71-250
Rec'd w/ltr dtd
E-1473
Revision 3
05/23/85

QUALITY ASSURANCE PROGRAM

FOR

DESIGN, MANUFACTURE, TEST, USE, MAINTENANCE AND REPAIR

OF

PACKAGINGS FOR TRANSPORT OF RADIOACTIVE MATERIALS

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25341

REVISION LOG

Rev. No.	Date	Approved	Description
0	12/28/78		Original Issue
1	12/7/79		Revised per U.S. Nuclear Regulatory Commission letter, Charles E. MacDonald, FCTC: RHO 71-0250, dated October 9, 1979.
2	2/14/80		Revised pages i, ii and 9, and added new Appendix A in response to U.S. Nuclear Regulatory Commission letter, Charles E. MacDonald, FCTC RHO 71-0250, dated January 17, 1980.
3	5/23/85		Revised pages i, ii Editorial-changed "Appendix E" to "Subpart H" throughout the manual to be consistent with latest 10CFR71. Updated Appendix A to include latest QA Procedures and Program Plans

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INTRODUCTION

The Code of Federal Regulations, Title 10, Part 71 (10 CFR 71) "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions", requires in paragraph 71.51 that a licensee establish, maintain and execute a Quality Assurance Program (QA Program) satisfying each of the applicable criteria specified in Subpart H of 10 CFR 71. A licensee is a person or organization that delivers licensed material in an approved packaging to a carrier for transport. The licensee is required to assure himself and the Nuclear Regulatory Commission that the QA Program, on which approval of the packaging is based, has been implemented. The present document describes how Transnuclear, Inc. (TN), as a licensee, intends to satisfy these requirements.

As a licensee, TN has QA responsibility for all phases of design, manufacture, test, use, maintenance, and repair of any packaging which TN delivers to a carrier for transport of licensed material. This QA responsibility exists whether TN has contractual responsibility for each of the individual phases or not.

For example, if TN intends to transport material in a packaging which was designed and fabricated by others without TN involvement, TN shall assure itself that these activities were performed, where applicable, in accord with the quality assurance requirements of 10 CFR 71, Paragraph 71.51. On the other hand, if a packaging is designed and fabricated by TN or under contract to TN, TN shall assure that the QA Program, as described herein, is implemented during these phases. Organizations that perform such work under direct contract to TN are

identified herein as major participating organizations. They may provide hardware, services or both.

The present document describes TN's generic QA Program for the design, manufacture, test, use, maintenance and repair of the packagings in accordance with 10 CFR 71, Paragraph 71.51. Additionally TN's applications for NRC package approval shall also contain specific provisions, as required. These specific provisions shall consider the complexity and the proposed use of the packaging and its components. Supplemental requirements may be added or the applicability of certain of the 18 criteria of Subpart H of 10 CFR 71 may be deleted.

3 The organization of this document follows that of Subpart H of 10 CFR 71, in that sections are numbered and titled the same as the corresponding 18 criteria of Subpart H.

1. ORGANIZATION

The organizational structure which has been set up at TN to establish and implement its QA Program is shown in Fig. 1. The authority and duties of the personnel performing activities affecting the safety related functions of packagings are described below.

The Chief Engineer is the person responsible for establishing the QA Program. He reports directly to the President of TN. The President shall approve the QA Program and any revisions thereto. The Chief Engineer shall approve Corporate QA Procedures and any revisions thereto. The minimum qualification requirements for the position of Chief Engineer are a bachelor's degree in engineering from an accredited institution and ten years of experience in engineering and quality assurance activities.

For each project one person from the TN organization shall be assigned as the QA Engineer for that project. The person who is assigned as the QA Engineer for a particular project shall have no other responsibilities on that project. He shall be functionally independent of any group or individual directly responsible for the activities which he monitors. He shall have the authority and organizational freedom to enforce QA requirements, to identify problem areas, to recommend or provide solutions to QA problems, and to verify the effectiveness of the solutions. As shown by the solid line in Fig. 1, he can communicate directly with the President. The minimum qualification requirements for the position of Project QA Engineer are a bachelor's degree in engineering, physical sciences, mathematics or quality assurance from an accredited institution and five years of experience in engineering activities with at least one year of experience in quality assurance activities.

