspections and surveillance activities in accordance with approved design and licensing requirements, applicable 10 CFR 71/10 CFR 72/10 CFR 50 criteria, procurement document requirements and contract specifications.

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

Criterion 8 - Identification and Control of Materials, Parts and Components

Quality Procedures have been established and are implemented to identify and control materials, parts and components. These procedures ensure identification of an item by appropriate means during the fabrication, installation and use of the item and prevent the inadvertent use of incorrect or defective items. The requirements for identification are established during the preparation of procedures and specifications. The methods and location of identification information are selected so as to not adversely affect the fit, function or quality of the items being identified.

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

Criterion 9 - Control of Special Processes

Quality Procedures have been established and are implemented for the control of special processes used in the fabrication and inspection of storage/transport systems. These processes may include welding, non-destructive examination and other processes special to a specific component as identified in the procurement documents.

Special processes are performed in accordance with written approved procedures. Personnel who perform special processes are formally trained and qualified in accordance with applicable codes, standards or specification criteria and other special requirements. Qualified records of procedures and personnel are filed and kept current by the organization that performs the special process.

Criterion 10 - Inspection

Quality Procedures have been established and are implemented for the inspection of materials, parts, processes or other activities affecting quality to verify conformance with documented instructions, procedures, specifications, drawings, or other procurement documents and for Transnuclear surveillance of supplier activities.

Personnel performing inspection shall be trained and qualified in accordance with written approved procedures. Inspections are performed by individuals other than those who performed or supervised the activity being inspected.

Inspection and process monitoring are both required where either one by itself will not provide adequate quality control.

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

Mandatory hold points, inspection equipment requirements, accept-reject criteria, personnel requirements, characteristics to inspect, variable/attribute recording instructions, reference documentation and other requirements are considered and included, as applicable during inspection planning.

Criterion 11 - Test Control

Quality Procedures are established and implemented to perform required proof, acceptance and operational tests, as identified in procurement documentation.

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

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

(a) The requirements and acceptance limits contained in the applicable test specifications or design and procurement documents;

(b) Instructions for performance of the test including environmental conditions;

(c) Test prerequisites such as test equipment and instrumentation requirements, personnel qualification requirements, fabrication or operational status of the item to be tested; and

(d) Provisions for data recording and retention.

Test results are documented and evaluated to ensure that acceptance criteria have been met. Tests performed after modifications, repairs or replacements of safety-related and important-to-safety structures, systems or components are performed in accordance with the original design and testing requirements or acceptable alternatives.

Criterion 12 - Control of Measuring and Test Equipment

Quality Procedures are established and implemented to ensure that tools, gages, instruments and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated and adjusted to maintain accuracy within required limits. These measuring devices are calibrated at scheduled intervals against certified standards having known valid relationships to national standards. If no national standards exist, the basis for calibration is documented. Intervals are based on required accuracy, precision, purpose, amount of use, stability characteristics and other conditions that could affect the measurements. Calibrations are performed in accordance with approved written procedures. Inspection, measuring and test equipment are marked to indicate calibration status.

Measuring and test equipment is identified and traceable to calibration records, and is labeled or tagged indicating the next required calibration due date.

When measuring and test equipment is found to be out of calibration, an evaluation is made and documented of the validity of inspections or test results performed and of the acceptability of items inspected or tested since the previous acceptable calibration. The status of measuring and test equipment under the calibration system is recorded and maintained. If any inspection, measuring or test equipment is consistently found to be out of calibration, it is repaired or replaced.

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

Criterion 13 - Handling, Storage and Shipping

Quality Procedures have been established and are implemented 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.

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

Criterion 14 - Inspection, Test and Operating Status

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

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

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

The status of nonconforming items are documented, identified, and segregated to prevent inadvertent use, in accordance with Criterion 15.

Criterion 15 - Nonconforming Material, Parts or Components

Quality Procedures have been established and are implemented 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.

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

Nonconforming items are identified and segregated to prevent their inadvertent use. 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. Nonconforming items are be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions are employed to preclude inadvertent use of the item.

Nonconforming conditions are documented on nonconformance reports and the affected organizations are notified. The nonconformance report includes a description of the nonconforming condition. As a minimum, nonconforming items are dispositioned as *use-as-is, reject, repair, or rework.*

Inspection requirements for nonconforming items following rework, repair or modification are detailed in the nonconformance reports, approved and signed following completion of the disposition.

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

Nonconforming items dispositioned "*use-as-is*" or "*repair*" include technical justification and independent verification requirements to indicate and ensure continued compliance with design, regulatory and contractual requirements.

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.

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

Nonconformance reports are made part of the inspection records and are periodically reviewed to identify quality trends. Unsatisfactory quality trends are documented on a Corrective Action Report as detailed in Criterion 16. The results of these reviews are reported to management for their assessment.

Nonconformance reports relating to activities internal to Transnuclear are issued to the management of the affected organization. The Quality Assurance Manager approves their disposition and performs follow-up activities to ensure proper closure.

Established procedures ensure the implementation of the requirements of 10 CFR 21 for the reporting of defects and noncompliance.

Criterion 16 - Corrective Action

Quality Procedures have been established and are implemented to identify significant conditions adverse to quality. Significant and/or repetitive failures, malfunctions and deficiencies in material, components, equipment and operations are promptly identified and documented on a Corrective Action Report and reported to the appropriate management. The cause of the condition and corrective action necessary to prevent recurrence are identified, implemented and then followed up to verify corrective action is completed and effective. Detailed requirements for this activity are delineated in Quality Procedures.

The Quality Assurance Manager is responsible for ensuring implementation of the corrective action program, including follow up and close out actions.

Criterion 17 - Quality Assurance Records

Quality Procedures have been established and are implemented for a Quality Records system. The purpose of the Quality Records system is to ensure that documented evidence pertaining to quality related activities is maintained and available for use by Transnuclear, its customers, and/or regulatory agencies, as applicable.

Quality Procedures identify the types of documents to be retained as Quality Records as well as those to be retained by the originating organization. *"Lifetime"* and *"Non-Permanent"* records are retained by Transnuclear or the Transnuclear client, as appropriate. The records are identified, indexed and stored in accessible locations.

Quality Records are maintained to furnish evidence of activities affecting the quality of structures, systems and components that are safety-related or important-to-safety according to applicable regulations. Identified quality records are maintained for the period specified by the applicable regulations. These records include records of design, procurement, fabrication, assembly and erection.

Where Transnuclear performs maintenance, these records include the use or operating logs, and the results of reviews, inspections, tests, and audits; results from monitoring of work performance and material analyses; results of maintenance, modification, and repair activities; qualification of personnel, procedures and equipment; records of calibration of measuring and test equipment; and related instructions, procedures, and drawings.

The Quality Procedures also identify the requirements for indexing, record retention period, storage method(s) and location(s), classification, and responsibility. Record storage facilities have been established to prevent destruction of the records by fire, flood, theft, and deterioration by environmental conditions (such as temperature or humidity). As an alternative, two identical sets of records may be maintained at separate locations.

Maintenance of records at Transnuclear is in accordance with written approved procedures. These procedures address duration of storage, responsibilities for safekeeping, preservation, and disposition of nonpermanent records. Maintenance of Quality Records is in accordance with the approved Quality Procedure. Transnuclear shall retain these records for at least three (3) years beyond the date of last engagement in the activities under the scope of this Quality Assurance Program for 10 CFR 71 related records and until the Nuclear Regulatory Commission terminates the C of C for 10 CFR 72 related records.

Criteria 18 - Audits

Quality Procedures have been established and implemented to plan and perform periodic audits to verify compliance with all aspects of the Quality Assurance Program and determine its effectiveness. The audit program identifies areas to be audited, such as design activities, procurement, fabrication, inspection, and testing of storage/transportation systems.

The audit program includes audits by Transnuclear of supplier Quality Assurance Programs, procedures and implementation activities to evaluate and verify that procedures and activities are adequate and comply with the overall Quality Assurance Program. Suppliers of safety-related or important-to-safety equipment, material or services are required to implement programs to verify compliance with all applicable aspects of their Quality Assurance Program and to determine its effectiveness.

Audits are scheduled in a manner to provide coverage and coordination with ongoing Quality Assurance Program activities commensurate with their status and importance of the activity.

