UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 5, 2022

Jean-Luc Palayer
Chief Operating Officer
Orano Transnuclear Americas' LLC
7160 Riverwood Drive, Suite 20
Columbia, MD 21046

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION INSPECTION REPORT NO. 72-1004/2022-202

Dear Jean-Luc Palayer:

On February 28 to March 3, 2022, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an announced onsite inspection at the Orano Transnuclear Americas' LLC (Orano) corporate office in Columbia, Maryland. The staff continued the inspection activities with an in-office review through May 10, 2022, followed by an exit meeting on June 1, 2022.

The purpose of the inspection was to verify and assess the adequacy of Orano's activities with regards to the design control of spent fuel storage systems with the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-level Radioactive Waste, and Reactor-related Greater Than Class C Waste," and selected portions of 10 CFR Part 21, "Reporting of Defects and Noncompliance."

The inspection scope included discussions and reviews of specific issues related to various design changes and evaluations of important to safety dry cask storage components. The NRC inspection team examined activities conducted under your NRC approved Quality Assurance (QA) program to determine whether Orano implemented the requirements associated with the Commission's rules and regulations and with the conditions of the applicable certificate of compliance (CoC). The team reviewed selected procedures, records, and interviewed specific personnel. The enclosed report presents the results of this inspection (Enclosure).

Based on the results of this inspection, the NRC inspection team determined that three Severity Level IV violations of NRC requirements occurred. The NRC is treating these violations as Non-Cited Violations (NCVs), consistent with section 2.3.2 of the Enforcement Policy. The NRC inspection team described these NCVs in the subject inspection report.

If you contest these violations, you should provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Director, Office of Nuclear Materials Safety and Safeguards; and (2) the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

This letter, its enclosure, and your response (if any) will be made available for public inspection and copying at http://www.nrc.gov/reading-rm/adams.html and at the NRC Public Document Room in accordance with Title 10 of the *Code of Federal Regulations* (CFR) 2.390, "Public Inspections, Exemptions, Requests for Withholding."

Sincerely,

Signed by Rivera-Varona, Aida
on 07/05/22

Aida Rivera-Varona Acting Chief
Inspections and Operations Branch
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

Docket No. 72-1004

Enclosure:
NRC Inspection Report No. 72-1004/2022-202

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION INSPECTION REPORT NO. 72-1004/2022-202 DOCUMENT DATED: July 5, 2022

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U.S. NUCLEAR REGULATORY COMMISSION
Office of Nuclear Material Safety and Safeguards
Division of Fuel Management

Inspection Report

Docket:	72-1004
Report:	72-1004/2022-202
Enterprise Identifier:	I-2022-202-0000
Certificate Holder:	Orano Transnuclear Americas' LLC
Facility:	Corporate Headquarters
Location:	Columbia, MD
Inspection Dates:	February 28 to March 3, 2022, with in-office review through May 10, 2022
Inspection Team:	Matthew Learn, Transportation and Storage Safety Inspector, Team Leader Jeremy Tapp, Transportation and Storage Safety Inspector Marlone Davis, Senior Transportation and Storage Safety Inspector Jon Woodfield, Transportation and Storage Safety Inspector Azmi Djapari, Transportation and Storage Inspector (In-Training) Patrick Koch, Structural Engineer
Approved By:	Aida Rivera-Varona, Acting Branch Chief Inspections and Operations Branch Division of Fuel Management Office of Nuclear Material Safety and Safeguards

Enclosure

U.S. NUCLEAR REGULATORY COMMISSION
Office of Nuclear Material Safety and Safeguards
Division of Fuel Management

EXECUTIVE SUMMARY

Orano Transnuclear Americas LLC
NRC Inspection Report 721004/2022-202

On February 28 to March 3, 2022, the U.S. NRC staff conducted an announced onsite inspection at the Orano Transnuclear Americas LLC (Orano) corporate office in Columbia, Maryland. The staff continued the inspection activities with an in-office review and held a debrief meeting on May 10, 2022, followed by an exit meeting on June 1, 2022.

The purpose of the inspection was to verify and assess the adequacy of Orano's activities with regards to the design control of spent fuel storage systems with the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-level Radioactive Waste, and Reactor-related Greater Than Class C Waste," and selected portions of 10 CFR Part 21, "Reporting of Defects and Noncompliance."

Quality Assurance Policy, Audits, and Corrective Action

- The team determined, for the items selected for review, that the CoC holder's QAP implementing procedures are in place and used effectively.