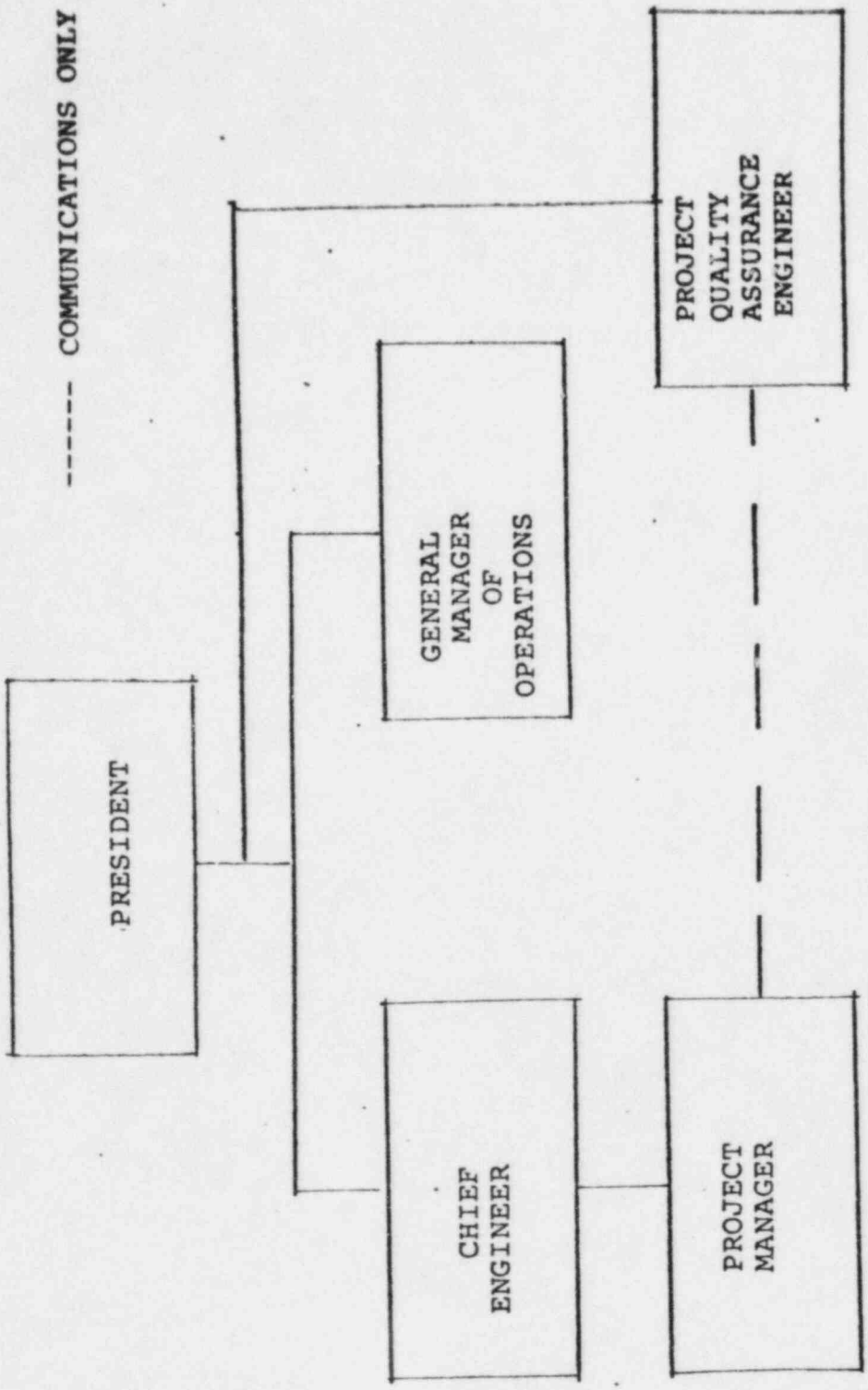

FIG.1 TN ORGANIZATION CHART

The QA Engineer has the following typical responsibilities:

a. Prepare TN's QA Program Plans and QA Procedures for specific projects.

b. Verify that major participating organizations have approved QA Programs, as required.

c. Approve QA Program Plans of participating organizations for a project for which he has been assigned as the QA Engineer.

d. Verify that major participating organizations have QA procedures, as required.

e. Assure that TN design documents contain applicable QA requirements.

f. Approve TN safety related procurement documents instructions, procedures and drawings.

g. Assure that further processing, delivery, installation or use of non-conforming items is controlled until proper disposition has occurred..

h. Perform audits to verify that QA requirements are being met.

The QA Engineer may delegate the performance of one or more of these functions to other qualified individuals at TN, or from contractor organizations, who do not have direct responsibility for performing the work being monitored.

A Project Manager or Project Engineer shall be responsible to the Chief Engineer for all technical aspects of a project including issuing of procurement documents, preparation of licensing documents, fabrication and delivery of the packaging and use of the packaging.

TN's General Manager of Operations or his designee shall be responsible for all transport operations after delivery of a packaging to TN. During the design and procurement phases, he reviews and provides input on transport and operations requirements.

A possible interrelationship between TN and another major participating organization is shown in Fig. 2. The other organization could be a design agent, packaging manufacturer, supplier, sub-contractor or user. The chart is provided to establish that any organization performing functions affecting quality must have a QA position with the required authority and organizational freedom as well as direct access to upper levels of management. The chart also shows the requirement for direct communication between Quality Assurance of TN and the other organization. As licensee, TN shall retain overall responsibility for the QA program.

Specific organization charts of major participating organizations shall be detailed in their respective QA documents, and shall be in full compliance with the QA requirements of 10 CFR Part 71.

