

INSPECTOR NOTES COVER SHEET

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Docket No.	07201004
Inspection Report No.	2005201
Inspection Date(s)	March 14-17, 2005
Inspection Location(s)	TN Office in Fremont, CA
Inspectors	Robert Temps Jim Pearson Frank Gee
Summary of Findings and Actions	<p>This inspection involved a review of Transnuclear's (TN) QA Program implementation at their office in Fremont, CA. Inspection activities focused on management controls, design activities, and fabrication controls, and how these activities are being controlled under previous TN-Fremont QA implementing procedures and under the new and recently implemented company-wide QA implementing procedures known as the Transnuclear Implementing Procedures or TIPs.</p> <p>Overall, TN-Fremont's activities were found to be in compliance with NRC Part 72 regulations and with TN's NRC approved QA Program. The team made several observations regarding certain activities, some under the new TIPs, where certain process controls could use clarification. TN issued Corrective Action Reports (CARs) in order to capture the issues and track them for resolution and closure. No significant adverse findings were noted and no cited or non-cited violations were identified.</p>
Lead Inspector Signature/Date	Robert R. Temps
Inspector Notes Approval Section Chief Signature/Date	Mary Jane Ross-Lee

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

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 Fremont office. 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 Fremont location, these are called Quality Procedures (QPs). However, TN is in the process of transitioning to one common set of QA implementing procedures, the Transnuclear Implementing Procedures or TIPs, that apply to all three office locations. The transition process is described in detail in TN Administrative Guideline MGT-03, "Transnuclear Implementing Procedures Transition Plan." Most of the TIPs were implemented as of August 2004 at all three offices; however, a separate document for the Fremont office lists the limited number of QPs that are still in effect as well as certain projects that are still subject to the QPs. Therefore, during the inspection, the team reviewed both QPs and TIPs as applicable for the activity and the project documents being inspected. The team assessed that the transition process appeared well thought out and is being properly controlled and monitored. As TN staff identify implementation questions during the transition process, TN management is providing needed guidance.

A review of the TIPs and QPs indicated that QA policies and lines of authority and responsibility are clearly described and that appropriate independence of personnel is maintained. In accordance with QP 1-1, "Quality Procedures Policy," Section 3.3, a graded approach to quality is described with affected items classified as Category A, B or C items. TIP 7.3, "Dedication of Commercial Grade Items," describes TN's program for parts dedication; however, from discussions with TN-Fremont staff, commercial grade dedication of items has not been performed for quite some time under the previous QP and none at all under the new TIP.

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. Where CAR or NCR closure is delayed, TN management is appropriately informed and late items are tracked.

The team noted that tracking and trending of CARs and NCRs is performed on a quarterly basis with reports issued to senior TN management. The team noted that one of the trends identified in the last three quarterly trending reports involved failure to follow procedure. With regard to this issue, the team observed that while corrective actions in the 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. Absent a more in-depth review of such

issues, during CAR resolution, the team considered that the issue of human performance was likely to recur. This observation was discussed with TN personnel and CAR 2005-028 was issued to capture the team's observation.

4.1.3 Documentation Controls

The team reviewed the document controlling procedures, controlling document preparation, and document distribution program used by TN. Discussions were held with the lead document control person and select TN personnel to verify that the personnel were knowledgeable in the area and/or that verification was completed to show compliance with TN procedures. The team verified control of controlled copies of procedures, specifications, engineering change notices and drawings, as well as required reading of TN procedures, and controlled access to controlled documents. The team also reviewed the records storage and capture process as well as multiple CARs for corrective action in regard to document and record control and found these acceptable .

4.1.4 Audit Program

The team reviewed selected portions of audits, travelers, procedures, internal and external audit schedules and drawings to identify personnel performing activities affecting quality. From the review, the team verified the qualifications and/or certifications of fourteen Ionics personnel who perform various activities such as welding processes, NDE processes, or quality auditing activities. From the document reviews and discussions with personnel, and through direct observation of fabrication activities, the team assessed that Ionics personnel were qualified and appropriately trained and/or certified for the performance of the quality-affecting activities.