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

Responsible management shall undertake corrective action as a follow-up to audit reports. The Quality Assurance Manager shall evaluate audit results for indications of adverse trends that could affect quality. When results of such assessments so indicate, appropriate corrective action will be implemented.

The Quality Assurance Manager shall follow up on audit findings to assure appropriate corrective action has been implemented and performs re-audits where considered appropriate.

A qualified lead auditor shall lead audits of project activities for which Transnuclear has direct responsibility.

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*

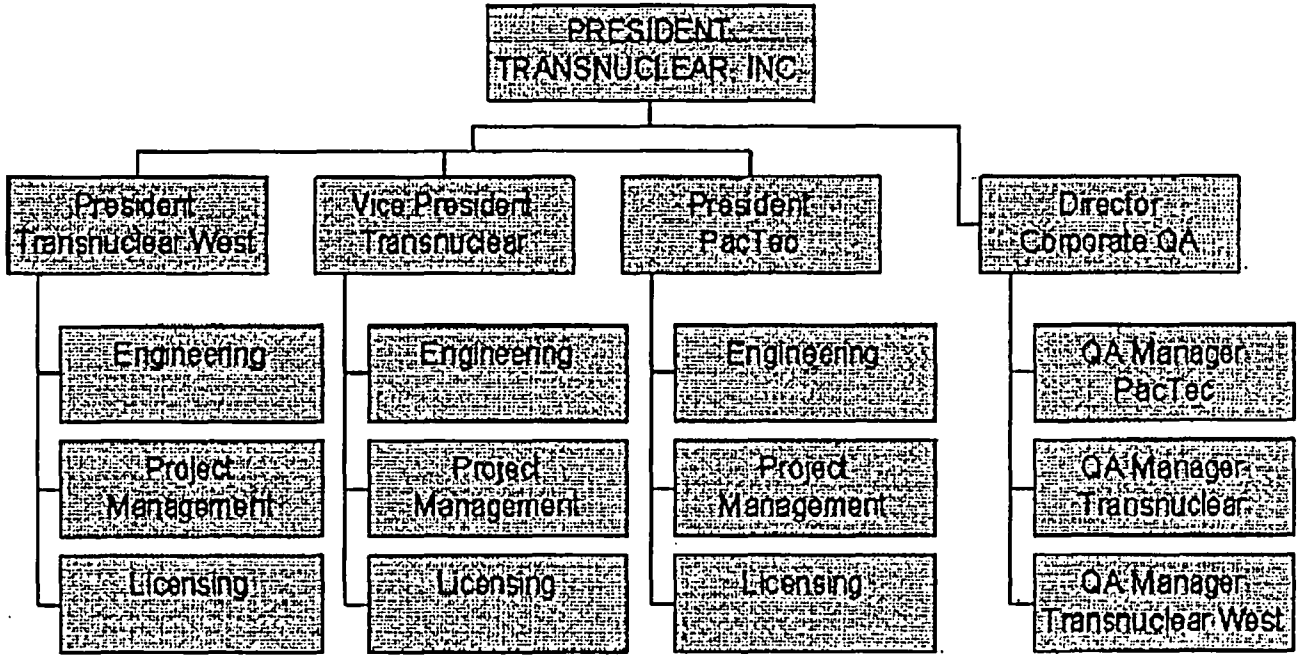
Title 10, Code of Federal Regulations, Part 71, Subpart H – *Packaging and Transportation of Radioactive Material, Quality Assurance*

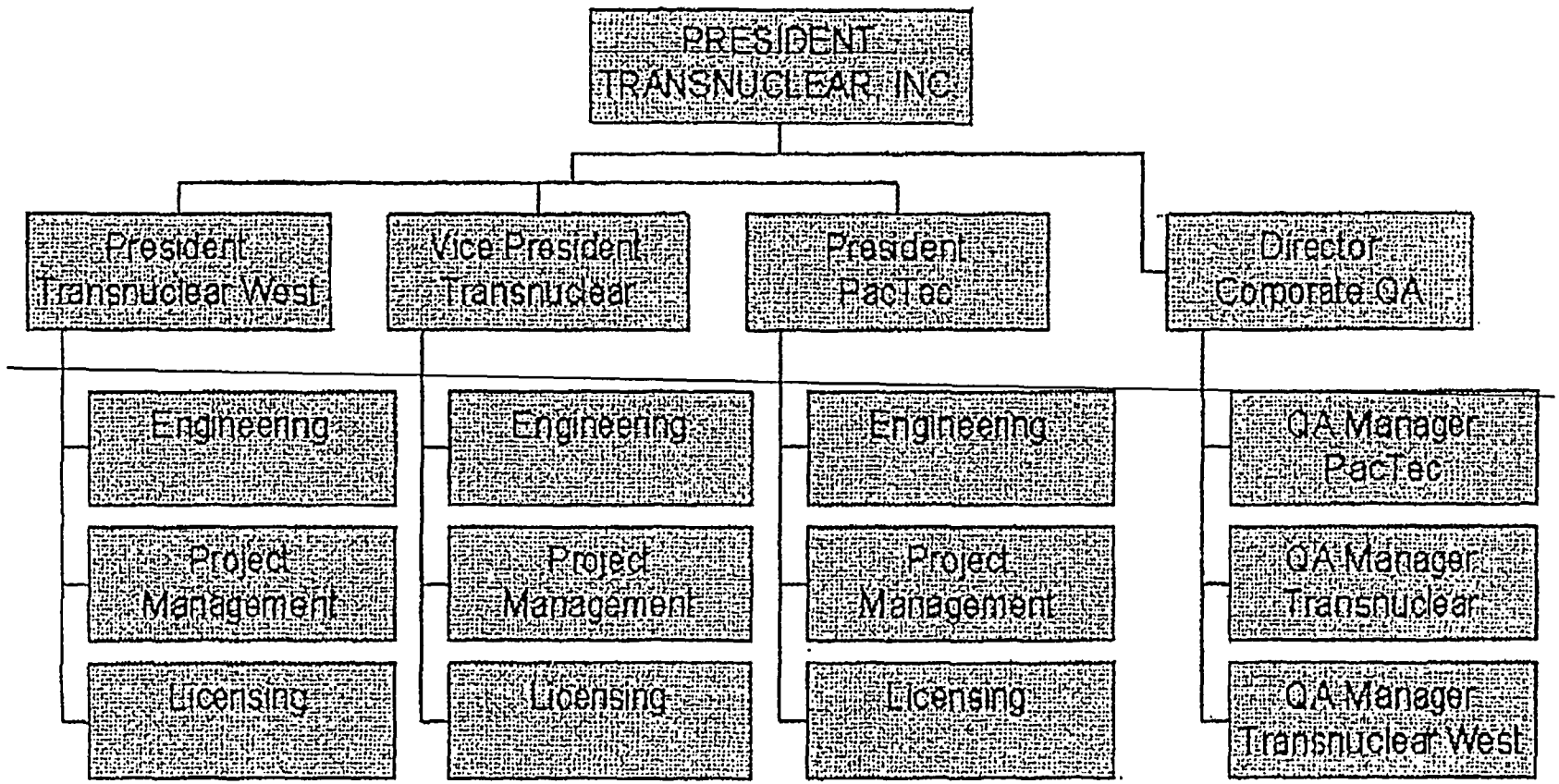
Title 10, Code of Federal Regulations, Part 72, Subpart G – *Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste, Quality Assurance*

Attachments

1) Transnuclear Functional Organization Chart

TRANSNUCLEAR, INC. ORGANIZATION




PRESIDENT
TRANSNUCLEAR INC
President
Transnuclear West
Vice President
Transnuclear
President
PacTec
Director
Corporate QA
Engineering
Project
Management
Licensing
Engineering
Project
Management
Licensing
Engineering
Project
Management
Licensing
QA Manager
PacTec
QA Manager
Transnuclear
QA Manager
Transnuclear West