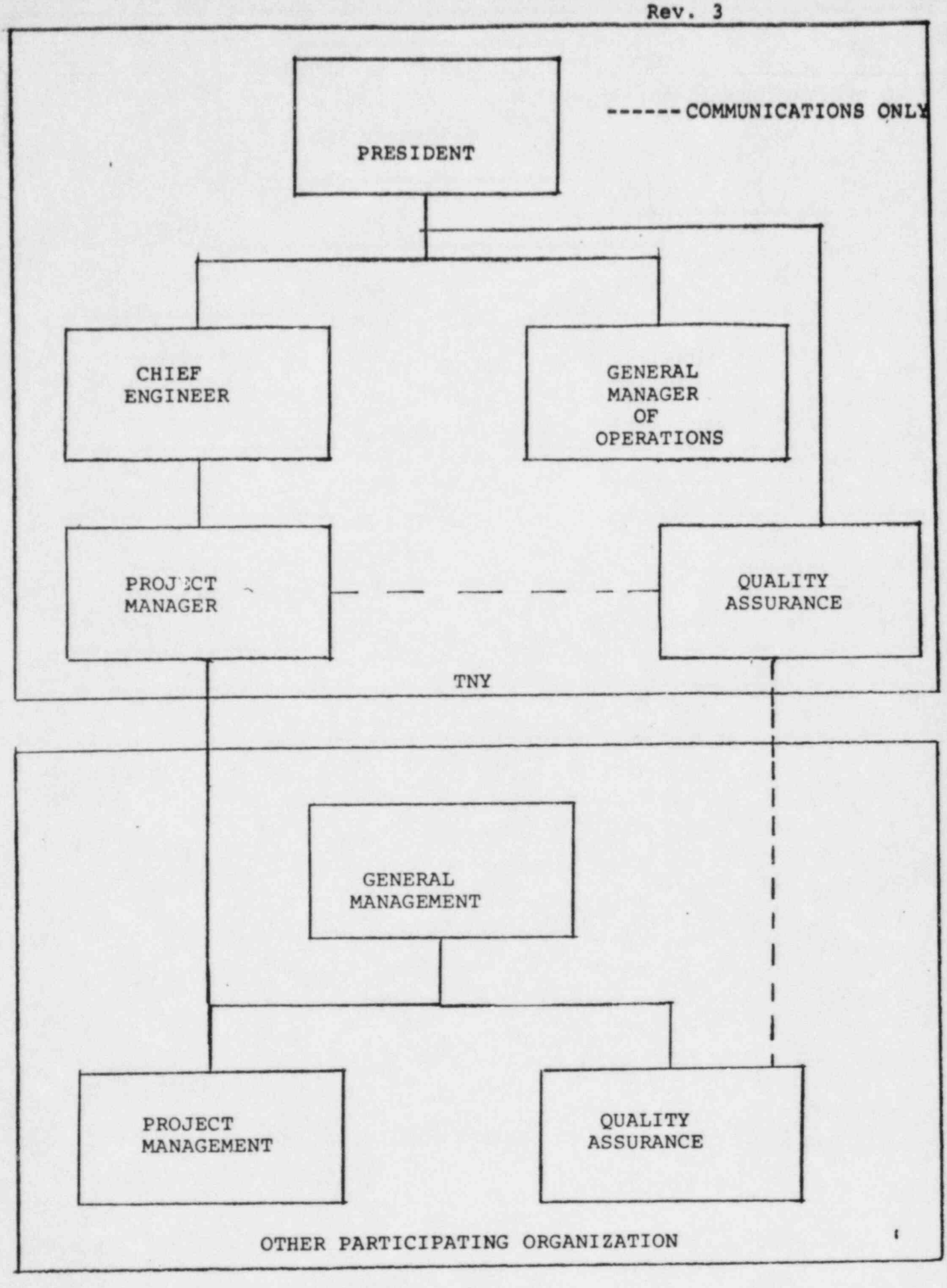

FIG. 2 TYPICAL OVERALL ORGANIZATIONAL CHART

2. QUALITY ASSURANCE PROGRAM

The program described herein is a generic program which shall be implemented by TN as a licensee who delivers a package to a carrier for transport of radioactive materials. The program is intended to be in full compliance with the requirements of Subpart H of 10 CFR 71.

It is the policy of Transnuclear, Inc. to establish and maintain an integrated quality assurance system which governs the design, manufacture, test, use, maintenance and repair of packagings for transport of radioactive materials. This system applies to all safety related packaging activities performed by TN, or its' contractors, to assure that the packagings meet the high standards of reliability and safety required during handling and transport. The quality assurance system utilizes Project QA Program Plans, Corporate QA Procedures and Project QA Procedures to define specific quality assurance requirements for implementation of the generic QA Program at TN. Comparable plans and procedures shall be utilized by TN contractors.

Specific QA Program Plans shall be prepared to detail the actual measures which are to be established and implemented for a particular packaging project or portion of a project. Each specific project QA Program Plan shall identify the participating organizations, their inter-relationships, and the responsibilities of each of the participants. The scope of specific QA Program Plans will differ based upon the type and complexity of the quality affecting activities to be performed. Specific QA Program Plans which have been developed by TN cover the following projects:

-Design, Procurement, Fabrication and Acceptance of TN-8 and TN-9 Irradiated Fuel Packagings.
-Procurement of Lifting Beams for TN-8 and TN-9 Irradiated Fuel Packagings
-Support Services for Commonwealth Edison Company, TN-9.1 Irradiated Fuel Packaging
-Design and Procurement of TN-125 Packagings for Transport of Radioactive Materials

QA Program Plans for new projects shall be established at the earliest time consistent with the schedule for accomplishing activities on such projects. Specific measures shall be established in the QA Program Plans directly or by reference to Corporate QA Procedures, which are applicable to all TN projects, or to Project QA Procedures which are only applicable to specific projects. The Corporate QA Procedures are used for activities such as Drawing Control, Procedure Format, Document Transmittals, etc. Project QA Procedures are used for specific project activities unique to a particular project. The TN Project QA Engineer shall identify all QA procedures required during a particular phase of a project during the development of the QA Program Plan. If QA procedures so identified do not yet exist, they shall be prepared as either Corporate or Project QA Procedures, approved, and issued prior to the performance of the activities covered by the procedures. Appendix A to this Program lists the QA Program Plans, Corporate QA Procedures and Project QA Procedures presently applicable to TN QA activities against a matrix of the 18 criteria of Subpart H of 10CFR71. 3

Preparation of the QA Program, and subsequent revisions thereto, are the responsibility of the Chief Engineer. The President of TN shall approve the original QA Program and any subsequent revisions. QA Program Plans for specific projects and any revisions thereto, shall be approved by the Project QA Engineer. Corporate QA

Procedures are approved by the Chief Engineer. Project QA Procedures are approved by the Project QA Engineer.

The distribution of the generic QA Program is controlled by TN's Chief Engineer. He is also responsible for the distribution of Corporate QA Procedures. The Project QA Engineer is responsible for the distribution of Project QA Procedures. He assures that responsible organizations and individuals are aware of all mandatory QA requirements for project activities under their cognizance and that copies of the general and specific QA program, plans and procedures are distributed to them, as applicable.

