NRC FORM 591S PART 1
(10-2013)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. CERTIFICATE/QUALITY ASSURANCE PROGRAM (QAP) HOLDER:	2. NRC/REGIONAL OFFICE
Orano TN Americas LLC 7135 Minstrel Way, Suite 300 Columbia, MD. 21045	Headquarters U. S. Nuclear Regulatory Commission Mail Stop 3WFN 14C-28 Washington, DC 20555-0001
REPORT NUMBER(S) 72-1004/2019-201	

3. CERTIFICATE/QAP DOCKET NUMBER(S)	4. INSPECTION LOCATION	5. DATE(S) OF INSPECTION
72-1004, 72-1021, 72-1027, 72-1029, 72-1030 and 72-1042	Columbia, MD.	March 26 - 29, 2019

CERTIFICATE/QUALITY ASSURANCE PROGRAM HOLDER:

The inspection was an examination of the activities conducted under your QAP as they relate to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your QAP Approval and/or Certificate(s) of Compliance. 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 were identified.

☐ 2. Previous violation(s) closed.

☐ 3. The violations(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, to exercise discretion, were satisfied.

_____ Non-cited violation(s) was/were discussed involving the following requirement(s) and Corrective Actions(s):

Based on the results of this inspection, the NRC opened an unresolved item regarding temporary field changes made to the design of the end walls and outlet vent covers for a Horizontal Storage Module (HSM) while Dry Shielded Canisters loaded with spent fuel assemblies were still stored in the HSM. A general licensee made these changes with engineering support from TN under the 10 CFR 72.48 regulation. The team needed additional information to determine if the issue of concern potentially constitutes a violation of NRC requirements.

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

TITLE	PRINTED NAME	SIGNATURE	DATE
CERTIFICATE/QAP REPRESENTATIVE	Douglas Brownson, Director Quality Assurance and Safety	Douglas Brownson	5/23/19
NRC INSPECTOR	Marlone Davis, Team Leader Sr. Storage and Transportation Safety Inspector	Marlone Davis	5/23/19
BRANCH CHIEF	Christian Araguas	Christian Araguas via E-MAIL concurrence	5/24/19

INSPECTOR NOTES COVER SHEET

Licensee/Certificate Holder	Orano Transnuclear (TN) Americas LLC 7135 Minstrel Way, Suite 300 Columbia, MD. 21045
Licensee/Certificate Holder contact and phone number	Mr. Douglas Brownson Director of Quality Assurance and Safety TN Americas LLC 410-910-6520
Docket No.	72-1004, 72-1021, 72-1027, 72-1029, 72-1030, and 72-1042
Inspection Report No.	72-1004/2019-201
Inspection Date(s)	March 26 - 29, 2019 April 12, 2019
Inspection Location(s)	TN Americas Division LLC Columbia, MD.
Inspectors and Technical Reviewers	Marlone Davis, Team Leader, Senior Safety Inspector Earl Love, Senior Safety Inspector Jeremy Tapp, Safety Inspector Antonio Rigato, Structural Engineer (Technical Reviewer) JoAnn Ireland, Thermal Engineer (Technical Reviewer) Donald Chug, Risk Analyst (Technical Reviewer)
Summary of Findings and Actions	During the period of March 26 through March 29, 2019, the U.S. Nuclear Regulatory Commission (NRC) completed a team inspection at Orano TN Americas corporate headquarters located in Columbia, MD. The team discussed the preliminary results of this inspection on March 29, 2019 and conducted an exit on April 12, 2019. The team did not identify any more than minor violations related to NRC requirements and in general, assessed that TN effectively implemented their NRC-approved Quality Assurance Program (QAP) for activities subject to 10 CFR Parts 21 and 72. However, the team did exit with one unresolved item associated with a temporary field change to remove the end wall and outlet vent covers of two Horizonal Storage Modules (HSMs) with loaded dry shielded canisters still stored in the HSMs. The team needed additional information to coordinate with their regional counterparts and to determine if the field change potentially constitutes a violation of NRC requirements. TN initiated condition reports to capture the minor violations and the URI.
Lead Inspector Signature/Date	Marlone Davis Marlone Davis 5/24/2019
Inspector Notes Approval Branch Chief Signature/Date	Christian Araguas Concurrence via E-MAIL 5/24/2019

