U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE

AUDIT REPORT

OF

TRANSNUCLEAR, INC.

HAWTHORNE, NY. NOVEMBER 18 - 19, 1996

AUDIT NUMBER OQA-SA-97-003

Prepared by: _____ **Date:** 12/20/96
G.D. Wood
Audit Team Leader

Approved by: _____ **Date:** 1/7/97
Donald G. Horton
Director
Office of Quality Assurance

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit OQA-SA-97-003, the audit team determined that Transnuclear, Inc. (TN) is satisfactorily implementing an adequate and effective QA program, with the exception of those areas where deficiencies existed, in accordance with 10CFR72, Subpart G, and TN implementing procedures for QA Program Elements:

1.0 Organization
2.0 Quality Assurance Program
3.0 Design Control
4.0 Procurement Document Control
5.0 Implementing Documents
6.0 Document Control
15.0 Nonconformances
17.0 Quality Assurance Records

The following QA Program Elements were considered Unsatisfactory due to identified deficiencies. The deficiencies are described in Section 5.5.2.

7.0 Control of Purchased Items and Services
10.0 Inspection
16.0 Corrective Action
18.0 Audits

The following QA Program Elements were not evaluated do to lack of implementation by Transnuclear:

8.0 Identification and Control of Items
9.0 Control of Special Processes
11.0 Test Control
12.0 Control of Measuring and Test Equipment
13.0 Handling, Storage, and Shipping
14.0 Inspection, Test and Operating Status

The audit team identified five deficiencies during the audit that resulted in the issuance of five Deficiency Reports (DR) described in Section 5.5.2. There were three deficiencies identified by the audit team that were corrected prior to the postaudit meeting. These conditions are described in Section 5.5.4 of this report. Additionally, there were two recommendations which are detailed in Section 6.0 of this report.

2.0 SCOPE

The audit was conducted to evaluate the adequacy, compliance, and effectiveness of the TN QA program as described in 10CFR72, Subpart G, and the TN implementing procedures. The following QA program elements/requirements were evaluated during the audit, in accordance with the approved audit plan.

QA PROGRAM ELEMENTS/REQUIREMENTS

1.0 Organization
2.0 Quality Assurance Program
3.0 Design Control
4.0 Procurement Document Control
5.0 Implementing Documents
6.0 Document Control
7.0 Control of Purchased Items and Services
10.0 Inspection
15.0 Nonconformances
16.0 Corrective Action
17.0 Quality Assurance Records
18.0 Audits

The following QA program elements/requirements were not reviewed during the audit because of lack of implementation by TN:

8.0 Identification and Control of Items
9.0 Control of Special Processes
11.0 Test Control
12.0 Control of Measuring and Test Equipment
13.0 Handling, Storage, and Shipping
14.0 Inspection, Test and Operating Status

3.0 AUDIT TEAM AND OBSERVERS

The following is a list of audit team members, their assigned areas of responsibility:

Name/Title/Organization	QA Program Elements/Requirements
Gary Wood/Audit Team Leader/OQA	1, 2, 4, 7, 10, and 15
Dennis Threatt/Auditor/OQA	3, 5, 6, 15, 16, and 18

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The preaudit meeting was held at the TN offices in Hawthorne, NY on November 18, 1996. A debriefing and coordination meeting was held on November 19, 1996, to discuss audit status. The audit was concluded with a postaudit meeting held at the TN offices in Hawthorne, NY on November 19, 1996. Personnel contacted during the audit are listed in Attachment 1. The list includes those who attended the preaudit and postaudit meetings.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, overall, the TN QA Program is adequate and is being satisfactorily implemented for the scope of this audit.

5.2 Stop Work or Immediate Corrective Actions Taken

There were no Stop Work Orders, immediate corrective actions or related additional items resulting from this audit.

5.3 QA Program Audit Activities

A summary table of audit results is provided in Attachment 2. The audit checklists contain the details of the audit evaluation along with identification of the objective evidence reviewed. The checklists are kept and maintained as QA Records.

5.4 Technical Activities

The following TN documents were reviewed during the audit:

QA Program Plans
QA Procedures
Document Control Records
Audit Reports
Auditor Certifications
QA Records
Design Review Summary Reports
Procurement Specifications
Personnel Training Files
Design Criteria

The specific documents reviewed during the audit are listed on the Objective Evidence Reviewed Sheets which are a part of the audit records package.

5.5 Summary of Deficiencies

The audit team identified five deficiencies for which five Deficiency Reports (DRs) were issued. Two additional deficiencies were identified and corrected prior to the postaudit meeting.