Major organizations participating in a project shall have approved quality assurance programs including written procedures and instructions to implement their respective programs. Their programs, procedures and instructions shall be in full compliance with the applicable criteria of Subpart H of 10 CFR 71. These QA programs shall be formally reviewed and accepted for use by the TN Project QA Engineer prior to the initiation of activities affecting quality. 3

Specific project QA Program Plans prepared by major participating organizations shall be approved by the TN Project QA Engineer. He shall perform audits and/or overchecks to assure that these programs and procedures are properly implemented by the participating organizations.

The Project QA Engineer is responsible for verifying on a particular project that all activities on safety-related systems, components and equipment are controlled by the QA program. In case of disputes with the TN Project Manager or others over quality matters he can request resolution by TN's President.

Safety related items shall be identified for each specific design and shall be submitted with an application for package approval. The complexity and importance of these items shall be defined and any special requirements shall be described.

TN shall hold annual QA Review Meetings to assess the adequacy and effectiveness of the generic and specific Project QA Programs. These review meetings shall be chaired by the President. The Chief Engineer and QA Engineers for ongoing projects shall attend. These reviews shall be documented and shall include a list of follow-up action items, designating responsibilities and schedules for implementation.

TN and major participating organizations shall provide suitable conditions, environment and equipment for activities affecting quality. Special controls, tools, equipment, etc. shall be provided to attain the appropriate level of quality. Inspections, tests and other controls shall be implemented to assure that the appropriate levels of quality are attained.

Personnel performing activities affecting quality shall be properly trained and indoctrinated as to the purpose, scope and proper implementation of the QA Program, the specific QA Program Plan, and QA Procedures to assure proficiency for the tasks which they are to perform. The proficiency of TN personnel performing activities affecting quality shall be maintained through a program of on-the-job training and indoctrination meetings as required.

3. DESIGN CONTROL

TN shall establish measures to assure that regulatory requirements and packaging design have been or are correctly translated into drawings, specifications, procedures and instructions. The design shall consider, but shall not be limited to the following design aspects: criticality, shielding, stresses, thermal and hydraulic performance, accident conditions, compatibility of materials, accessibility for in-service inspection, maintenance and repair.

Measures shall be established for the selection of suitable materials, parts, equipment, and processes for safety-related structures, systems and components. Valid industry standards and specifications shall be utilized to the greatest practical extent.

Written instructions, procedures and/or plans shall identify the methods of control for the design of the packaging. These documents shall identify the safety related items, regulatory requirements, applicable codes or standards, design criteria and measures for coordination and control of design interfaces, and appropriate quality standards. Deviations from applicable codes and standards shall be identified and controlled.

Design calculations and drawings shall be prepared and checked in accord with approved procedures. The adequacy of the design may be verified by test of a prototype or scale model. Materials, parts and equipment which are standard, commercial (off the shelf) or which have been previously approved for a different application shall be reviewed for suitability prior to selection.

In addition, the design shall be formally reviewed by individuals or groups, other than those who performed the original design. These reviews shall be in the form of Design Review Meetings for packaging designs which are developed by TN. For such designs, the Project Manager shall schedule and chair review meetings. These meetings shall be held to confirm that various aspects of the design have been properly considered, including conformance to license requirements when applicable. The Project Manager and Project QA Engineer shall review design documents to assure that the design characteristics of the packaging can be controlled, inspected, and tested and that appropriate inspection and test criteria have been identified. The Design Review Meetings shall also assure that there has been, is and will be appropriate coordination between organizations participating in the design, quality control, fabrication, and testing of the packaging.

Any errors or deficiencies in the design or design documents, including the design process, that could adversely affect safety-related components or sub-components of a packaging shall be documented, and corrective action shall be taken in accordance with Section 16 of this Program.

TN shall assure that measures are established and implemented to verify that the fabrication and assembly drawings, prepared by the Manufacturer are consistent with design documents. For packagings of TN design, TN shall review all fabrication drawings, approve design changes and establish procedures for the documentary control of design changes.

All design changes, including field changes, shall be subject to the same or equivalent design control measures as are applicable to the original design.

TN shall establish measures to assure that the approved design and operating conditions are not changed unless the effect of the changes on the design are evaluated and approved. For any change which affects the basis for the Certificate of Compliance of a packaging, approval for the change shall be obtained from the Nuclear Regulatory Commission prior to its use under the modified conditions.

4. PROCUREMENT DOCUMENT CONTROL

Procurement documents shall be prepared which clearly define all design requirements including quality assurance requirements, and shall reference all applicable documents, including codes, standards, regulatory requirements and the package design, as specified in the application for approval. These documents shall serve as the principal technical documents for the procurement of materials, spare parts, components, equipment or services to be used in the manufacture, test, use, maintenance or repair of the packaging.

These documents may be prepared by TN or by one or more major participating organizations, e.g. Design Agent, Manufacturer, etc. Each of these organizations shall have a documented, approved quality assurance program which shall be supplemented by detailed procedures and instructions as required to assure adequate control for preparing safety related procurement documents. Changes and revisions to these documents shall be reviewed and approved in an equivalent manner as the original document in accordance with documented procedures. These programs shall also include measures to qualify/accept the quality assurance programs of their suppliers and subcontractors for safety related equipment, materials or services.

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

Safety related procurement documents prepared and/or issued by TN shall be reviewed by the Project QA Engineer to determine that appropriate quality requirements are

correctly stated, inspectable and controllable. The QA Engineer shall also verify that adequate acceptance and rejection criteria are identified and that the procurement document was prepared, reviewed and approved in accordance with the applicable procedures. The QA Engineer's written approval of the procurement documents shall signify that he has verified these items prior to the release of the procurement documents.

