NRC FORM 591S PART 1
(8-2002)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/CERTIFICATE HOLDER	2. NRC/REGIONAL OFFICE
Transnuclear, Inc. 4 Skyline Drive Hawthorne, NY 10532 REPORT NUMBER(S) 72-1004/05-202	US Nuclear Regulatory Commission Spent Fuel Project Office 11555 Rockville Pike Rockville, MD 20852-2738

3. LICENSEE/CERTIFICATE NUMBER(S)	4. INSPECTION LOCATION	5. DATE(S) OF INSPECTION
72-1004	Hawthorne, NY	06/06-09/2005

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license or Certificate of Compliance (CoC). The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☒ 1. Based on the inspection findings, no violations or nonconformances were identified.

☐ 2. *Previous violation(s) or nonconformance(s) closed.*

☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

_____ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

☐ 4. During this inspection certain of your activities, as described below and/or attached, were in violation or nonconformance of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION OR NONCONFORMANCE, which may be subject to posting in accordance with 10 CFR 19.11.

(Violations, Nonconformances, and Corrective Actions)

STATEMENT OF CORRECTIVE ACTIONS

☐ I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested; **OR**

☐ Written Response requested in 30 days ☐ YES ☐ NO

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE	Steven C. White		06/09/05
NRC INSPECTOR	Robert R. Temps		06/09/05

INSPECTOR NOTES COVER SHEET

Licensee/Certificate Holder (name and address)	Transnuclear, Inc. 4 Skyline Drive Hawthorne, NY 10532
Licensee/Certificate Holder contact and phone number	Steve White 914-347-2345
Docket No.	07201004
Inspection Report No.	2005202
Inspection Date(s)	June 6 - 9, 2005
Inspection Location(s)	TN Office in Hawthorne, NY
Inspectors	Robert Temps Frank Jacobs Mike Karmis
Summary of Findings and Actions	This inspection involved a review of Transnuclear's (TN) QA Program implementation at their office in Hawthorne, NY. Inspection activities focused on management controls, design activities, and fabrication controls, and how these activities are being controlled under previous TN-Hawthorne QA implementing procedures and under the new company-wide QA implementing procedures known as the Transnuclear Implementing Procedures or TIPs. Followup to corrective actions reports issued by TN after the March 2005 inspection at their Fremont, CA, facility was also performed. Overall, TN-Hawthorne's activities were found to be in compliance with NRC Part 72 regulations and with TN's NRC approved QA Program. No significant adverse findings were noted and no cited or non-cited violations were identified. Corrective Action Reports (CARs) issued as a result of the March 2005 NRC TN-Fremont inspection were reviewed and corrective actions were assessed to be appropriate. Based on the results of this inspection and the March 2005 inspection at TN-Fremont, the team concluded that actions taken by TN in response to programmatic concerns identified in the July 2002 inspection at TN-Hawthorne have been adequately addressed and resolved.
Lead Inspector Signature/Date	Robert R. Temps Robert R Temps 06/20/05
Inspector Notes Approval Section Chief Signature/Date	Mary Jane Ross-Lee Mary Jane Ross-Lee 6/21/05

INSPECTOR NOTES: IP 60851WAS USED IN CONJUNCTION WITH APPLICABLE PARTS OF NUREG/CR 6314. INSPECTION RESULTS USING THE NUREG/CR 6314 FORMAT ARE DOCUMENTED BELOW:

INSPECTION BACKGROUND:

On July 29 through August 2, 2002, the U.S. Nuclear Regulatory Commission (NRC) performed an announced team inspection (reference ML022270222 for the associated inspection report) at the Transnuclear, Inc., office in Hawthorne, New York. The team inspected TN's activities associated with spent fuel storage to determine if they were conducted in accordance with the requirements of 10 CFR Parts 21 and 72, and TN's NRC-approved quality assurance (QA) program. During the inspection, the team identified a number of violations and weaknesses in the implementation of TN's QA program. These issues were of particular concern in view of the previous NRC inspection of TN in May of 1997 (reference NRC Inspection Report 71-0250/97-205; 72-1021/97-206). As a result of that inspection, NRC expressed concern that the identified nonconformances indicated a lack of attention to detail which if not corrected could lead to a degradation of TN's QA program.

As a result of the 2002 inspection, it was NRC's assessment that programmatic problems existed in the implementation of TN's QA program. NRC determined that the actions taken by TN to correct the 1997 inspection findings were not effective in improving QA program performance and in addressing the issue of lack of attention to detail. As described in the 2002 inspection report, violations were identified in activities regarding 10 CFR 72.48 evaluations, procurement, and resolution of nonconforming conditions and conditions adverse to quality. Further, the team noted that a lack of attention to detail was prevalent in the multiple examples identified of failure to follow QA implementing procedures, and in the lack of specificity in many of the QA implementing procedures regarding process controls for QA activities.