Explanation of Proposed Changes to Transnuclear, Inc. QAPDM, Revision 2

Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
1	1	Cover Sheet	Cover sheet revised to shown new revision and date and approvals by Alan Hansen, Bill Gallo and Steve White	Change	No	Updating of information only
2	ALL	ALL	Paragraphs have been numbered in order to better reference statements of requirement; "Criterion" deleted from each section's title line	Editorial	No	Style preference and removal of redundancy
3	ALL	ALL	QA Department is now a single "tree"; all QA Managers report through Director, Corporate Quality Assurance.	Change	No	Organizational change that does not change QA reporting level to President
4	ALL	ALL	"QA Procedures" or "QAPs" now "Transnuclear Implementing Procedures (TIPs)"	Change	No	Updating of information only, nomenclature changed to reflect new title for implementing procedures
5	ALL	ALL	"... and are implemented" previously used as a "boilerplate" modifier for QAPs is always required and understood so the phrase has been eliminated.	Change	No	Grammar cleanup
6	ALL	ALL	"Assure" has replaced "ensure" to fit with a manual stating how we assure quality	Change	No	Style - word preference
7	ALL	ALL	Pages renumbered to fit new content	Editorial	No	Updating of information only
8	ALL	ALL	Revision 3 included on all pages	Editorial	No	Updating of information only
9	2	Introduction - first paragraph	Inserted" Transnuclear, Inc."; deleted "This"	Editorial	No	Grammar cleanup
10	2	Introduction - first paragraph	Inserted "Manual for 10 CFR 71, Subpart H, and 10 CFR 72, Subpart G,"	Change	No	Addition of statement of scope that agrees with previous versions
11	2	Introduction - first paragraph	Added "... Manual (QAPDM)" to "Quality Assurance Program Description" to more fully describe this document	Change	No	Clarification of description of this document; allows use of "QAPDM" as descriptor in balance of document
12	2	Introduction - first paragraph	Added "(s)" to "Certificate ... of Compliance"	Editorial	No	Reflects that TN has more than one Certificate
13	2	Introduction - first paragraph	Replaced "Quality Assurance Program Description" with "QAPDM"	Editorial	No	Grammar cleanup (see Change 11).
14	2	Introduction - list of locations	Corrected Company Name to "Transnuclear, Inc." from "Transnuclear West, Inc." in list of company locations	Change	No	Revised to agree with current business entity name; no organizational changes involved.
15	2	Introduction - list of locations	Corrected address for PacTec; replaced "4507 D Pacific Highway East" with "1102 Broadway Plaza, Suite 300" in list of Company locations	Change	No	Updating of information only
16	2	Introduction - list of locations	Added "Transnuclear, Inc., 7135 Minstrel Way, Columbia, Md. 21045" to list of company locations	Change	No	Updating of information only

Explanation of Proposed Changes to Transnuclear, Inc. QAPDM, Revision 2

Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
17	2	Introduction - list of locations	Added "Transnuclear, Inc., 310 Woodward Drive, Aiken, SC 29803" to list of Company locations	Change	No	Updating of information only
18	2	Introduction - third paragraph	Replaced "Quality Assurance Program Description" with "QAPDM" - two instances	Editorial	No	Grammar cleanup; see Change 11.
19	2	Introduction - fourth paragraph	Replaced "Quality Assurance Program Description" with "QAPDM"	Editorial	No	Grammar cleanup (see Change 11).
20	2	Introduction - fourth paragraph; first sentence	Added "Transnuclear, Inc. Quality Assurance Program Description Manual for ASME Section III, Division 1 and Division 3 (ASME QAPDM)" to description of contents of the total TN quality program	Change	No	More fully describes the subtier programs and procedures that support and implement the requirements stated in this QAPDM
21	2	Introduction - fourth paragraph; first sentence	Replaced "implementing Quality" with "Transnuclear Implementing... (TIPs)."	Change	No	Updating of title of implementing procedures only (see Change 4)
22	2	Introduction - fourth paragraph; second sentence	Inserted "The TIPs are..."	Change	No	Added for grammar and complete sentence structure
23	2	Introduction - fourth paragraph; second sentence	Replaced "eighteen (18) criteria" with "requirements"	Change	No	Revised reference to contents of CFRs and ASME standards to more generally describe statements of requirements
24	2	Introduction - fourth paragraph; second sentence	Replaced commas with semicolons as separators	Editorial	No	Grammar cleanup
25	2	Introduction - fourth paragraph; second sentence	Added "and -ASME Section III, Division 1 (NCA 4000) and Division 3 (WA 4000)" to description of what other codes and standards this QAPDM can implement	Change	No	Revised reference to other sets of requirements that TN may chose to meet with the commitments contained in this QAPDM
26	2	Introduction - (new) paragraph four	Added new paragraph "Transnuclear maintains ASME Certificates of Authorization for the design, fabrication and delivery of products in accordance with the requirements of the Transnuclear ASME QAPDM, which specifies additional ASME Code-related requirements applicable to ASME Code projects only."	Change	No	Revised reference to other sets of requirements that TN may chose to meet with the commitments contained in this QAPDM
27	2	Introduction - (original Rev. 2) fourth paragraph, first sentence	Replaced " The statement of policy and authority" with "This Introduction constitutes the statement of policy and quality assurance authority" and added "by signing this manual"	Change	No	Grammar cleanup and sentence restructuring

Explanation of Proposed Changes to Transnuclear, Inc. QAPDM, Revision 2

Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
28	2	Introduction - (original Rev. 2) fourth paragraph, first sentence	Replaced "QA" with "Quality Assurance"	Editorial	No	Use of words in place of acronyms for clarification
29	2	Introduction - (original Rev. 2) fourth paragraph, second sentence	Replaced "quality." with "all quality affecting activities."	Editorial	No	Revised to be more descriptive of what activities are covered by this QAPDM
30	2	Introduction - (original Rev. 2) fourth paragraph, first sentence	Replaced "The QA Program" with "This QAPDM"	Editorial	No	Grammar cleanup (see Change 11).
31	2	Introduction - (original Rev. 2) fifth paragraph, first sentence	Deleted "statement of policy and authority includes a statement that" and appended second sentence by deleting ". It also states that " and adding "and" as a conjunction.	Change	No	Removed redundant sentence construction; this sentence is the statement of policy being referenced; Grammar and sentence cleanup were necessary.
32	2	Introduction - (original Rev. 2) fifth paragraph, second sentence	Deleted "with the Transnuclear Quality Assurance Program" from second sentence that was appended in Change 31.	Change	No	Removal of redundancy; this is the statement of policy for this document that is a the Transnuclear Quality Assurance Program.
33	2	Introduction - (original Rev. 2) sixth paragraph, first sentence	Added "The Director, Corporate Quality Assurance has been delegated the overall responsibility for assuring the adequacy and effectiveness of the Quality Assurance Program. "	Change	No	Revised to recognize that the responsibility for the assurance of adequacy and effectiveness of the QA program is now vested in a Corporate Level Director who reports to the President and has QA Managers who in turn report to him; reflects an organizational change that does not affect the independence and authority of those responsible for assuring quality
34	2	Introduction - (original Rev. 2) sixth paragraph, first sentence	Deleted "for the respective operating entity is given" ; added "are assigned"	Change	No	Removed redundant reference to reflect that the QA Managers report in to a corporate location on matters of quality (see Change 33)

Explanation of Proposed Changes to Transnuclear, Inc. QAPDM, Revision 2

Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
35	2	Introduction - (original Rev. 2) sixth paragraph, first sentence	Replaced "Quality Assurance Procedures" with "TIPS" and replaced "Quality Assurance Program" with "QAPDM"	Change	No	Revised to reflect new nomenclature (see Changes 4, 11 & 13)
36	3	Introduction - (original Rev. 2) seventh paragraph, first sentence	Deleted "respective" and revised "has" to "have"	Change	No	Revised to removed redundant modifier and achieve verb noun agreement.
37	4	Header	Deleted header	Change	No	Removed a redundant header - information included in new cover sheet
38	4	Criterion 1 - first paragraph, first sentence	Replaced "QA" with "Quality Assurance"	Editorial	No	Use of words in place of acronyms for clarification
39	4	Criterion 1 - first paragraph, second sentence	Replaced "as contained in" with "of"	Editorial	No	Grammar cleanup
40	4	Criterion 1 - first paragraph, third sentence	Deleted "the"; deleted "eighteen (18)"	Change	No	Grammar cleanup and expanded applicability to include all statements of requirement; some of the documents that this QAPDM applies to may not have requirements listed in 18 criteria.
41	4	Criterion 1 - second paragraph, first sentence	Replaced "by" with "in"; replaced "Quality Assurance Program" with "QAPDM"	Editorial	No	Grammar cleanup and use of previously defined acronym (see Change 13)
42	4	Criterion 1 - second paragraph, second sentence	Replaced "Each" with "The entire"	Editorial	No	Grammar style
43	4	Criterion 1 - second paragraph, second sentence	Added "and responsibilities."	Change	No	Revised to include not only assigned activities but also assigned responsibilities.
44	4	Criterion 1 - third paragraph, first sentence	Deleted "of the respective operating entity"	Change	No	The company locations are described in the Introductions and this is a redundant modifier.
45	4	Criterion 1 - fourth paragraph, first sentence	Inserted "is responsible for the development, implementation and administration of the Transnuclear QAPDM and TIPs."	Change	No	Stated in more detail the duties of the QA Department regarding QAPDM and TIPs.