Synopses of deficiencies documented as CARs, DRs, and/or PRs and those corrected during the audit are detailed below.

5.5.1 Corrective Action Requests (CARs)

There were no CARs identified as a result of this audit.

5.5.2 Deficiency Reports (DRS)

YM-97-D-009

The flow down of requirements from the TN QA Program, Dry Transfer System Design for Spent Fuel, E-13045, to TN QA Procedure 16.1, Corrective Action, Revision 0, was insufficient. The E-13045 requirement that inspection reports and test reports be reviewed for the need for corrective action was omitted from the referenced procedure.

YM-97-D-010

No objective evidence was available to substantiate that personnel providing dispositions to Nonconformance Reports had been qualified in accordance with TN QA Procedure 2.1, Qualification of Inspection and Test Personnel, Revision 2.

YM-97-D-011

The Lead Auditor who conducted Internal Audit 95-02 audited the areas of Design Control, Document Control, and Records. The Lead Auditor, as Project QA Engineer for Project 1051, had direct responsibility for these activities.

YM-97-D-021

NES was contracted to perform the annual internal audit of the Transnuclear QA Program. There was no objective evidence that a source evaluation was performed to qualify NES as an acceptable supplier of audit services as required by TN QA Procedure 7.1, Revision 2, Paragraph 3.0.

YM-97-D-022

A Qualification and Certification Record, required by TN Procedure 2.1, Revision 2, Paragraph 4.2, was not available for individuals performing source and receipt inspections at the TN cask supplier.

5.5.3 Performance Reports (PRs)

There were no PRS identified as a result of this audit.

5.5.4 Deficiencies Corrected During the Audit

Deficiencies considered isolated in nature and only require remedial action may be corrected during the audit. The following deficiencies were identified and corrected during the audit:

1. Contrary to the requirements of Paragraph 4.4 of TN QA Procedure 2.2, Revision 2, QA Procedure Format, revisions to procedures were not being identified in the margin by both a vertical bar and the revision number. This condition was satisfactorily resolved via revision of the procedure to remove the requirement for including the revision number.

2. TN QA Program document E-9213, Revision 2, Quality Assurance Program for Design, Fabrication, Inspection, Modification and Testing of Storage Systems for Spent Fuel and Radioactive Materials, contained errors in reference to 10CFR72. E-9213 made reference to Appendix G which should have been Subpart G and the procedure matrix erroneously referred to 10CFR71, Subpart H, rather than 10CFR72, Subpart G. QA Program document E-9213 was revised and reissued prior to completion of the audit.

3. TN QA Program document E-9213, Revision 2, required that design meeting reports identify action items resulting from design review meetings and assign an individual and due date for resolving the action item. QA Procedure 3.2, Revision 5, Design Control, required action items to be assigned to individuals but did not require due dates to be assigned. The procedure was revised to require due dates to be assigned.

5.5.5 Follow-up of Previously Identified CARs

This section was not applicable, as there were no previously issued CARs identified that would require follow-up.

6.0 RECOMMENDATIONS

1. Transnuclear QA Procedure 3.1, Revision 4, Control of Engineering Calculations, states that the calculation shall be approved by the Chief Engineer. Transnuclear QA Procedure 3.2, Revision 5, Design Control, states that design documents associated with the Design Review shall be approved after the meeting if approval is granted as evidenced by the meeting minutes. Procedure 3.2 also states that approval shall be by the Chief Engineer, Project Engineer, and QA Engineer. It is recommended that the procedures be revised to clarify the process for design approval to ensure that appropriate controls are maintained for approved design documents.

2. Transnuclear internal audits were being performed by the one QA person on the Transnuclear staff (reference DR # YM-97-D-011). This person also had responsibilities for performing line functions assigned to QA such as design reviews and control of records. It is recommended that Transnuclear identify other qualified personnel within the company to be trained as Lead Auditors in order to maintain the independence of the audit function as required by the Transnuclear QA Program.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit

ATTACHMENT 1
Personnel Contacted During the Audit

Name	Organization/Title	Preaudit Meeting	Contacted During Audit	Postaudit Meeting
Tara Neider	Transnuclear/Dir. Engrg Projects	X	X	X
Elizabeth Danko	Transnuclear/Supervisor QA/QA Eng.	X	X	X
Dave Dawson	Transnuclear/Vice President	X	X	X
Alan Hanson	Transnuclear/President	X	X	X