A followup inspection was conducted on October 21 through 24, 2003, at the TN-Hawthorne office. The inspection was limited in scope and focused on two areas; independent verification of the completion and adequacy of TN's corrective actions to six violations identified in the July 2002 inspection at TN Hawthorne, and assessing TN's progress in addressing programmatic issues related to the violations that were discussed at meetings held with TN in September 2002 and July 2003 at NRC Headquarters. Regarding the corrective actions that TN took in response to the NRC-identified violations from the July 2002 inspection, the team assessed that overall, TN's corrective actions were complete and appropriate to the issues identified in each violation and that no further NRC review of the violation responses is required.

With respect to the programmatic issues, the team assessed that TN has made progress in addressing the issues by strengthening various programs and procedures. Examples included the creation and staffing of the Director of Corporate Quality Assurance position, more rigorous evaluation and trending of issues entered into the corrective action system, and improved procedures and training in the area of 10 CFR 72.48 evaluations. However, given that many of the program and procedure changes were recent, and that other changes were still to be implemented, a comprehensive assessment of TN's progress in addressing all of the programmatic issues could not be made until such time as the majority of changes had been implemented for a meaningful period of time.

The purpose of the inspections performed at TN-Fremont in March 2005 and this inspection at TN-Hawthorne, documented in this report, was to provide a final assessment of TN's actions with respect to the 2002 inspection programmatic issues. As noted above, this assessment would wait until a meaningful time period for implementation had passed.

4.1.1 Quality Assurance Policy

The team reviewed TN's NRC approved Quality Assurance Program (QAP) and other procedures that govern QA policy and administration in the Hawthorne office. As noted in the March 2005 inspection report, TN's NRC approved QAP applies across all its corporate offices: Hawthorne, NY; Fremont, CA; and at the PacTec facility in Tacoma, WA. While each office operates under the same NRC approved QA program, they previously have implemented the QAP requirements through separate and different QA implementing procedures. At the time of this inspection, TN has effectively transitioned to one common set of QA implementing procedures, the Transnuclear Implementing Procedures or TIPs, that apply to all three office locations. The transition process was reviewed in March 2005 and was noted to be described in TN Administrative Guideline MGT-03, "Transnuclear Implementing Procedures Transition Plan." That Guideline has since been replaced by TIP 1.1, "Transition to Transnuclear Implementing Procedures," dated April 25, 2005. The TIP essentially provides a cross-reference between each location's previous QA implementing procedures and the corresponding TIPs that now addresses the subject procedure. The team assessed that the transition process continues to be properly controlled and monitored and that adjustments continue to be made to the procedures as TN staff identifies issues with their implementation.

4.1.2 Nonconformance Controls

The team reviewed the procedures controlling the problem identification and corrective action program used by TN. Discussions were held with QA personnel, and the team also reviewed selected Corrective Action Reports (CARs) and Non Conformance Reports (NCRs). TN's resolution of the issues documented in the various reports was assessed to be appropriate and the reports were closed in a timeframe commensurate to their importance. No concerns were identified in this area.

In the March 2005 inspection report, it was noted that tracking and trending of CARs and NCRs is performed on a quarterly basis with reports issued to senior TN management. The team had observed that while corrective actions in CARs were generally effective in addressing and resolving technical and hardware issues, in general, the CARs did not explore how human error may have contributed to the issues other than through assignment of apparent cause codes dealing with human error. That observation was discussed with TN personnel and CAR 2005-028 was issued to capture the team's observation. During this inspection, TN's corrective actions for the CAR were reviewed and discussed with TN personnel and the actions taken and planned were assessed to be adequate.

4.1.3 Documentation Controls

The team reviewed the procedures for document control, document preparation, and document distribution used by TN. The Document Control Administrator was interviewed regarding the distribution process for controlled documents to ensure approved and current procedures are

available to individuals performing activities affecting quality. A Controlled Document Transmittal Form (CDTF) is used to record delivery and receipt of controlled documents. The CDTF also documents acknowledgment of reading and understanding of documents when required for training purposes. Followup action for unreturned CDTFs is proceduralized. To better control changes to forms referenced by procedures, TN is making each form an attachment to its associated procedure, rather then as a stand-alone document, at the next revision of the associated TIP. Through interviews and review of documents, the team verified control of procedures, specifications, engineering change notices and drawings. No concerns were identified.