The team determined that Ionics QA personnel perform planned annual audits of the Ionics QA Program, as well as audit and surveillance activities of suppliers on the approved supplier list (ASL). The annual audit is led by a contract Lead Auditor who has the required independence from the QA organization. Ionics is also audited by the vendors who have contracted with them for cask fabrication activities. Vendor audit reports were reviewed, as well as numerous periodic surveillance reports. Audit findings were documented in Ionics Request for Corrective Action (RCAs) and were addressed in a time frame commensurate with their importance. The team noted that the cask vendors maintain essentially near-continuous on-site coverage during fabrication activities.

The team verified through interviews and record reviews that auditors and lead auditors had been trained and certified as required. In addition, from the team's review of audit related CARS and audit procedures, they observed that corrective actions related to audits were acceptable with the exception of one CAR regarding required Lead Auditor testing which had been closed without an adequate basis for the corrective action described. CAR 2005-026 was issued by TN during the inspection to provide corrective action to the previous CAR.

4.2.1 Design Development

The team reviewed nine safety review screenings (SRSs) of engineering change notices of San Onofre Unit 1 project and eight SRSs and two safety evaluations (SEs) for the Fort Calhoun project. The changes ranged from clarifications to new analyses and spanned multiple

disciplines such as; structural, thermal, criticality, and shielding. The team also reviewed a sample of calculations in various disciplines. The team determined that the processes were performed in accordance with TN procedures and also verified, from a sampling of personnel, that qualifications for design and quality engineers, and inspectors were adequate.

The team reviewed the administration procedure, TIP 3.1, "Design Control," Revision 0, for the responsibilities, design criteria specification, design review and verification process, methods of verification, design change controls and reviews, and record maintenance. Through the team's review of TN Quality Manual and design control procedures, the area of design control was determined to be adequately controlled by TN procedures.

The team sampled two project plans, San Onofre Unit 1 Dry Cask Storage and Fort Calhoun Station. Project plans communicate the interface requirements and define the client requirements for unique or off-the-shelf TN Products. The team determined through an interview, that the project manager had a good understanding of his functions and responsibilities for his projects. The team determined that the reviewed project plans complied with TN procedures.

4.2.2 Modifications (72.48 process)

The team reviewed three modifications:

- Changes for the support rod and spacer sleeve material for San Onofre Units 2 and 3.
- Changes for the 32PT associated with structural changes for the lifting lugs.
- Changes for the 24PTH, associated with seismic and shielding changes for the horizontal storage module for high burn-up fuel.

The team reviewed the procedures and associated forms for the screening and review process of modifications under 10 CFR 72.48. The process is controlled primarily by the criteria found on the following TN forms:

- Form 3.5-1, "10 CFR 72.48 Applicability and 10 CFR 71 Review Form."
- Form 3.5-2, "10 CFR 72.48 Screening Form."
- Form 3.5-3, "10 CFR 72.48 Evaluation Form."

The team determined that the screening and evaluations of modifications were performed in accordance with TN procedures.

4.3.1 Material Procurement

The team reviewed procurement procedures, interviewed procurement QA personnel, 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 Approved Suppliers List (ASL) had been used.

In reviewing the purchase orders and the ASL, the team made two observations. The first observation dealt with conditions or limitations listed for each supplier in the ASL. 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. It was also not clear which of the limitations applied to TN, such as ones dealing with the need for QA audit requirements. The second observation involved the fact that the ASL developed under the QPs was clear as to the requirements for Category A, B and C suppliers inclusion on the ASL, whereas under the new TIP, this area was not as clearly addressed. TN issued CAR 2005-209 to document the team's observations in this area.

Overall, the team concluded that TN's procurement activities were being performed in accordance with their controlling procedures. Procurement personnel clearly understood the procurement process and the procedures used. Methods used to approve addition of suppliers to the ASL were appropriate and the audits and surveillance used to qualify and maintain suppliers on the ASL were adequate.