TN's safety related procurement documents shall identify which documents (e.g. drawings, specifications, procedures, inspection and fabrication plans, inspection and test records, personnel and procedure qualifications, and chemical and physical test results of materials) are to be prepared by a supplier and which documents are to be submitted to TN or its agents for review, information and/or approval. The procurement documents shall also specify which documents are to be retained, controlled and maintained by the supplier for specified periods and which records shall be transmitted to TN prior to use of the packaging. Duplicate records may be maintained for specified periods by both the supplier and TN to facilitate permanent record storage.

Procurement documents shall also include requirements to insure that TN or its agents have reasonable rights of access to the supplier's facility and records for source inspection and audit prior to contract award, and inspection and audits during and after completion of fabrication.

5. INSTRUCTIONS, PROCEDURES AND DRAWINGS

Methods for complying with each of the applicable 18 criteria of Subpart H of 10CFR71, for activities affecting quality during design, manufacture, test, use, maintenance and repair shall be specified in instructions, procedures and/or drawings. They shall be prepared, reviewed, approved and controlled in accord with written document control procedures. 3

These instructions, procedures and drawings shall include quantitative and/or qualitative acceptance criteria to permit verification that activities affecting quality have been satisfactorily accomplished.

The QA Engineer on a project shall review and approve Project instructions, procedures and drawings which are prepared by TN. These documents may include, but are not limited to specifications, drawings, special process, calibration, test, operating, maintenance and repair instructions and procedures and any changes thereto.

6. DOCUMENT CONTROL

TN shall establish and implement procedures to control the issuance of TN documents which prescribe activities affecting quality. These procedures shall define document control measures to assure adequate review, approval, release and distribution of original documents and subsequent revisions. These documents may include, but are not limited to design specifications, drawings, procurement documents, and special process, test and operating procedures. A specific QA Plan for each project shall identify the persons, groups and/or organizations responsible for reviewing and approving documents and their revisions for that project.

Major participating organizations shall establish and implement document control procedures in accord with their approved QA program.

Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless otherwise delegated by TN or a major participating organization. Approved changes shall be included in the applicable drawings, procedures, instructions or other documents prior to the implementation of the change.

The Project Manager shall be responsible for the control of Project documents which are issued by TN. He shall also be responsible for the receipt and distribution of Project documents to and from participating organizations. He shall maintain an up-to-date file of all Project records.

Documents shall be available at the location where activities affecting quality are performed prior to commencing the work.

For certain types of documents which are issued by TN, the Project Manager shall maintain Master Lists to identify current revisions. He shall update and distribute these lists to responsible personnel to preclude the use of superseded documents. Major participating organizations shall utilize the same or equivalent measures.

7. CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

Measures shall be established and implemented to assure that all purchased material, equipment, and services conform to procurement documents.

An engineering source evaluation of prospective supplier's facilities shall be performed by the TN Project Manager to confirm that the organization has the technical capability to supply safety related equipment, materials or services in accordance with the project's design, manufacturing, quality assurance and procurement requirements.

The TN Project QA Engineer shall perform source evaluation audits of potential suppliers in accordance with TN Corporate QA Procedures to verify that they can comply with the criteria of Subpart H of 10CFR71 that are applicable to the material, equipment, or service being procured. 3

The resultant reports of the engineering source evaluations and source evaluation audits shall be filed and retained in accordance with Section 17 and the applicable QA procedures.

The Project QA Engineer shall inspect and audit contractors and sub-contractors at suitable intervals to verify that they comply with quality requirements and to assess the effectiveness of their QA program.

Suppliers shall provide objective evidence that packagings and associated items, including repaired or spare parts, meet all quality requirements. All items

shall be properly identified. Appropriate records shall be available prior to use or installation to permit verification of conformance with procurement documents. These records shall be retained accessibly (See Section 17). The supplier shall furnish to TN all documentation which identifies all procurement requirements which have not been met together with nonconformance reports dispositioned "accept as is" or "repair". These documents shall be reviewed by the Project Manager and TN's design agent (if applicable) to assure conformance with the license application. The Project QA Enginer shall accept these documents in writing.

Supplier's certificates of conformance for safety related material and components furnished to TN shall be periodically evaluated by audits, independent inspections or tests to assure that they are valid. The frequency and extent of these evaluations shall be related to the safety importance of the procured material or equipment. An acceptance test program approved by TN shall be performed for each packaging, in accordance with the requirements of the certificate of compliance and/or the packaging application.

TN or its agents shall perform receiving inspections on safety related components and equipment furnished to TN, to assure that the component or equipment is properly identified and corresponds to the receiving documentation. The inspections shall verify that the component or equipment conforms to the requirements of previously established criteria. These inspections shall be performed utilizing previously established inspection instructions. Fabrication records, acceptance test records and certificates of conformance shall be available at TN's facilities prior to first use of the component or equipment by TN.

Safety related component and equipment suppliers shall have QA programs which contain measures equivalent to the above, and in addition assure that accepted material, components and equipment are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for further work or installation. Nonconforming materials, parts or components shall be controlled in accordance with Section 15.

8. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

Measures shall be established and implemented to identify and control materials, parts, and components. These measures shall assure identification of an item by an appropriate means during the fabrication, installation and use of the item and shall prevent the inadvertent use of incorrect or defective items. The requirements for identification shall be established during the preparation of procurement specifications and design drawings. The methods and location of identification information shall be selected so as to not adversely affect the fit, function or quality of the items being identified.

The identification and control of safety-related items shall be traceable through procurement, fabrication, inspection and test records. Correct identification of components, materials and components shall be verified and documented prior to release of the equipment, materials or components for fabrication, assembly shipping and installation.