4.1.4 Audit Program

The team reviewed the procedures for TN's Approved Suppliers List (ASL) and for triennial audits and annual evaluations of suppliers on the ASL. The team noted some minor errors and discrepancies, and areas for improvement, in the recently developed or revised procedures. TN took immediate action to correct or clarify the issues, and incorporated the changes in procedure revisions already in progress for the affected procedures. The team reviewed the 2005 Audit & Evaluation Schedule for suppliers, and reviewed selected audit reports and Supplier Evaluation Forms (for annual evaluations). The audits were thorough and well-documented, and corrective actions were appropriately followed up. The annual evaluations were adequate.

The team reviewed the internal audit schedules for 2004 and 2005. Audits were scheduled and conducted periodically, and covered all applicable aspects of the QA program. The 2005 Management Audit and the 2004 audit of the Hawthorne office were reviewed. The management audit was performed by a qualified contractor, and the Hawthorne audit was performed by a lead auditor from the Fremont office, providing appropriate independence from the areas being audited. Audit findings were documented on Corrective Action Reports, and previous audit findings were followed up. The audits were assessed to be thorough and well-documented.

The team reviewed TN procedures and records for indoctrination, training, qualification, and certification of personnel performing audits and evaluations. The reviewed procedures and records were satisfactory and no concerns were identified.

4.2.1 Design Development

The team interviewed TN engineering and quality personnel responsible for the preparation and approval of design documents. All personnel interviewed were able to provide detailed descriptions of the control and review processes for design control activities being performed at TN. Included in the discussions with these individuals was the role that the new TIPs, such as 3.1, "Design Control," 3.2, "Calculations," and 3.5,"Licensing Reviews," play in the control of design documents used to specify requirements. Engineering personnel and the Document Control Manager described the development, issuance, and control of the Safety Analysis Report (SAR) drawings and the process where Design Change Requests (DCRs) are reviewed and approved, or forwarded for 10 CFR Part 72.48 review, under the requirements of TIP 3.5. Through review of TIPs 3.1, 3.2 and 3.5, and by discussion and review of documents, the team assessed that TN's design control process was adequate.

4.2.2 Design Changes

The team reviewed selected drawings, procedures and records, and observed selected activities being performed to determine that fabrication, test, and maintenance activities meet SAR design commitments and requirements documented in the CoC. The team reviewed DCRs, and various drawings and calculations, as well as associated 10 CFR 72.48 when applicable, for adherence to the governing TIPs. The team reviewed the following documents associated with the design control process:

Design Change Requests (TIP Form 3.2-2):

10494-05, Rev 0
10494-14, Rev 0
10494-13 (Open, LR Number 721030-004)
10494-14, Rev 0
1031-03, Rev 0

Calculations:

1049-17, Rev 0 (Reference 72.48 Evaluation LR No. 721021-004)
1049-93, Rev 0, "Gap In Neutron Shielding"
1083-21, Rev 0, "TN-32 MCNP Models For Near Field Doses"
1083-20, "TN-32 MCNP Models For Determining Off-Site Doses"

License Review (LR) No:

721030-001 "On-Site Transfer Cask Parts List"
721030-002 "On-Site Transfer Cask Structural Assembly"
721021-003 "TN-32 Dry Storage Cask"
721021-004 "Use As Is Resin Neutron Box"
721021-002 "Revise Burnup for BPRA"
721021-005 "Acceptance of Non-Conforming Poison Plates"

Drawing No:

10494-72-1 through 4
10494-30-1 through 14
10494-72-4

Corrective Action Report (CAR) No:

2003-056
2004-1016

The documents reviewed were found to be complete and in order. Revisions to drawings occurring due to an approved DCR were verified to have been accomplished. Signatures for

checking, review and approval were accomplished as required by the TIPs. No concerns were identified and implementation of the controlling processes was assessed to be adequate.

4.3.1 Material Procurement

In the March 2005 inspection report, the team made observations regarding purchase orders and the ASL. One observation dealt with conditions or limitations listed for each supplier in the ASL in that it was not always clear as to which limitations were being imposed on the supplier and under what conditions all or some of the limitations applied. The other observation concerned the fact that the ASL requirements for Category A, B and C suppliers inclusion on the ASL under the new TIPs was not as clearly addressed. TN had issued CAR 2005-209 to document the team's observations in this area. During this inspection, TN's corrective actions for the CAR were reviewed and discussed with TN personnel and the actions taken and planned were assessed to be adequate.

During this inspection, the team reviewed procurement procedures, reviewed various approved vendor audits/surveillances, and traced the procurement history of items and services to verify that they were procured from qualified suppliers and met specifications. In all cases reviewed, the team determined that only suppliers on the ASL had been used. Overall, the team concluded that TN's procurement activities were being performed in accordance with their controlling procedures.