Document Control

- The team concluded that the CoC holder is effectively implementing its document and records control program and has adequate procedures in place to ensure compliance with the applicable regulations and QA program requirements.

- The team determined a method existed to ensure that design changes initiated by the CoC holder were communicated to the licensee; the licensee was notified of the design changes in a timely manner to minimize production or operations impacts; and the licensee has reviewed and/or approved these design changes that were approved by the vendor or CoC holder.

Nonconformance Controls

- The team determined that sampled nonconforming conditions, which were resolved by design changes, were reviewed and approved by the CoC holder.

- The team determined whether all nonconforming conditions identified before completion of fabrication were appropriately resolved before the Dry Cask Storage System (DCSS) components affected were released to the licensee

Design Control and 10 CFR 72.48

- The team determined that generally the vendor had established an effective method for tracking, evaluating, and dispositioning changes or modifications to the DCSS component design. The team identified one issue associated with the design control process. This resulted in one Severity Level IV NCV of 10 CFR 72.146.

- For selected design changes, the team determine that generally applicable documentation was complete and accurate, including relevant 10 CFR 50.59 or 72.48 evaluations. The team identified two issues associated with the design changes. This resulted in two Severity Level IV NCVs of 10 CFR 72.48.

REPORT DETAILS

1.0 Design Control of Independent Spent Fuel Storage Installation (ISFSI) Components (Inspection Procedure (IP) 60851)

1.1 Quality Assurance Policy, Audits, and Corrective Action

1.1.1 Inspection Scope

The team determined whether the CoC holder's QAP implementing procedures are in place and used effectively. *(Inspection Requirement 02.01)*

The team reviewed Orano Transnuclear Americas' LLC (Orano) Quality Assurance Program Description Manual (QAPDM), Revision 17 as previously reviewed and approved by the NRC and Transnuclear Implementing Procedures (TIPs) to verify and evaluate the effectiveness of the QA program implementation. The team performed reviews of the quality program, policies, and procedures, and discussed portions of these documents with selected personnel to determine whether Orano adequately controlled and implemented activities subject to 10 CFR Part 72 regulations.

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

- TIP 16.1, "Corrective Action," Revision 32
- TIP 16.3, "Corrective Action Review Board," Revision 18

The team discussed the CAP controls with the Orano staff and reviewed a sample of corrective action reports (CARs) for appropriate disposition. The team evaluated whether Orano completed CARs for identified deficiencies in a technically sound and timely manner. As part of the sample of CARs, the team reviewed two CARs generated as a result of NRC identified violations at the Hitachi Zosen fabrication facility to ensure adequate corrective actions were implemented to correct the issues. The team also evaluated a sample of cause analyses, trend analyses, and verified that the CARs provided a connection to the 10 CFR Part 21 program. The team sampled CARs since 2019. In addition, as required by TIP 16.3, the team reviewed the performance monitoring and trending report for 2021.

The team reviewed Orano's internal and external audit program and associated quality procedures to assess the effectiveness of controls established for the scheduling, planning, and performance of audits. The team also reviewed the qualifications, training records, and annual evaluations for Orano Lead Auditors to determine if they met the procedure requirements. The team reviewed the following QAP section and quality procedure documents associated with internal and external audits to verify they are being properly implemented:

- QAPDM, Section 18.0, "Audits," Revision 17

- TIP-7.1, “Supplier Evaluations,” Revision 25
- TIP-7.2, “Supplier Audits,” Revision 13
- TIP-7.5, “Supplier Oversight,” Revision 13
- TIP-7.6, “Commercial Grade Surveys,” Revision 9
- TIP-7.11, “Approved Suppliers List,” Revision 16
- TIP-7.12, “Supplier Performance Monitoring,” Revision 13
- TIP-18.1, “Internal Audits,” Revision 18
- TIP-18.2, “Surveillances,” Revision 5

The team reviewed the 2019, 2020, and 2021 Internal Audit & Surveillance Schedules to verify that all 18 QAP criteria were audited, as applicable, each year and completed. The team verified that for the internal audits that were postponed in 2020, reference was made to a CAR for tracking. The team also verified that the CAR had been closed and all the postponed 2020 internal audits performed in 2021.

The team reviewed and assessed several of the internal audits completed since the last corporate inspection to determine if they were performed in accordance with procedures and if Orano identified deficiencies, and whether Orano addressed these deficiencies within their CAP.

The team reviewed the current procedure for the qualification of audit personnel and reviewed the lead auditor qualification and annual proficiency evaluations forms for three lead auditors.