9. CONTROL OF SPECIAL PROCESSES

Measures shall be established and implemented for the control of special processes used in the manufacture and repair of packagings. These processes include welding, non-destructive testing and other processes special to a specific packaging as identified in the application for packaging approval.

Special processes shall be performed in accordance with approved written procedures. Personnel who perform special processes shall be formally trained and qualified in accordance with applicable codes, standards or specifications. Qualification records of procedures and personnel shall be filed and kept current by the organization which performs the special process.

10. INSPECTION

Measures shall be established and implemented to inspect materials, parts, processes or other activities affecting quality to verify conformance with documented instructions, procedures, specifications, drawings, or other procurement documents. These inspections shall be performed by personnel other than those who performed the activity being inspected. Inspectors shall be qualified in accordance with the applicable codes, standards, and the training programs of TN or its contractors. Inspector qualifications and certifications shall be maintained current and these records shall be retained in accordance with Section 17 of this Program.

Inspections shall be performed in accord with approved, written instructions and procedures. The instructions and procedures shall include and address acceptance criteria; identify the characteristics and activities to be inspected; identify the individuals or groups responsible for performance of the inspection operations; describe the method of inspection; record evidence of completion and verifying of a manufacturing, inspection or test operation; and record the identity of the recording inspector or data recorder and the results of the inspection operation. When direct inspection is not possible, provisions shall be established for indirect control by monitoring processing methods, equipment, and personnel.

Mandatory hold points shall be established for inspections or witnessing, as required. Work shall not proceed beyond a hold point without the consent of the designated inspector.

Modifications and/or repairs to and replacements of safety related components or equipment shall be inspected in accordance with the original design and inspection requirements or acceptable alternatives.

11. TEST CONTROL

A program shall be established and implemented to perform required proof, acceptance and operational tests, as identified in procurement documents and the application for package approval.

The tests shall be performed by qualified personnel in accordance with approved, written instructions, procedures and/or checklists. Test procedures shall incorporate or reference the applicable requirements and acceptance limits contained in the design and procurement documents; instructions for performance of the test; test prerequisites such as test equipment requirements, personnel qualification requirements, fabrication or operational status of the item to be tested, and the provisions for data recording and retention; and mandatory inspection hold points to allow witnessing by TN or it's agents.

Test results shall be documented and evaluated. They shall demonstrate that acceptance criteria have been met. Acceptance of test results for a specific project shall be acknowledged in writing by the TN Project Manager for that project or his designee. Tests performed after modifications, repairs or replacements of safety related components or equipment shall be performed in accordance with the original design and testing requirements or acceptable alternatives.

12. CONTROL OF MEASURING AND TEST EQUIPMENT

Measures shall be established and implemented to assure 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 necessary limits. These measuring devices shall be calibrated at scheduled intervals against certified standards having known, valid relationships to national standards. All calibrations shall be performed in accordance with approved written procedures.

Measuring and test equipment shall be identified and traceable to the calibration records, and shall be labeled or tagged indicating the next required calibration date. Standards utilized for calibration of measuring and test equipment shall have an uncertainty requirement of no greater than one-fourth of the tolerance of the equipment being calibrated, unless limited by the state of the art of the equipment or calibrating standard.

When measuring and test equipment is found to be out of calibration, measures shall be taken and documented to determine the validity of inspections performed during the period the equipment was out of calibration. The complete status of all measuring and test equipment under the calibration system shall be recorded and maintained.

Test equipment shall be subjected to a proof test to demonstrate that it performs its intended function prior to its use for testing packaging components or the complete packaging.

Operational checks shall be performed on test equipment, as required, to assure that the equipment is still functioning properly prior to actual testing of packaging components or the complete packaging.

13. HANDLING, STORAGE AND SHIPPING

Measures shall be established and implemented to assure that all materials, components, assemblies, spare parts, special tools, equipment and the packaging itself are handled, stored, packaged and shipped in a manner which prevents damage, loss of identity or deterioration. These activities shall be carried out in accordance with written approved procedures.

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

Shipping procedures shall assure that all conditions of the Certificate of Compliance are satisfied prior to delivery of radioactive material to a carrier for transport in an approved package.

14. INSPECTION, TEST AND OPERATING STATUS

Measures shall be established and implemented to assure that the status of required inspections and tests of packagings and associated items are clearly indicated by some suitable means, e.g. tags, labels, cards, form sheets, check lists, etc. The status of nonconforming items is of particular concern (see Section 15).

By passing of required inspections, tests, or other critical operations shall be controlled in accordance with written procedures or instructions by the TN QA Engineer and/or TN's inspection agent.

Where appropriate, the operating status of components of the packaging, e.g. valves, switches, etc. shall be indicated to prevent inadvertent operation.

The application and removal of status indicators shall be in accord with approved written instructions and procedures.

15. NONCONFORMING MATERIALS, PARTS OR COMPONENTS

Measures shall be established and implemented to control materials, parts, and components which do not conform to requirements so as to prevent their inadvertent use in subsequent manufacturing operations or during service.

These measures shall be described in approved written instructions and procedures. The nonconforming items shall include items which do not meet specification or drawing requirements, as well as items which are not fabricated or tested in accordance with approved written procedures or by qualified processes or by qualified personnel, where the use of such procedures, processes or personnel is required by the fabrication, test, inspection or quality control documents.

Nonconforming items shall be identified and segregated to prevent their inadvertent use. Nonconformance reports shall be utilized for the procedural control of nonconformances. They shall describe the nonconformances and provide for their disposition. Inspection requirements for nonconforming items following rework, repair or modification shall be detailed in the nonconformance reports which shall be approved and signed following completion of the disposition. The acceptability of the rework or repair of nonconforming materials, parts, and components shall be verified by reinspecting and/or retesting the reworked or repaired item to the original requirements, or by a method which is at least equal to the original inspection and/or testing method. Inspection, testing, rework, and repair procedures shall be documented and controlled.