Explanation of Proposed Changes to Transnuclear, Inc. QAPDM, Revision 2

Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
46	4	Criterion 1 - fourth paragraph, first sentence	Inserted "The QA Department"; deleted "of the respective operating entity"; inserted "and has"; deleted "The Quality Assurance Departments have"	Change	No	Revised and completed sentence structure for new second sentence, removed redundant noun, and removed redundant modifier (see Change 44).
47	4	Criterion 1 - fifth paragraph, first sentence	Deleted "The"; added "personnel are"; deleted "within their respective operating entity"; replaced "the Director, Corporate QA" with " a QA Manager or the Supervisor, Supplier Oversight."	Change	Yes, but still meets regulations, see ** EXPLANATION	Revised sentence structure to focus on personnel rather than a department; deleted a redundant reference (see Change 44); corrected actual reporting chain of individuals in the QA departments to include the QA Manager and the Supervisor, Supplier Oversight who all report to the Director, Corporate QA. (The Supervisor, Supplier Oversight is a new position). **EXPLANATION - This change more fully describes the actual organization as it has existed for some time and to include a new managerial position - the Supervisor, Supplier Oversight. This correction could be viewed as an acceptable reduction since the reporting chain of all QA personnel is still independent of production pressure and the clear reporting line to the President is unchanged.
48	4	Criterion 1 - fifth paragraph, third sentence	Deleted "The Quality Assurance Departments are headed by Quality Assurance Managers who, by delegation from the President, are responsible for the development, verification of implementation and administration of the Transnuclear Quality Assurance Program within that organization."	Change	No	Due to Changes 45, 46, & 47 this entire sentence is now redundant and can be removed with no reduction in commitment.
49	4	Criterion 1 - fifth paragraph, fourth sentence	Replaced "the QA Manager has" with "they have"; added "of Transnuclear, Inc."	Editorial	No	Grammar cleanup - no change in content or statement of requirement.

Explanation of Proposed Changes to Transnuclear, Inc. QAPDM, Revision 2

Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
50	4	Criterion 1 - fifth paragraph, sixth sentence	Relocated "Records" to beginning of sentence; inserted "QA personnel"; revised "qualification" to "qualifications'" replaced "in" with "as"; replaced Record files" with "records".	Change	No	Revision of sentence using active language and clearer grammar with no change in content or statement of requirement.
51	4 & 5	Criterion 1 - sixth paragraph, first and second sentences	Added "also"; deleted "assurance that quality acceptance requirements have been developed for inspections and Non-Destructive Examination activities. It is also their responsibility to delegate"; added "delegating"	Change	Yes, but still meets regulations, see ** EXPLANATION	Combination of two sentences with deletion of an inaccurate statement. ** EXPLANATION - This change corrects the assignment of a duty that belongs to Engineering instead of QA and combines the two statements of requirement (two sentences) into one that accurately describes the conditions that must exist for delegation of quality related tasks. This could be considered a reduction in commitment however, it is an acceptable one since Engineering more appropriately performs the function. QA always has the right and responsibility to overview all quality affecting activities, including establishing acceptance criteria for inspections and NDE, and this is unchanged by this revision.
52	5	Criterion 1 - eighth paragraph, first sentence	Deleted "Functional"; deleted "shown at the end of"; inserted "included in"; replaced "program description" with "QAPDM"; replaced "Attachment" with "Figure 1"	Change	No	Deletion of redundant descriptor. Use of previously defined acronym (see Change 13). Re-label of an Attachment as a Figure more appropriately describes the chart.
53	5	Criterion 2 - first paragraph, first sentence	Added "and codes"	Change	No	Added to acknowledge that the statements of requirement included in this document may have sources other than regulations

Explanation of Proposed Changes to Transnuclear, Inc. QAPDM, Revision 2

Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
54	5	Criterion 2 - first paragraph, second sentence	Replaced "The Transnuclear Quality Assurance Program is comprised of this QA Program Description containing corporate quality policy, supplemented by a series of written approved Quality Procedures containing detailed implementation instructions." with "The Transnuclear Quality Assurance Program is comprised of this QAPDM, the ASME QAPDM, and Transnuclear Implementing Procedures (TIPs)."	Change	No	Revision more completely describes the construction of the entire Transnuclear Quality program including this QAPDM. (See changes 20 & 21 and 25 & 26)
55	5	Criterion 2 - first paragraph, new sentence	Added "The TIPs are designed and administered to meet the requirements of 10CFR71, Subpart H; 10CFR72, Subpart G; 10CFR50, Appendix B; ASME Section III, Division 1 (NCA 4000) and Division 3 (WA 4000)."	Change	No	Revision more completely describes the construction of the entire Transnuclear Quality program including this QAPDM. Acknowledges that this document may be utilized in meeting other requirements that expressed in 10 CFR. (See changes 20 & 21 and 25 & 26)
56	5	Criterion 2 - first paragraph, fourth sentence	Added ", provisions of the ASME Code when applicable,"	Change	No	Revision more completely describes the construction of the entire Transnuclear Quality program including this QAPDM. Acknowledges that this document may be utilized in meeting other requirements that expressed in 10 CFR. (See changes 20 & 21)
57	5	Criterion 2 - first paragraph, fourth sentence	Deleted "the"; revised "design" to "designs"	Editorial	No	Grammar cleanup
58	5	Criterion 2 - first paragraph, fourth sentence	Added "and complied with at all times."	Change	No	Adds to the statement of requirement that not only do specific provisions of approved designs must be met, they must always be complied with.
59	5	Criterion 2 - second paragraph, first sentence	Deleted "the"	Editorial	No	Editorial removal of redundant article

Explanation of Proposed Changes to Transnuclear, Inc. QAPDM, Revision 2

Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
60	5	Criterion 2 - third paragraph, first sentence	Added "and Code" ; added "Inc. locations as well as at'" deleted "and their"; added "facilities."	Change	No	Inclusion of Code acknowledges that Transnuclear may have to meet ASME Code requirements as well as regulatory requirements. Revised sentence structure to more clearly define when and where this program must be applied. Completed the sentence by revising "supplier" to "suppliers' facilities."
61	5	Criterion 2 - third paragraph, second sentence	Replaced "QA Manager for each Transnuclear operating entity" with "Director, Corporate Quality Assurance"	Change	Yes, but still meets regulations, see ** EXPLANATION	Revised to more accurately describe the evaluation of the Quality Assurance Program. **EXPLANATION - With the activation of a single QA organization, the specific assignment of the Director, Corporate QA more appropriately assigns responsibility for the overall evaluation of the QAPDM rather than individual locations have this assignment for only their locations. This could be considered a change in commitment however, it is an acceptable one since the activity is still assigned to the QA department.
62	5	Criterion 2 - third paragraph, second sentence	Replaced "eighteen (18) criteria" with "baseline commitments"	Change	No	Added to acknowledge that the statements of requirement included in this document may have sources other than regulations (see Change 53)
63	5	Criterion 2 - third paragraph, second sentence	Deleted "within that entity"	Change	No	Revised to be consistent with Change 61 acknowledging that the QA program received a centralized evaluation
64	5	Criterion 3 - first paragraph	Replaced "Quality" with "Implementing"; substituted "established" for "developed"	Change	No	Updating of nomenclature (see Change 4). Style preference.

