

E-22487 June 21, 2005

ATTENTION: Document Control Desk Mr. E. William Brach Director, Spent Fuel Project Office Office of Nuclear Material Safety and Safeguards 11555 Rockville Pike Rockville, MD 20852

Subject: Proposed Revision 4 to the Transnuclear QA Program Description Manual

Dear Mr. Brach:

We are hereby submitting an update to our Quality Assurance Program Description Manual (QAPDM) to reflect an address change for our Fremont, CA Office. This is the only change reflected in Revision 4.

Please note that Revision 3 of the Transnuclear QAPDM was previously approved under Docket No. 71-0250 for use in accordance with the requirements of 10 CFR 71 and 10 CFR 72.

Any questions regarding this proposed change may be addressed to me at 914-347-2345. Thank you for your consideration.

Very truly yours,

.Steven C. White Director, Corporate Quality Assurance Transnuclear, Inc.

<u>c (w attachment)</u>:

c (w/o attachment):

Mr. Robert Lewis 11555 Rockville Pike Mail Stop 013-D13 Rockville, MD 20852 A. Hanson G. Field W. Gallo T. Neider

Ums501

FOUR SKYLINE DRIVE, HAWTHORNE, NEW YORK 10532 Phone: 914-347-2345 + Fax: 914-347-2346



# TRANSNUCLEAR, INC.

# **Quality Assurance Program Description**

# Manual

# for

# 10 CFR 71, Subpart H and 10 CFR 72, Subpart G

**Revision 4** June 21, 2005

Alan S. Hanson President

Steven C. White Director, Corporate Quality Assurance

6-21-2005 Date

Date



#### 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

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Transnuclear, Inc. 2201 Walnut Ave., 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.

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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.

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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-tosafety 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

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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

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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.

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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

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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 <u>Control\_of\_Purchased\_Materials, Parts\_and</u> <u>Components</u>

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

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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 <u>Identification and Control of Materials, Parts and</u> <u>Components</u>

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.

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# 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

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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.

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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

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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 reinspecting 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

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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 <u>Corrective Action</u>

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.

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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 <u>Audits</u>

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.

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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

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corrective actions have been implemented and directs the performance of re-audits when deemed necessary.

#### 19.0 <u>References</u>

- 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



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