Nonconformance reports shall be utilized to notify other affected organizations. Items which are not in conformance with TN approved documents shall be reviewed by TN's Project Manager and QA Engineer. Their disposition shall be approved by TN's QA Engineer. Nonconformances with documents such as fabrication details, which may not require TN approval, may be resolved without TN approval by major participating organizations, as appropriate, in accord with their approved QA programs.

Nonconformance reports shall be made part of the inspection records. They shall also be reviewed periodically to identify quality trends. The results of these reviews shall be reported to management for their assessment.

Procedures shall be established and implemented to report defects and noncompliances in accord with the provisions of 10 CFR 21.

16. CORRECTIVE ACTION

Measures shall be established and implemented to assure that conditions adverse to quality are promptly identified and corrected to preclude repetition.

Personnel responsible for quality assurance shall periodically review nonconformance reports and operating reports relating to failures, malfunctions and deficiencies to assess the need for corrective actions. They shall advise their respective managements of such needs, document decisions and appropriate courses of action, and perform the necessary follow up to verify that the corrective actions have been taken.

17. QUALITY ASSURANCE RECORDS

For each packaging, or other safety related component or equipment, a program shall be established and implemented to assure that sufficient written records are maintained to furnish evidence of activities affecting quality. These records include, but are not limited to, design records, records of use and the results of reviews, inspections, tests, audits, monitoring of work performance, materials analyses, and related procedures such as qualifications of personnel and equipment. The record program shall be based on ANSI N45.2.9 "Requirements for Collection, Storage, and Maintenance of Quality Assurance Records for Nuclear Power Plants".

Quality assurance records shall be collected by the originating organization as the documents are completed. They shall be stored by these organization(s) until delivery of the packaging, component or equipment. The requirements and responsibilities for record transmittals, record retention, and maintenance by the originating organization(s) prior to completion of the work shall be in accordance with the applicable codes, standards, procurement documents, and the organizations' QA program. Approved, written procedures shall be utilized to control and maintain QA records.

Inspection and test records shall contain, where applicable, the description of the type of observation; evidence of the completion and verification of a manufacturing, inspection, or test operation; the date and results of the inspection or test; any information related to conditions adverse to quality; the identification of the inspector,

data recorder, or test operator; and evidence of the acceptability of the test or inspection results.

The record program shall identify which types of records are to be transmitted to TN for retention at TN and which ones shall be retained by the originating organization in accord with procurement document requirements, Section 4. "Lifetime" records shall be retained by TN. The records shall be identified, indexed and stored in accessible locations. The record storage facility shall be constructed, located and secured in accordance with written procedures to prevent destruction of the records by fire, flooding, theft, and deterioration by environmental conditions such as temperature and humidity. Alternatively, duplicate storage of records at two separate and segregated locations may be utilized to prevent loss or destruction.

Maintenance of records at TN shall be in accord with written approved procedures. These procedures shall address duration of storage, responsibilities for safekeeping, preservation, and disposition of nonpermanent records. Maintenance of records at participating organizations shall be in accord with their approved program.

18. AUDITS

A comprehensive program of planned and periodic audits shall be established and implemented by TN to verify compliance with all aspects of the TN QA Program and to determine its effectiveness. The audit program shall include audits by TN of it's suppliers' QA programs, procedures and activities to verify and evaluate that the suppliers' procedures and activities are meaningful and comply with the overall QA Program. Suppliers of safety related equipment, material or services to TN shall implement a program to verify compliance with all aspects of their QA program and to determine its effectiveness.

The audit program shall describe the areas to be audited, such as design activities, fabrication, testing, use, maintenance and repair of packagings. The schedule for such audits shall be based upon the safety importance of the activities being audited.

The audits shall be performed by qualified personnel not having direct responsibilities in the areas being audited. The audits shall be conducted in accord with written approved procedures and/or check lists. Audit results shall be documented, and shall be reviewed with personnel having responsibility for the area audited. Agreements on corrective actions and schedules for implementation shall be established and recorded. Reaudits of deficient areas shall be scheduled on a timely basis to verify implementation of agreed upon corrective actions. Audit reports shall 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 their implementation.

Audit reports shall be distributed to management. The reports shall be reviewed for indications of adverse trends which could affect quality. If the results of such assessments so indicate, pertinent sections of the QA program shall be revised.

Audits of project activities for which TN has direct responsibility shall be performed by the project QA Engineer, except for audits of activities under his cognizance. The latter shall be performed by qualified personnel, nominated by TN's President, who have no responsibility for the activities being audited.

APPENDIX A

MATRIX OF EXISTING QA PROCEDURES AND PROGRAM PLANS AGAINST THE APPLICABLE CRITERIA OF SUBPART H OF 10CFR71

QA Document Identification	Title	Appendix E Criteria 10CFR71																	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Quality Assurance Program Plans																			
E-232	Quality Assurance Program Plan for the Design, Procurement, Fabrication and Acceptance of TN-8 and TN-9 Irradiated Fuel Packagings	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
E-482	Quality Assurance Manual for the Procurement of Lifting Beams for Model TN-8 and TN-9 Irradiated Fuel Packagings	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
E-1536	Quality Assurance Program Plan-Support Services for Commonwealth Edison Company: TN-9.1 Irradiated Fuel Packagings	X	X				X									X	X	X	X
E-1673	Quality Assurance Program Plan for the Design and Procurement of TN-125 Packagings for Transport of Radioactive Materials	X	X	X	X	X	X										X	X	X
E-2350	Quality Assurance Program Plan for TN-9.2 Packaging Operations at La Hague	X	X			X	X		X			X	X	X		X	X	X	X