Inspector Notes

On March 26 to March 29, 2019, the U.S. Nuclear Regulatory Commission (NRC) performed an inspection at the Orano Transnuclear Americas LLC (TN) corporate headquarters located in Columbia, MD. The NRC performed the last programmatic inspection at TN's corporate office on April 4 – 8, 2016 (ML16126A546). Since the last corporate inspection, the NRC has conducted five fabrication inspections related to the TN Americas dry cask storage system (DCSS) designs at various facilities. These included inspections at Hitachi-Zosen in Arau, Japan (ML16187A007) in May 2016, Custom Nuclear Fabrication facility in Canonsburg, PA (ML16243A392) in July 2016, Moyock NC (ML17151B025) in April 2017, Larsen & Toubro Limited (L&T) Heavy Engineering Division in India (ML18127A058) in March 2018 and Columbiana Hi Tech (CHT) in Kernersville, NC (ML18215A387) in June 2018. The NRC conducted these inspections to determine if activities involving fabrication were performed in accordance with the requirements of Title 10, Code of Federal Regulations (10 CFR), Parts 21, 71, and 72, the applicable certificate of compliance (CoC) and final safety analysis report (FSAR), and TN's NRC-approved quality assurance program (QAP).

The purpose of this inspection was to verify and assess TN's implementation and compliance with 10 CFR Part 72 requirements related to the design, modification, procurement, and design changes of the DCSS maintained under their NRC Approved QAP. The inspectors assessed TN's quality related activities based on a review of permanent quality records and other supporting documentation related to design, modifications, corrective actions, nonconformance, and audits, as applicable. The team reviewed corrective actions identified from previous fabrication inspections. Additionally, the team reviewed several 10 CFR 72.48 evaluations and TN screenings as identified in biannual summary reports.

The NRC has TN registered as the CoC holder for the following 10 CFR Part 72 models:

Model #	**Docket#**	**Amendment#**
NUHOMS	72-1004	15
TN-32 and 32B	72-1021	1
TN-68	72-1027	1
Advanced NUHOMS	72-1029	4
NUHOMS-HD	72-1030	2
NUHOMS EOS	72-1042	0

The team of NRC inspectors conducted the inspection in accordance with NUREG-6314, "Quality Assurance Inspections for Shipping and Storage Containers," and NRC Inspection Procedures 60851, "Design Control of ISFSI Components," and 60857, "Review of 10 CFR 72.48 Evaluations." The team discussed the preliminary results of this inspection on March 29, 2019 at the completion of the inspection week. The team conducted the final exit briefing on April 12, 2019. During the exit briefing, the lead inspector of the team informed TN of the final inspection results. The team did not identify any more than minor violations related to NRC requirements and in general, assessed that TN effectively implemented their NRC-approved QAP for activities subject to 10 CFR Parts 21 and 72. However, the team did exit with one unresolved item (URI) associated with a temporary field change to remove the end wall and outlet vent covers of two Horizonal Storage Modules (HSMs) with loaded dry shielded canisters still stored in the HSMs. The team needed additional information to coordinate with their regional counterparts and to determine if the field change potentially constitutes a violation of NRC requirements. TN initiated condition reports to capture the minor violations and the URI.

Inspector Notes: As described below, the team performed applicable sections of inspection procedures 60851 and 60857 with documentation of the inspection results using the basic headings outlined in NUREG-6314.