Explanation of Proposed Changes to Transnuclear, Inc. QAPDM, Revision 2

Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
65	5	Criterion 3 - first paragraph - list	Replaced "is" with "are"	Editorial	No	Grammar cleanup
66	6	Criterion 3 - first paragraph - list	Deleted "the"; changed "activity" to "activities"	Editorial	No	Grammar cleanup
67	6	Criterion 3 - first paragraph - list	Replaced "licensing amendment for transport applications" with "amending licenses for Transport Amendments"	Editorial	No	Correcting sentence structure and grammar
68	6	Criterion 3 - first paragraph - list	Revised "storage" with "Storage Applications"	Editorial	No	Completing sentence structure and correcting grammar
69	6	Criterion 3 - first paragraph - list	Added "corrected,"	Change	No	Clarified statement of requirement
70	6	Criterion 3 - second paragraph	Added "."	Editorial	No	Correction of punctuation
71	6	Criterion 3 - third paragraph	Replaced "Quality Procedures" with "approved TIPs"	Change	No	Updating of nomenclature (see Change 4) and adding an appropriate modifier
72	6	Criterion 4 - first paragraph, first sentence	Added "Transnuclear Implementing Procedures have been established to assure that"; changed "Procedures" to "procedures"	Change	No	Completing sentence structure and correcting grammar
73	6	Criterion 4 - first paragraph, first sentence	Replaced "which" with "to"; replaced "-" with "and"	Editorial	No	Grammar cleanup
74	6	Criterion 4 - first paragraph, second sentence	Added "maintenance and operations,"; replaced "-" with "and/or"	Change	No	Includes maintenance and operations to include Aiken operations. Grammar cleanup.
75	6	Criterion 4 - second paragraph, first sentence	Deleted "Supplier evaluations and selection, objective evidence of supplier quality,"; added "the"; changed "procurement" with "Procurement"; replaced "to" with "through"; deleted "source surveillance, and receipt inspection are"; added "is"; replaced "written [approved] Quality Procedures" with "approved TIPs"	Change	No	Removed statements of requirements that are fully redundant to statements of requirements Sec. 7 - paragraphs 7.2, 7.5, 7.6. Grammar cleanup. Updating of nomenclature (see Change 4). Style preference.
76	6	Criterion 4 - third paragraph, first sentence	Replaced "Quality Procedures" with "approved TIPs"	Change	No	Updating of nomenclature (see Change 4) and adding an appropriate modifier
77	7	Criterion 4 - fourth paragraph, first sentence	Replaced "with" with "in"	Editorial	No	Grammar cleanup. Updating of nomenclature (see Change 4). Style preference.

Explanation of Proposed Changes to Transnuclear, Inc. QAPDM, Revision 2

Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
78	7	Criterion 4 - fourth paragraph, second sentence	Replaced "Quality Assurance [personnel]" with "Transnuclear [personnel]"	Change	Yes, but still meets regulations, see ** EXPLANATION	Acknowledging that personnel other than QA personnel may assign quality requirements in purchase documents. ** EXPLANATION - This QAPDM states that the attainment of quality is not the sole responsibility of the QA Department. This change acknowledges that others may impose quality requirements during the procurement process. QA always has the right and responsibility to overview all quality affecting activities, including the inclusion of quality requirements in purchase documents and this is unchanged by this revision.
79	7	Criterion 4 - fourth paragraph, second sentence	Deleted "the"; deleted "or"; added "or ASME Section III,"	Change	No	Grammar cleanup of articles. Acknowledged that this QAPDM may be used to meet requirements over and above those contained in 10 CFR.
80	7	Criterion 4 - fifth paragraph, first sentence	Delete "the"; revised "supplier" to "suppliers"	Editorial	No	Acknowledges that there may be more than one supplier in the procurement chain. Revised grammar and singular to plural for suppliers.
81	7	Criterion 4 -- sixth paragraph, first sentence	Replaced "QA" with "Quality Assurance"; revised "Records" to "records"; added "provide" and "of"	Editorial	No	Use of words in place of acronyms for clarification. Correction of capitalization. Completed sentence structure and grammar.

Explanation of Proposed Changes to Transnuclear, Inc. QAPDM, Revision 2

Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
82	7	Criterion 4 - seventh paragraph, first sentence	Replaced "Quality Assurance personnel" with "Transnuclear"; changed "maintain" to "maintains"; changed "suppliers" to "supplier's"; replaced "documentation for" to "performance of"	Change	Yes, but still meets regulations, see ** EXPLANATION	Acknowledging that Transnuclear rather than just QA personnel maintains the rights of access to a supplier's facilities. Corrected grammar. Revised description of when access is required ** EXPLANATION - This QAPDM states that the attainment of quality is not the sole responsibility of the QA Department. This change acknowledges that others may require access to a supplier's facilities. QA always has the right and responsibility to overview all quality affecting activities, including the management of fabrication and this is unchanged by this revision.
83	7	Criterion 4 - seventh paragraph, first sentence	Changed "documentation" to "documents"	Editorial	No	Grammar cleanup. Style - word preference.
84	7	Criterion 4 - eighth paragraph, first sentence	Added space to "10 CFR 21"; changed "Noncompliance" to "Noncompliances"	Editorial	No	Grammar cleanup.
85	7	Criterion 5 - first paragraph - first sentence	Added "Transnuclear Implementing Procedures have been established to assure that"; changed "Methods" to "methods"; deleted "eighteen (18)"; relocated "or"; added "ASME Section III"	Editorial	No	Revision of sentence using active language and clearer grammar with no change in content or statement of requirement. Removed unnecessary number-modifier. Acknowledged that this QAPDM may be used to meet requirements other than those in 10 CFR.
86	7	Criterion 5 - second paragraph - first sentence	Replaced "the Quality Procedures" with "approved TIPs"	Change	No	Updating of nomenclature (see Change 4) and adding an appropriate modifier
87	7	Criterion 5 - third paragraph - first sentence	Added "and controls"	Change	No	Added a more complete description of how changes are to be controlled.

Explanation of Proposed Changes to Transnuclear, Inc. QAPDM, Revision 2

Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
88	7	Criterion 6 - first paragraph - first sentence	Added "Transnuclear Implementing Procedures"; deleted "Measures"; deleted "and are implemented"	Change	No	Grammar and sentence structure change to better describe what "measures" are to be established. Deleted redundant phrase "and are implemented" that is already addressed by using "Transnuclear Implementing Procedures" (see Change 5).
89	7	Criterion 6 - first paragraph - first sentence	Added " and to assure" and deleted "Quality Procedures define document control measures to ensure" in order to combine two sentences.	Change	No	Grammar and sentence structure change to better describe what is to be established. Deleted redundant phrase .
90	7	Criterion 6 - first paragraph - second sentence	Deleted ", and"	Editorial	No	Grammar cleanup.
91	8	Criterion 6 - first paragraph - list	Added "Manuals and TIPs"; deleted "Procedures"; changed "Procedures" to "procedures"	Change	No	Updating of nomenclature (see Change 4). Capitalization cleanup.
92	8	Criterion 6 - second paragraph - first sentence	Deleted "equally"	Change	No	Deleted redundant modifier. Organizations must be qualified not necessary equally as long as minimums are met.
93	8	Criterion 6 - fourth paragraph - first sentence	Added "only"	Change	No	Clarified statement of requirement
94	8	Criterion 7 - first paragraph - first sentence	Replaced "Quality" with "Transnuclear Implementing"; deleted "and are implemented"; replaced "ensure" with "assure"	Change	No	Nomenclature change. (see Change 4). Deletion of redundant phrase (see Change 5). Style preference - word choice (see Change 6).