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Quality Assurance Program Plans																			
E-2506	Quality Assurance Program Plan for the Engineering Of the TN-9C Packaging Modification	X	X	X	X	X	X										X	X	X
E-2684	Quality Assurance Program Plan for TN-9.2 Packaging Operations at AGNS	X	X			X	X		X		X	X	X	X		X	X	X	X
E-3165	Quality Assurance Program Plan for the Procurement Of Pneumatic Actuating Systems for TN-8/9 Lift Beams	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
3																			
E-3486	Quality Assurance Program Plan for the Design, Procurement, Fabrication and Acceptance of Crane Hook Adapters	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
4																			
E-4006	Quality Assurance Program Plan for the Design, Procurement, Fabrication, Testing and Acceptance of Canisters/Spacers and Special Handling Tools for Use in TN-9 Packagings.	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

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	Quality Assurance Program Plans																			
4	E-4012	Quality Assurance Program Plan for Operations and Maintenance of TN Packagaings and Ancillary Safety-Related Equipment	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	E-4621	Quality Assurance Program Plan for Design, Procurement, Fabrication, Testing and Acceptance of TN-REG and TN-BRP Transport/ Storage Packagings and Safety Related Ancillary Equipment.	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
5	E-4988	Quality Assurance Program Plan for the Design, Procurement, Fabrication, Testing and Acceptance of Cask Drop Protection System Base Plate Assembly for Use with TN-8/9 Packagings	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	E-5514	Quality Assurance Program Plan for Operation, Maintenance and Use of the TN-9.1 Spent Fuel Cask System	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

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Quality Assurance Program Plans																			
E-5603	Quality Assurance Program Plan for GPUN Spent Fuel Transportation Services, Project 1033	X	X				X	X						X		X		X	
E-6027	Quality Assurance Program Plan for Design, Procurement, Fabrication, Testing and Acceptance of Oyster Creek Canister/ Spacers and Special Handling Tools for Use in TN-9 Packagings	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Corporate Quality Assurance Procedures																			
1.1	Procedure for Obtaining Unescorted Access to Nuclear Power Stations	X	X				X											X	X
1.2	Personnel Training and Project Responsibility	X	X																
2.2	Q/A Procedure Format		X			X	X												

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		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Corporate Quality Assurance Procedures																			
3.1	Control of Engineering Calculations	X	X	X		X	X											X	
3.2	Design Control	X	X	X	X		X	X										X	
5 3.3	Computer Program Control	X	X	X	X	X	X	X				X				X	X	X	
4.1	Procurement Specification Preparation and Control for Special Equipment	X	X	X	X		X	X										X	X
4 4.2	Procurement Document Preparation and Control of Commercial Grade Items	X	X	X	X	X	X	X	X		X	X		X	X	X		X	
5.1	Drawing Control	X	X	X		X	X											X	
5.2	Control of Operating Manuals	X	X			X	X											X	
5 5.3	Preparation and Control of Test, Inspection, Maintenance and Operations Procedures	X	X			X	X				X	X	X					X	
6.1	Document Transmittals	X	X	X	X	X	X											X	

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		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Corporate Quality Assurance Procedures																			
6.2	Distribution of Controlled Documents	X	X	X	X	X	X											X	
7.1	Procurement Source Evaluation	X	X			X	X	X										X	X
7.2	Receipt Inspection		X		X	X	X	X			X	X	X		X	X	X	X	
8.1	Identification and Control of Parts and Equipment	X	X					X	X		X			X	X	X			
4 11.1	Test Control		X	X		X	X		X		X	X	X		X	X		X	
12.1	Control of Measuring and Test Equipment		X			X	X		X		X	X	X	X	X	X	X	X	X
15.1	Reporting of Defects & Noncompliance	X	X								X					X	X	X	
4 15.2	Nonconformance Control	X	X		X	X	X	X	X		X	X				X	X	X	
17.1	Temporary Working Files-Procurement	X	X	X	X	X	X											X	
17.2	Permanent Storage and Maintenance of Design and Procurement Records	X	X	X	X	X	X				X							X	X

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Corporate Quality Assurance Procedures																			
18.1	Source Evaluation Overchecks	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
18.2	Audits of Agent for Design Procurement	X	X	X	X	X	X	X										X	X
18.3	QA Audits	X	X	X		X	X										X	X	X
Project Quality Assurance Procedures																			
9317-17.1	Temporary Filing of Duplicate TNP QA Records	X	X	X	X	X	X											X	X
9317-17.2	Procedure for Receipt Inspection of Design and Fabrication Records	X	X	X	X	X	X	X			X							X	X
9317.1-17.1	Procedure for Receipt Inspection of TN-9.1 Design & Procurement Records	X	X	X	X	X	X	X			X							X	X
9317.2-4.1	Basis for Design Specification	X	X	X	X	X	X	X										X	
9317.2-5.1	Control of Manufacturer's Drawings	X	X	X	X	X	X	X										X	

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	Project Quality Assurance Procedures																			
	9317.2-15.1	Control of Nonconformances	X	X	X	X	X	X	X	X							X	X	X	
3	1023-1.1	U-Clearance Requirement for Access to Vepco Surry and North Anna Nuclear Power Stations	X	X															X	X
	1023-111-2.1	Quality Assurance Plan Supplement for Vepco Crane Hook Adapters	X	X	X															X
4	1023-131-2.1	Quality Assurance Plan Supplement for Vepco Horizontal Lift Beam	X	X	X															X
	1029-2.1	Quality Assurance Plan Supplement for Crane Hook Adapters for West Valley	X	X	X	X							X							X
5	1029-2.2	Quality Assurance Plan for Lid Lifting Systems Used onCrane Hook Adapters	X	X	X	X							X							X

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