1.0 Management Controls

1.1 Quality Assurance Policy

The team reviewed Orano Transnuclear Americas' LLC (TN) Quality Assurance Program Description Manual (QAPDM), Revision 16 and TN Implementing Procedures (TIPs) to verify and evaluate the effectiveness of the Quality Assurance (QA) program implementation. The team preformed reviews of the quality program, policies, and procedures, and discussed portions of these documents with selected personnel to determine whether TN adequately controlled and implemented activities subject to 10 CFR Part 72 regulations. The team reviewed the TN organizational charts and interviewed QA personnel to evaluate their independence from cost, schedule, and production activities. The team reviewed Section 2 of the QAPDM and TIP 2.1, "Indoctrination and Training," Revision 12, 15, and 25 to evaluate training and certification of personnel involved in quality activities. This review included the initial QA indoctrination and job-specific QA training for selected personnel in the Quality Assurance area. The team also reviewed the management assessments performed on the status and effectiveness of the QA program from 2017 and 2018.

Overall, the team assessed that the implementation of TN's QA program was adequate with no concerns identified. The team determined that both management assessments reports reviewed the appropriate areas under the quality program including corrective actions, semi-annual trend reviews, performance indicators, audits, and third-party inspections. The team noted that in general, the QA program performance has been improving. For the job-specific QA training, the team compared the training documented to the training required in the master document list. The team did not identified issues with the personnel indoctrination and training records reviewed.

In addition, the team noted that TN evaluated the most recent proposed changes to the QAPDM per the requirements of 10 CFR 71.106. TN determined that the proposed changes did not constitute a reduction in program commitment or effectiveness. However, TN submitted the changes to the NRC for prior review and approval due to changes needed to the NRC approval document (NRC Form 311). The team also discussed the QA program biennial report requirements per 71.106 and the overall process with TN personnel and noted that the quality procedures have been adequately updated to implement the associated regulatory requirements.

1.2 Nonconformance and Corrective Action Controls

The team reviewed selected records and interviewed personnel to verify that TN effectively implemented the nonconformance control and corrective action program (CAP). Specifically, the team reviewed TN's policies and the following approved implementing procedures that govern the nonconformance and CAP for TN to verify compliance with applicable requirements to 10 CFR Part 72:

- TIP 15.1, "Reportability Determinations and Postings," Revision 19
- TIP 15.2, "Control of Nonconforming Items," Revision 18

- TIP 15.3, "Review of Supplier Nonconformances," Revision 19
- TIP 16.1, "Corrective Action," Revision 28
- TIP 16.3, "Corrective Action Review Board," Revision 17

The team discussed the nonconformance and CAP controls with the TN staff and reviewed a sample of supplier nonconformance reports (SNCRs), and corrective action reports (CARs) for appropriate disposition. The team evaluated whether TN completed CARs for identified deficiencies in a technically sound and timely manner. The team also evaluated a sample of cause analyses, trend analyses, and verified that the SNCRs and CARs provided a connection to the 10 CFR Part 21 program. The team sampled four SNCRs since 2016 which consisted of a variety of component types and suppliers that included a mix of accept-as-is and repair component dispositions. The team sampled 11 CARs since 2017, which included a review of fabrication deficiencies, personnel training gaps, audit issues, and quality program issues in the areas of corrective actions, procurement, and material traceability. TN classifies their CARs into four different levels depending on the significance of the issue with Level 1 being the most significant. The sample chosen by the team consisted of a mix of Level 2 and Level 3 CARs. There were no Level 1 CARs written since the last inspection in 2016. In addition, as required by TIP 16.3, the team reviewed the performance monitoring and trending reports for 2017 and 2018. Further, the team reviewed program controls for 10 CFR Part 21, "Reporting of Defects and Noncompliances," including TIP 15.1.

Overall, the team concluded that TN had an adequate nonconformance control and CAP in place to identify, track and resolve quality related deficiencies and deviations. The team determined that TN appropriately dispositioned the nonconformances reviewed and closed them in a timely manner commensurate with the safety significance, in accordance with the quality procedure. The team found that the corrective actions taken by TN were adequate and closed out in a timeframe commensurate with the safety significance of the issue, when possible. The team found the reports reviewed to be comprehensive and provide valuable information to identify areas for improvement. The team noted that the reports show an overall increase in timely CAR closure due to increased management attention and less human performance issues. The team also verified that TN was meeting the 10 CFR Part 21 posting requirements of both the regulations and TIP 15.1. The team found that TN posted the 10 CFR Part 21 regulations, Section 206 of the Energy Reorganization Act of 1974, and TIP 15.1 on a board where employees could readily see them. No issues were identified by the team regarding 10 CFR Part 21 program controls or implementation at TN. The team assessed that TN's procedures in these areas adequately implemented the requirements of the regulation.