Explanation of Proposed Changes to Transnuclear, Inc. QAPDM, Revision 2

Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
95	8	Criterion 7 - second paragraph - first sentence	Added "and approved"; deleted "QA"; replaced "suggested" with "proposed"; added "being purchased"; deleted "and the Approved Suppliers List"	Change	Yes, but still meets regulations, see ** EXPLANATION	Added details of what activity occurs. Broadened population of Transnuclear personnel may approve procurement documents. Substituted and equivalent-but better descriptive word. Removed a redundant statement of requirement regarding the Approved Suppliers List check. ** EXPLANATION - This QAPDM states that the attainment of quality is not the sole responsibility of the QA Department. This change acknowledges that others who are authorized may approve procurement documents as well as QA. QA always has the right and responsibility to overview all quality affecting activities, including the inclusion of quality requirements in purchase documents and this is unchanged by this revision.
96	8	Criterion 7 - third paragraph - list	Deleted "or"; added "or ASME Section III"	Change	No	Grammar cleanup. Acknowledged that this QAPDM may be used to meet requirements over and above those contained in 10 CFR.
97	8	Criterion 7 - third paragraph - list	Added "review of the supplier's"; replaced "Quality Program" with "quality controls"; replaced "regulations to be" with "requirements being"	Change	No	More specifically described what activities will be performed to qualify a supplier. Broadened the scope of the controls whose implementation will be verified. Acknowledged that there may be other requirements that are not included in regulations.
98	8	Criterion 7 - fourth paragraph - first sentence	Replaced "Audits/surveys are conducted by qualified personnel." with "Qualified personnel conduct audits and surveys."	Editorial	No	Sentence restructuring using active instead of passive construction.
99	8	Criterion 7 - fourth paragraph - second sentence	Added "Assurance"	Editorial	No	Clarifies that Quality records are Quality Assurance records.

Explanation of Proposed Changes to Transnuclear, Inc. QAPDM, Revision 2

Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
100	8	Criterion 7 - fourth paragraph - third sentence	Added "continue to"; added "continued"	Change	No	Added a clarifying modifier.
101	8	Criterion 7 - fifth paragraph - second sentence	Replaced "with" with "to"; replaced "being" with "that are"	Editorial	No	Grammar cleanup
102	8	Criterion 7 - fifth paragraph - third sentence	Replaced "acceptance" with "review and approval"	Change	No	Revised to better describe an activity. Activity remains the same.
103	8	Criterion 7 - fifth paragraph - fourth sentence	Replaced "ensure" with "assure"	Editorial	No	Style - word preference (see Change 6)
104	9	Criterion 7 - sixth paragraph - first sentence	Deleted "The Quality Assurance Program provides for"; added "Periodic"; added "is performed"	Change	No	Sentence restructuring using active instead of passive construction.
105	9	Criterion 7 - sixth paragraph - second sentence	Added "or project"; added "and surveillances are performed"; deleted "conduct"; added "approved TIPs"; deleted "Quality Procedures"	Change	No	Better defined where the need for surveillance may be identified. Clarified that not only does surveillance planning occur but surveillances are also conducted. Updated nomenclature regarding title of new implementing procedures (see Change 4)

Explanation of Proposed Changes to Transnuclear, Inc. QAPDM, Revision 2

Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
106	9	Criterion 7 - seventh paragraph - first sentence	Deleted "is prepared and approved by authorized QA personnel"; added "the"; deleted "and surveillance"; added "to verify compliance with"; deleted "in accordance with"; replaced "and" with "or"; added "is performed in accordance with approved TIPs"	Change	Yes, but still meets regulations, see ** EXPLANATION	Revision acknowledges that others - other than QA - may perform quality planning for surveillances and inspections. Revision also clarifies why such activities are planned and performed. Revision imposes a statement of requirement that all such activities need be conducted in accordance with approved implementing procedures. ** EXPLANATION - This QAPDM states that the attainment of quality is not the sole responsibility of the QA Department. This change acknowledges that others may plan surveillance and inspection activities as long as such planning is in accordance with approved procedures. QA always has the right and responsibility to overview all quality affecting activities, including the planning and performance of inspections and surveillances and this is unchanged by this revision.
107	9	Criterion 7 - eighth paragraph - first sentence	Deleted "assurance"; deleted "requirements are"; added "is"	Change	No	Broadened the description of controls to be verified when commercial grade dedication is being used. Grammar cleanup and sentence restructuring for clarification.
108	9	Criterion 7 - eighth paragraph - first sentence	Deleted "the"; replaced "Quality Procedures" "approved TIPs"	Change	No	Grammar cleanup. Updated nomenclature regarding title of new implementing procedures (see Change 4)
109	9	Criterion 8 - first paragraph - first sentence	Replaced "Quality" with "Transnuclear Implementing" ; deleted "and are implemented"	Change	No	Nomenclature change. (see Change 4). Deletion of redundant phrase (see Change 5).

Explanation of Proposed Changes to Transnuclear, Inc. QAPDM, Revision 2

Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
110	9	Criterion 8 - first paragraph - second sentence	Replaced "ensure" with "assure"; replaced "item" with "items"; deleted "the"	Change	No	Style preference - word choice (see Change 6).
111	9	Criterion 8 - second paragraph - first sentence	Deleted "The"; revised "requirements" to "Requirements"	Editorial	No	Grammar cleanup
112	9	Criterion 8 - third paragraph - first sentence	Deleted "The"; revised "methods" to "Methods"; deleted "information"	Change	No	Style preference. Eliminated redundant noun.
113	9	Criterion 9 - first paragraph - first sentence	Replaced "Quality" with "Transnuclear Implementing" ; deleted "and are implemented"; replaced "for the" with "to"; deleted "of"	Change	No	Nomenclature change. (see Change 4). Deletion of redundant phrase (see Change 5).
114	9	Criterion 9 - first paragraph - second sentence	Replaced "and" with "or"; added "special"; deleted "special to a specific component'; deleted "the"	Change	No	Grammar cleanup. Clarification of what constitutes a special process.
115	9	Criterion 9 - third paragraph - first sentence	Deleted "formally"; deleted "or"; added "or"; deleted "criteria"	Change	No	Removal of a redundant adverb. To be trained and qualified in accordance with codes, standards, specifications or other special requirements constitutes "formally trained". Grammar cleanup.
116	9	Criterion 9 - third paragraph - second sentence	Replaced "Qualified records of" with "Records of qualified"	Change	No	Grammar and sentence correction and use of active instead of passive sentence construction.
117	9	Criterion 10 - first paragraph - first sentence	Replaced "Quality" with "Transnuclear Implementing" ; deleted "and are implemented"; added "to assure that"; deleted "for the"; added "or surveillance is performed to verify that"; deleted "of"; deleted "to verify"; deleted "other"; deleted "and for Transnuclear surveillance of supplier activities."	Change	No	Nomenclature change. (see Change 4). Deletion of redundant phrase (see Change 5). Grammar and sentence revised to clarify purpose of inspection activities.
118	10	Criterion 10 - second paragraph - first sentence	Added "and surveillance activities"	Change	No	Expands scope to include surveillances as equivalent to inspections.
119	10	Criterion 10 - third paragraph - first sentence	Added "and surveillance"; added "subject"; revised "activity" to "activities"; deleted "being inspected."	Change	No	Expands scope to include surveillances as equivalent to inspections. Style and word choice preference.

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Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
120	10	Criterion 10 - fourth paragraph - first sentence	Added "and surveillance"; added "assurance"; deleted "adequate"; added "of"; deleted "control"	Change	No	Expands scope to include surveillances as equivalent to inspections. Style and word choice preference.
121	10	Criterion 10 - sixth paragraph - first sentence	Replaced "accept-reject" with "acceptance"; added qualification"; added "performance"; deleted "to inspect"; replaced "/" with "and/or"; replaced "documentation" with "documents"; added "and surveillance"	Change	No	Style and word choice preference. Expands scope to include surveillances as equivalent to inspections.
122	10	Criterion 11 - first paragraph - first sentence	Replaced "Quality" with "Transnuclear Implementing" ; replaced "are" with "have been"; deleted "and implemented"; added "assure that"; deleted "perform"; added "design or"; added "are performed and appropriately controlled"	Change	No	Nomenclature change. (see Change 4). Deletion of redundant phrase (see Change 5). Grammar and sentence revised to clarify testing requirements.
123	10	Criterion 11 - third paragraph - list	Replaced "The requirements and acceptance limits" with "Acceptance criteria"	Editorial	No	Style and word choice preference.
124	10	Criterion 11 - third paragraph - list	Delete "the" ; revise "test" to "tests"	Editorial	No	Grammar cleanup.
125	10	Criterion 11 - third paragraph - list	Revise "item" to "items"	Editorial	No	Grammar cleanup.
126	10	Criterion 11 - third paragraph - list	Added "record's"	Change	No	Grammar cleanup.
127	10	Criterion 11 - fifth paragraph - first sentence	Replaced "perfomed" with "to be conducted"	Editorial	No	Style and word choice preference.
128	11	Criterion 12 - first paragraph - first sentence	Replaced "Quality" with "Transnuclear Implementing" ; deleted "and implemented"; replaced "ensure" with "assure" ; added "(M&TE)"	Change	No	Nomenclature change. (see Change 4). Deletion of redundant phrase (see Change 5). Style - word preference (see Change 6). Establishment of acronym for use later.
129	11	Criterion 12 - second paragraph - first sentence	Replaced "These measuring devices" with "M&TE"	Editorial	No	Use of previously defined acronym
130	11	Criterion 12 - second paragraph - second sentence	Replaced "is" with "are"	Editorial	No	Grammar cleanup
131	11	Criterion 12 - second paragraph - second sentence	Added "Calibration"; changed "Intervals" to "intervals"	Editorial	No	Style and word choice preference.

