



72-1021
72-1027
72-1004
71-0192
71-0250

August 31, 2000

E-18441

Mr. Chet Poslusny, Jr., Acting Chief
Transportation and Storage Safety and Inspection Section
Spent Fuel Project Office
Office of Nuclear Material Safety and Safeguards
US NRC
Washington, D.C. 20555-0001

Subject: Docket Nos. 72-1021, 72-1027 (TAC Nos. L22909 and L22901) and
Docket No. 72-1004 (TAC No. L22711)

Reference: TN letter E-18440 to C. Poslusny, NRC dated August 31, 2000

Dear Mr. Poslusny:

As an effort to work more effectively as one company, Transnuclear, Inc. and Transnuclear West have prepared a joint QA Program which is enclosed for your review. Transnuclear West is a wholly-owned subsidiary of Transnuclear, Inc. Upon your approval, this QA Program will supersede the Transnuclear Inc. QA Program and the Transnuclear West QA Program. The program is applicable to both 10CFR71 and 10CFR72 activities, and has been submitted for review for compliance with 10CFR71 Subpart H under separate cover. Packaging Technology, a wholly-owned subsidiary of Transnuclear, Inc. is included in the QA Program.

Rulemaking should not be necessary for this action because approval of the revised QA Program will not change the language in Transnuclear's or Transnuclear West's Certificates of Compliance.

We look forward to your approval of the QA Program. Please contact me or Bill Sutherland regarding this request.

Sincerely,

Alan S. Hanson
President and CEO
Transnuclear, Inc.
CEO Transnuclear West

cc: B. Sutherland

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Controlled Document Transmittal

Transmittal #: DC-655

Purpose: Approval

Action: N/A

Project: 91047

Date: 8/31/00

From: Rick Flinn

Chet Poslusny, Jr., Acting Chief
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DDN	REV	TITLE:	Copy#
E-18441	01	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 & Transport Systems for Spent Fuel and Radioactive Material	Uncontrolled

Please sign, date and return this Controlled Document Transmittal Form to me by: 9/15/00

I acknowledge receipt of the above document(s).

Signature: _____ Date: _____

**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 1
(Complete Revision)

August 30, 2000

Transnuclear, Inc.
Four Skyline Drive
Hawthorne, NY 10532

UNCONTROLLED

Approvals

Name & Title	Signature	Date
Alan S. Hanson, President	<i>Alan S. Hanson</i>	8/30/00
W. R. Sutherland, QA Manager	<i>W.R. Sutherland</i>	8/30/00

Transnuclear West Inc.
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Approvals

Name & Title	Signature	Date
Robert M. Grenier, President	<i>Robert M. Grenier</i>	8/30/00
R. A. Ayres, QA Manager	<i>RAA</i>	8/30/00

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

Approvals

Name & Title	Signature	Date
Robert A. Johnson, President	<i>Robert A. Johnson</i>	8/29/00
B. C. Counterman, QA Manager	<i>B. C. Counterman</i>	8/29/00

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, reporting to the President of that organization, 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 President of that entity. 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. 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 Assurance 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 sub-tier 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