1.3 Documentation Controls

The team reviewed the document control section of the TN QAPDM and the TIPs that address document controls to verify they are being properly implemented. The team specifically reviewed TIP 6.1, Revision 19, "Document Control," and TIP 17.1, Revision 17, "Control of Quality Assurance Records."

Overall, the team identified no concerns in the documentation control and records management areas. The team verified from various interviews, observation of activities, as well as the review of multiple documents associated with other aspects of this inspection, that adequate document control and records management exist at TN.

1.4 Internal Audit Program

The team reviewed the TN internal audit program to determine if it was comprehensive and TN scheduled and performed internal audits in accordance with Section 18 of the QAPDM and approved implementing procedures. Specifically, the team reviewed the following procedures:

- TIP 18.1, "Internal Audits," Revision 16
- TIP 18.2, "Surveillances," Revision 5
- TIP 2.2, "Qualification and Certification of Audit Personnel," Revision 12

The team reviewed a selection of internal audits performed in 2017 and 2018. This review included the 2017 and 2018 internal audit schedules and plans to verify that personnel conducted these audits in accordance with the program. The team also reviewed a selection of lead auditor training and qualification records to evaluate whether TN trained, and qualified lead auditors as required by approved procedures. In addition to the internal audit program, the team reviewed the surveillance program implemented at TN's corporate office.

Overall, the team did not identify any concerns with TN's internal audit program. The team verified that for the audits sampled, TN conducted audits with qualified and certified personnel, scheduled and evaluated applicable elements of the QA program, and resolved the deficiencies assessed by the audit team in a timely manner. The team determined that for the internal audits reviewed, they were comprehensive in nature, used checklists to perform the audit, identified several issues, and TN wrote the audit reports in a timely manner. The team found that the internal audit schedules and planned annual audits, at a minimum, covered all 18 quality criteria. For the auditor training, the team assessed that TN trained and qualified all personnel as required by approved procedures. Through discussion with TN personnel, the team determined that surveillances were primarily performed at fabricator locations, but a surveillance has been performed at the corporate office for software verification and validation.

2.0 Design Controls

2.1 Development and Modification

The team reviewed TN TIPs specifically related to design development/control and modification activities and held discussions with TN engineering, quality assurance and project management staff. The team focused its review on a sample of TN's design activities related to design change requests and change notices related to the applicable EOS-37PTH and 89BTH (Certificate of Compliance 1042 Amendment 0) Dry Cask Storage System. The team reviewed four separate design changes (DCR Nos. 1001400, 1001625, 1002212 and 1002440) for compliance to TIP 3.1, Revision 21, "Design Control." The team reviewed TN's completed TIP Form 3.1-2 for each DCR and the associated documentation behind the form.

The team found all parts of the DCR forms to be properly processed in accordance with TIP 3.1. The team also found that the attached supporting documentation (i.e., drawing, specification, FSAR change notice (FCN) and licensing reviews) justifying the change to be adequate. Based on the sample selected, the team concluded that TN had adequately followed their design change process, as applicable.

2.2 Design Changes (10 CFR 72.48)

The team reviewed selected records and interviewed personnel to evaluate TN's design change process. The team focused its review in the following areas: (1) design change requests (DCR)s and (2) adequacy of 10 CFR 72.48 screenings and evaluations. The team reviewed TN procedures related to the implementation instructions for 10 CFR 72.48 evaluations and control of design change activities. Specifically, the team reviewed TN approved procedure TIP 3.5, "Licensing Reviews," Revision 19. The team reviewed a list of screenings and evaluations performed by TN to meet regulatory requirements associated with 10 CFR 72.48 regulations. The team selected a representative sample of screenings and evaluations based on a judgement of risk significance and potential impact on the functionality of the DCSS. The team used Inspection Procedure 60857 and draft instructions of a risk-informed selection process that the staff is in the process of developing to assist in the selection of 72.48 screenings and evaluations.