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Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
132	11	Criterion 12 - fourth paragraph - second sentence	Replaced "Measuring and Test Equipment" with "M&TE"; changed "is" to "are"; relocated "labeled or tagged indicating the next required calibration due date" from end of sentence to middle of listing of requirements.	Editorial	No	Use of previously defined acronym. Grammar cleanup. Relocation of requirement with no changes.
133	11	Criterion 12 - fifth paragraph - first sentence	Replaced "When measuring and test equipment is" with "If M&TE are"; replaced "made" with "performed"; added "regarding"; deleted "of"; changed "test" to "tests"; deleted "results"; deleted "of"	Editorial	No	Use of previously defined acronym. Grammar and sentence structure revised to provide a better statement of the same requirement.
134	11	Criterion 12 - fifth paragraph - second sentence	Added "current"; replaced "measuring and testing equipment under the calibration system" with "M&TE"	Change	No	Addition of an appropriate adjective. Use of previously defined acronym. Restructuring of sentence to clarify the statement of requirement.
135	11	Criterion 12 - fifth paragraph - third sentence	Replaced "If any inspection, measuring or test equipment is" with "Any M&TE that are"; replaced "it is" with "shall be"	Editorial	No	Use of previously defined acronym. Restructuring of sentence to clarify the statement of requirement.
136	11	Criterion 13 - first paragraph - first sentence	Replaced "Quality" with "Transnuclear Implementing" ; deleted "and are implemented"; replaced "ensure" with "assure"	Change	No	Nomenclature change. (see Change 4). Deletion of redundant phrase (see Change 5). Style - word preference (see Change 6).
137	11	Criterion 14 - first paragraph - first sentence	Replaced "Quality" with "Transnuclear Implementing" ; deleted "and are implemented"; replaced "ensure" with "assure"	Change	No	Nomenclature change. (see Change 4). Deletion of redundant phrase (see Change 5). Style - word preference (see Change 6).
138	11	Criterion 14 - first paragraph - first sentence	Deleted "controlled, written"; added "instructions or"; deleted "or instructions"	Change	No	Deletion of redundant adjectives, that is, approved instructions or procedures are written and controlled. Sentence structure revised to clarify the statement of requirement.
139	11	Criterion 14 - third paragraph - second sentence	Added "performed"; added "approved instructions and procedures"; deleted "Quality Procedures"	Change	No	Grammar and sentence structure revised to provide a clear statement of requirement. Nomenclature change. (see Change 4).

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Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
140	12	Criterion 14 - fourth paragraph - first sentence	Replaced "The status of" with "Any"; added "are"; deleted "is documented"; added "and controlled"; deleted "and segregated to prevent inadvertent use"; replaced "Criterion" with "Section"; added "of this QAPDM"	Change	No	Grammar and sentence structure revised to provide a clear statement of requirement. Removal of a redundant statement of requirement that is in another section of the QAPDM that is referenced. Nomenclature change. (see Change 4).
141	12	Criterion 15 - first paragraph - first sentence	Replaced "Quality" with "Transnuclear Implementing" ; deleted "and are implemented"	Change	No	Nomenclature change. (see Change 4). Deletion of redundant phrase (see Change 5).
142	12	Criterion 15 - second paragraph - first sentence	Added "those"	Editorial	No	Style and word choice.
143	12	Criterion 15 - second paragraph - second sentence	Replaced "control documents" with "assurance requirements"	Change	No	Style and word choice preference - quality control documents are a subset of what Transnuclear considers quality assurance requirements.
144	12	Criterion 15 - third paragraph - first sentence	Added "until properly dispositioned"	Change	No	Added essential words from fourth paragraph, first sentence that is being deleted since it is redundant to this sentence after this revision.
145	12	Criterion 15 - third paragraph - third sentence	Replaced "is" with "shall be"	Editorial	No	Style and word choice preference.
146	12	Criterion 15 - fourth paragraph - first and second sentences	Deleted "Nonconforming items are to be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions are employed to preclude inadvertent use of the item."	Change	No	This statement of requirement is redundant to the third paragraph, first, second, third and fourth sentences after revision noted above in Change 144. No reduction in requirements.
147	12	Criterion 15 - fifth paragraph - first sentence	Added "(NCRs)";	Editorial	No	Establishment of acronym for use later.
148	12	Criterion 15 - fifth paragraph - second sentence	Deleted "As a minimum"; changed "nonconforming" to "Nonconforming"	Editorial	No	Grammar and sentence structure revised to provide a clear statement of requirement.

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Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
149	12	Criterion 15 - sixth paragraph - first sentence	Added "or surveillance"; added "and"; deleted "and signed"	Change	No	Added surveillances as another way to re-inspect items. Grammar cleanup. Deleted a redundant action - for purposes of the QAPDM "approved' is considered the same as "signed"
150	12	Criterion 15 - seventh paragraph - first sentence	Replaced "are" with "is"; replaced "and/or" with "/"	Editorial	No	Grammar cleanup.
151	12	Criterion 15 - eighth paragraph - first sentence	Added "The disposition of"; changed "Nonconforming" to "nonconforming"; replaced "dispostioned" with "as"; added "shall"; deleted "requirements to indicate and"; replaced "ensure continued" with "to assure"	Change	No	Sentence restructuring and grammar to more clearly state the requirement with no change. Style - word preference. (see Change 6)
152	13	Criterion 15 - tenth paragraph - first sentence	Added "or specification"	Change	No	Expanded the scope of requirements to be complied with or an NCR will be required.
153	13	Criterion 15 - eleventh paragraph - second sentence	Replaced "Criterion" with "Section"; added "of this QAPDM"	Editorial	No	Nomenclature change. (see Change 4). Addition of a modifier to identify the document containing the referenced section
154	13	Criterion 15 - eleventh paragraph - third sentence	Deleted "for their assessment"	Change	No	Deletion of a redundant statement of action. Results of trend reviews are reported to management. They may take many actions - including assessment - that do not have to be listed.
155	13	Criterion 15 - twelfth paragraph - second sentence	Added "appropriate"; replaced "ensure" with "assure"	Change	No	Revision acknowledges that only the QA Manager at the affected company location need to approve the disposition of internal NCRs.
156	13	Criterion 15 - thirteenth paragraph - first sentence	Replaced "Established procedures ensure the implementation of" with "Compliance with the evaluation and reporting....is controlled by approved TIPs"; added "related to"; deleted "for the reporting"	Change	No	Sentence restructuring and grammar to more clearly state the requirement with no change. Nomenclature change (see Change 4)
157	13	Criterion 16 - first paragraph - first sentence	Replaced "Quality" with "Transnuclear Implementing" ; deleted "and are implemented"	Change	No	Nomenclature change. (see Change 4). Deletion of redundant phrase (see Change 5).