The team reviewed selected 72.48 screenings and evaluations performed since the last corporate inspection in 2016. The team requested TN to develop a table with both the screenings and evaluations since the biennial summaries of changes, test, and experiments related to TN CoCs models only had a description of the evaluations. The team reviewed nine screenings and seven evaluations. In addition, the screenings and evaluations had several DCRs, design calculations, and FCNs associated with the licensing reviews (LRs). The team also reviewed the training and qualifications records of personnel that performed LR for 10 CFR 72.48 screenings and evaluations.

The team assessed that TN had established requirements for performing and documenting LRs pursuant to 10 CFR 72.48. The team verified for the most part that TN provided adequate technical content, methods, and followed their LR process.

LR No. 721004-1702 – Standardized NUHOMS HSM Model 202

Based on the results of the initial review of LR No. 721004-1702, Revision 1, the NRC opened an unresolved item regarding a temporary field change made to the end walls and outlet vent covers of two Horizonal Storage Modules (HSMs) while dry shielded canisters loaded with spent fuel assemblies were still stored in the HSMs. A general licensee made these changes with engineering support from TN under the provisions of 10 CFR 72.48 requirements. As a part of the review, the team had concerns about the following: (1) operator manual action to meet 72.104; (2) tornado pressure on the temporary steel plate used following the removal of the end wall and outlet vent covers; and (3) blocking of the vents and how it would impact the technical specification surveillance requirements. The team needed additional information to coordinate with their regional counterparts and to determine if the field change potentially constitutes a violation of NRC requirements. The team wanted to review some of the general licensee's documents that TN had to request prior to the end of the inspection.

3.0 Fabrication Controls (Limited to: Material Procurement and Design Fabrication Interface)

The team reviewed documents associated with order entry and project planning, design control, procurement specifications, procurement document control, and preparation of certificates of conformance. The team also interviewed a TN Project Manager related to some of these areas. Much of the interview focused on project planning, design control, fabrication readiness and

procurement control. As a part of this review, the team reviewed a sample of TN TIP's including but not limited to:

- TIP 2.5, Revision 14, "Order Entry and Project Planning,"
- TIP 4.1, Revision 6, "Procurement Documentation Control,"
- TIP 5.2, Revision 11, "Specifications,"
- TIP 5.5, Revision 22, "Preparation of Certificates of Conformance,"
- TIP 5.8, Revision 1, "Fabrication Drawing Control,"
- TIP 7.4, Revision 7, "Fabrication Readiness Reviews,"
- TIP 7.11, Revision 14, "Approved Suppliers List," and
- TIP 7.12, Revision 8, "Supplier Performance Monitoring."

The team reviewed TN's Project Plan applicable to Duke Energy Progress for On Site Spent Fuel Storage at the H.B. Robinson Nuclear Plant (RNP) for Ten (10) Model 24PTH L Type 1C DSCs to be fabricated at Hitachi Zosen (HZ), Japan. The team reviewed a sample of other Project Pans specific to On-Site Spent Fuel Storage and various DSC's systems and related engineering services at Duke Energy Progress - Brunswick Nuclear Plant; Omaha Public Power District - Fort Calhoun Station; and FirstEnergy Davis-Besse Nuclear Power Plant.

Overall, the team determined that TN was effectively implementing its order entry, project planning. The team reviewed several TN Purchase Orders to HZ and subsequent Change Orders associated with the Fabrication, Assembly and Testing of 24PTH and 32PT DSCs for the RNP and Dominion Nuclear Ct., Inc. (Millstone Nuclear Power Plant), respectively. Transport Cask MP197HB (excluding Design). The team noted TN's purchase orders were compliant to TN's TIP 4.1, "Procurement Documentation Control." The team reviewed TN's TIP governing external audits and controls of vendors on its Approved Suppliers List (ASL), Revision No. 136 dated 2/14/2019 and noted audit and evaluation surveys reviewed were within their required periodicity for maintaining the subject companies on the ASL. Overall, the team determined that TN was effectively implementing its procurement procedures. The team did not identify any concerns in this area.

4.0 Other Issues Reviewed by the Inspection Team

Corrective Action Follow-up to 2018 Orano TN Americas at Larsen & Toubro Inspection Non-Cited Violation

The team reviewed TN's corrective actions associated with the non-cited violation identified during the 2018 inspection (72-1004/2018-201) at Larsen & Toubro in Vadodara, India, to verify that TN adequately completed the corrective actions. Specifically, TN failed to have available documentary evidence that material conformed to the procurement specifications. CAR 2018-067, Revision 1, dated July 24, 2018 documented TN's corrective actions for the violation. For this issue where procurement of Helicoils and washers was incomplete and objective evidence of verification of critical characteristics was not sufficient, the team determined that TN generated a commercial grade dedication plan for the affected Helicoils, tested the components, and completed the dedication process by writing the final report accepting them. The team noted that the affected washers were not dedicated because TN will not be using the washers in the final TN-LC package configuration as an approved alternative option is being used. The team determined the corrective actions in response to the non-cited violation were adequate and the violation is considered closed.

Procurement of the TN-32B Lid Bolts

The team performed an evaluation of TN's procurement of the modified TN-32B confinement boundary cask lid bolts for the high bum-up (HBU) demonstration cask located on the North Anna Power Station's (NAPS's) Independent Spent Fuel Storage Installation (ISFSI). Specifically, TN procured forty-eight (48) high strength bolts to accommodate future transportation impact loads. The team noted that TN experienced mixed success in procuring material meeting the applicable American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code Section III, Subsection NB. In the case of the HBU demonstration cask lid bolts, TN's approved supplier did not have material readily available and was unsuccessful meeting the ASME NB-2333 lateral expansion requirement. The TN-32B HBU demonstration cask pertains to a site-specific license held by Dominion Power and that a LR under TN's Implementing Procedure was not required. The team noted TN initiated NCR No. 2017-396 to address the deficient condition and that TN informed NAPS (Dominion Power) of the nonconforming condition as required by Dominion Power's purchase order. Overall, the team did not identify any concerns with TN's notification to Dominion Power of a failure to meet ASME Code impact properties specific to HBU demonstration cask lid bolts.

The team noted a previous condition in 2014 that involved a noncompliance related to the minimum lateral expansion of lid bolts on an OS200 Transfer Cask that is part of TN's fleet of leased transfer equipment. The team noted that the originally supplied lid bolts have been replaced and currently satisfy the licensing requirements of the applicable NUHOMS FSAR, as updated and technical specifications. TN initiated CAR 2019-119 to identify that when replacement efforts were being planned it was found that the first licensee user of the cask had retuned the cask without the lid bolts and advised TN that the lid bolts were lost. TN's CAR acknowledges a potential that the bolts may be found and placed into future service applications. As such, TN initiated actions to investigate further to account for the bolts and conduct a recall to prevent inadvertent use of nonconforming material without an appropriate disposition.

Safety Conscious Work Environment (SCWE)

The team reviewed TN Americas LLC information related to their SCWE programs and procedures. The team included this inspection area as part of a follow-up to fabrication inspection at CHT. The team used IPs 71152, Appendix A and IP 93100 to evaluate TN's programs and procedures. The team interviewed selected TN engineers and quality assurance personnel within TN's corporate organization concerning TN's SCWE and Employee Concerns Program (ECP). The team asked personnel if they would raise nuclear safety concerns without the fear of retaliation. All personnel interviewed stated that they would raise nuclear safety concerns and would not fear retaliation. In addition, the team noted that TN trained all personnel and were familiar with the corrective action program, a SCWE and ECP. The team assessed that TN personnel felt that they would use the programs if they needed to raise a concern. Based on the interviews conducted, the team assess that personnel are not hesitant to raise nuclear safety concerns.