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Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
158	13	Criterion 16 - first paragraph - second sentence	Added "(CARs)"; deleted "the"	Editorial	No	Establishes an acronym for later use. Grammar cleanup.
159	13	Criterion 16 - first paragraph - third sentence	Deleted "then"	Editorial	No	Grammar cleanup.
160	13	Criterion 16 - first paragraph - fourth sentence	Deleted "Detailed requirements for this activity are delineated in Quality Procedures."	Editorial	No	Removal of a redundant statement found in the first sentence of this paragraph as revised.
161	13	Criterion 16 - second paragraph - first sentence	Replaced "Quality Assurance Manager" with "Director, Corporate Quality Assurance (DCA)"	Change	Yes, but still meets regulations, see ** EXPLANATION	Revised to more accurately describe the responsibility for the Corrective Action program. **EXPLANATION - With the activation of a single QA organization, the specific assignment of the Director, Corporate QA more appropriately assigns overall responsibility for the Corrective Action Program. This could be considered a change in commitment, however it is an acceptable one since the activity is still assigned to the QA department whose independence and autonomy is unchanged.
162	13	Criterion 16 - second paragraph - first sentence	Added "The DCA may delegate certain activities in the Corrective Action process to others."	Change	No	A redundant statement of requirement deemed necessary for emphasis in this context.
163	13	Criterion 17 - first paragraph - first sentence	Replaced "Quality" with "Transnuclear Implementing" ; deleted "and are implemented"; replaced "for a Quality Records system" with "to assure the control of quality records."	Change	No	Nomenclature change. (see Change 4). Deletion of redundant phrase (see Change 5).Sentence restructuring and grammar to more clearly state the requirement with no change.
164	13	Criterion 17 - second paragraph - first sentence	Replaced "Quality Procedures" with "Approved procedures"; added "Assurance"; revised "Records" to "records"	Change	No	Nomenclature change (see Change 4). Added an adjective to fully label the records being maintained. Grammar cleanup.

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Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
165	13	Criterion 17 - second paragraph - second sentence	Replaced "the Transnuclear client" with its' customers"	Editorial	No	Style - word preference
166	13	Criterion 17 - second paragraph - third sentence	Replaced "The records" with "Records"	Editorial	No	Sentence structure and grammar cleanup.
167	13	Criterion 17 - third paragraph - first sentence	Added "Assurance" ; added "for periods specified in regulations" ; deleted "according to applicable regulations."	Change	No	Sentence structure and grammar cleanup. Added an adjective to more fully label the records being maintained.
168	13	Criterion 17 - third paragraph - second sentence	Deleted "Identified quality records are maintained for the period specified by the applicable regulations. "	Editorial	No	This sentence is totally redundant after incorporation of previous changes (see Change 163)
169	14	Criterion 17 - fourth paragraph - first sentence	Replaced "Where" with "When"; replaced "or" with "of"; deleted "and the"	Editorial	No	Sentence structure and grammar cleanup.
170	14	Criterion 17 - fifth paragraph - first sentence	Deleted "The Quality Assurance Procedures also identify the"; Revised "requirements" to "Requirements"; added "preservation measures, disposition of non-permanent records,"; added "for safekeeping are specified in approved TIPs."	Change	No	Restructuring of sentence and use of new nomenclature for implementing procedures. Added two additional statements of requirement and modified one to assure all required elements were addressed.
171	14	Criterion 17 - sixth paragraph - first & second sentence	Deleted "Maintenance of records at Transnuclear is in accordance with written approved procedures. The procedures address duration of storage, responsibilities for safekeeping, preservation, and disposition of nonpermanent records. Maintenance of Quality Records is in accordance with the approved Quality Procedure."	Change	No	All three of these sentences are redundant when Change 166 is incorporated and can be deleted with no reduction in commitment.
172	14	Criterion 17 - sixth paragraph - first & second sentence	Replaced "these" with "required" ; replaced "Quality Assurance Program" with "QAPDM"; replaced "C of C" with "Certificate of Compliance"	Editorial	No	Grammar changes and use of a previously defined acronym. Removal of a previously not defined acronym.
173	14	Criterion 18 - first paragraph - first sentence	Replaced "Quality" with "Transnuclear Implementing" ; deleted "and implemented"; added "assure that"; deleted "plan and perform"; added "are performed."	Change	No	Nomenclature change. (see Change 4). Deletion of redundant phrase (see Change 5).Sentence restructuring and grammar to more clearly state the requirement with no change.

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Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
174	14	Criterion 18 - first paragraph - first sentence	Replaced "The audit program identifies" with "Those areas and activities"; change "system" to "systems"; added "are identified in audit planning"	Change	No	Sentence restructuring and grammar to more clearly state the requirement with no change.
175	14	Criterion 18 - second paragraph - first sentence	Deleted "The audit program includes audits by"; added "audits"; deleted "of"; replaced "the overall Quality Assurance Program." with "applicable requirements."	Change	No	Sentence restructuring and grammar to more clearly state the requirement with no change. Style and word preference changes.
176	14	Criterion 18 - second paragraph - second sentence	Deleted "Suppliers of safety related or important to safety equipment, material, or services are required to implement programs to verify compliance with all applicable aspects of their Quality Assurance Program and to determine its effectiveness."	Change	Yes, but still meets regulations, see ** EXPLANATION	** EXPLANATION This statement of requirement is redundant to Section 7 of this QAPDM. Suppliers are audited to assure they have implemented a quality assurance program and as a matter of course , routine audits or effectiveness assessments are a result. This statement of requirement also is not consistent with the auditing done by Transnuclear - the subject of this section of the QAPDM.
177	14	Criterion 18 - third paragraph - first sentence	Added "planned and"; changed "activity" to "activities"	Change	No	More fully describes that audit planning is required. Grammar cleanup.
178	14	Criterion 18 - fourth paragraph - first sentence	Added "plans and"	Change	No	More fully describes that audit planning is required. Grammar cleanup.
179	14	Criterion 18 - fourth paragraph - fourth sentence	Deleted "by the auditor"; changed "area" to areas"; changed "activity" to "activities"	Change	No	The content of QA audits is described; such evaluations may be by the auditor, the Lead Auditor, or a technical specialist. Assigning responsibility for only a part of the audit process in this section is not required.
180	15	Criterion 18 - fifth paragraph - first sentence	Added "when appropriate"	Change	No	This addition of this qualifier specifically states that there may be times when corrective actions are not required, for instance if the audit report id not have any findings.

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Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
181	15	Criterion 18 - fifth paragraph - second sentence	Replaced "Quality Assurance Manager" with "Director, Corporate Quality Assurance (DCA)"	Change	Yes, but still meets regulations, see ** EXPLANATION	Revised to more accurately describe the responsibility for the overall Audit Program. **EXPLANATION - With the activation of a single QA organization, the specific assignment of the Director, Corporate QA more appropriately assigns overall responsibility for the Audit Program. This could be considered a change in commitment however, it is an acceptable one since the activity is still assigned to the QA department whose independence and autonomy is unchanged.
182	15	Criterion 18 - sixth paragraph - first sentence	Replaced "Quality Assurance Manager" with "Director, Corporate Quality Assurance (DCA)"	Change	Yes, but still meets regulations, see ** EXPLANATION	Revised to more accurately describe the responsibility for the overall Audit program. **EXPLANATION - With the activation of a single QA organization, the specific assignment of the Director, Corporate QA more appropriately Assigns overall responsibility for the Audit Program. This could be considered a change in commitment however, it is an acceptable one since the activity is still assigned to the QA department whose independence and autonomy is unchanged.
183	15	Criterion 18 - sixth paragraph - first sentence	Added "that"; changed "has" to "have"; added "directs the performance of"; deleted "a performs reaudit where considered appropriate.": added "directs the performance of re-audits when deemed necessary."	Change	No	Sentence restructuring and grammar to more clearly state the requirement with no change.

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Change	Rev. 2 Page	Rev. 2 Paragraph/Sentence	What Changed	Category	Possible Reduction	Comment
184	15	Criterion 18 - sixth paragraph - second sentence	Deleted "A qualified lead auditor shall lead audits of projects for which Transnuclear has direct responsibility.:	Change	No	This a redundant statement of requirement from paragraph four that requires trained and qualified auditors for all audits. This requirement is unchanged.
185	15	References	Added "ASME Section III, Division 1 (NCA 4000 Quality Assurance)" and "ASME Section III, Division 3 (WA 4000 Quality Assurance)"	Change	No	Adding references does not change the statements of requirements as documented in this QAPDM.
186	15 & 16	Figure 1	Re-labeled the Organization Chart as "Figure 1" instead of "Attachment 1"	Editorial	No	Re-labeling is an editorial change as long as it is properly referenced in text.
187	16	Figure 1	Changes to Organization Chart	Change	No	Although there are many changes in titles and reporting arrangements, the clear lines of accountability are unchanged between the President, the Director, Corporate Quality Assurance, the Quality Assurance Managers, and the individuals in the QA Department who are responsible for assuring that this QAPDM is implemented. Therefore, the autonomy and authority of the QA function is unchanged.