The team reviewed the 2020 Senior Manager, Quality Assurance Report on the QAPDM which was written for the President of Orano.

The team chose five suppliers off the Orano approved supplier list and requested the latest supplier annual evaluations and supplier three-year audits to review and assess for procedure compliance. As part of the external supplier audit review, the team selected supplier audits related to important to safety (ITS) Category A vendor supplied equipment and materials. The team also reviewed the audit results to determine if Orano identified deficiencies.

Orano stated the only material purchased out of the Orano headquarters to be used in fabrication are poison plates and they are shipped directly to a fabricator where receipt inspection is performed, therefore the team reviewed a Orano headquarters purchase order for poison plates.

1.1.2 Observation and Findings

The team assessed that the overall implementation of Orano's QA program was adequate. The team concluded that Orano had an adequate CAP in place to identify, track and resolve quality related deficiencies and deviations. The team found that the corrective actions taken by Orano 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 determined the CoC holder's QAP internal and external audit implementing procedures are in place and used effectively.

The internal audits reviewed by the team were all very thorough and all the findings and observations in the reports had CAR numbers associated with them. Also in the audit reports, CARs written for previous findings were all reviewed by the Orano audit team for closure.

The team determined the lead auditor qualifications and annual proficiency evaluation forms for the three lead auditors selected for review were well documented and there were no issues with the records.

The team assessed that all the supplier audit reports reviewed used the correct forms and they were properly filled out. All reports contained the audit plan, audit checklists, and any supplier finding reports. Some of the three-year audits were performed by Nuclear Industry Assessment Committee (NIAC). The forms have a checklist to evaluate NIAC audit reports and then the NIAC report is attached to the checklist.

No findings of significance were identified.

1.1.3 Conclusions

The team determined, for the items selected for review, that the CoC holder's QAP implementing procedures are in place and used effectively.

1.2 Document Control

1.2.1 Inspection Scope

The team determined whether a method exists to ensure that design changes initiated by the CoC holder are communicated to the licensee; the licensee was notified of the design changes in a timely manner to minimize production or operations impacts; and the licensee has reviewed and/or approved these design changes that were approved by the CoC holder. *(Inspection Requirement 02.02)*

The team reviewed Orano's documentation and quality records control program and associated quality procedures to assess the effectiveness of controls established for the development, review, approval, issuance, use, and revision of quality documents. The team also reviewed the tracking, verification, and storage of quality records. The team reviewed the following QAP sections and quality procedure documents associated with document control and records to verify they are being properly implemented:

- QAPDM, Section 6.0, "Document Control," Revision 17
- QAPDM, Section 17.0, "Quality Assurance Records," Revision 17
- TIP-4.1, "Procurement Document Control," Revision 36
- TIP-5.1, "Drawing Control," Revision 14
- TIP-5.4, "Control of Licensing Documents," Revision 21
- TIP-5.6, "Implementing Procedures and QA Manual Control," Revision 32
- TIP-5.8, "Fabrication Drawing Control," Revision 2

- TIP-6.1, “Document Control,” Revision 21
- TIP-17.1, “Control of Quality Assurance Records,” Revision 19
-

The team also interviewed QA personnel regarding documentation and record controls.

1.2.2 Observation and Findings

Orano’s corporate headquarters in Columbia, Maryland has the primary responsibility for document controls at Orano. Orano fabricators only receive controlled electronic copies of design documents from the Orano Document Control Administrator (DCA). The manufacturing facilities are generally not responsible for entering quality records associated with the manufacturing of products directly into the Orano document control system.

The team discussed the document control process with the DCA. The team determined that adequate controls were in place to ensure that 1) document approval could only be performed by qualified personnel; 2) all technical departments reviewed the original issuance of a quality document for applicability to their discipline; 3) revisions are approved by the original signatories; and 4) old document revisions are clearly separated from the current revision and a database is kept up to date with the current revision number. New or revised design related document notification is sent out to Orano staff and fabricators by Orano Project Managers through the DCA. The distribution list is generally the individuals associated with the project for which the document applies and is maintained by the responsible Project Manager.

If the new or revised document is not project specific, such as a TIP; it will be electronically distributed throughout Orano for staff reading and electronic acknowledgment back to Orano headquarters. The DCA transmits all new procedures and updates to the Orano electronic learning system (ELS) administrator. The ELS administrator controls the Orano electronic master training matrix for all employees and updates each employees training record when new and revised procedures have been acknowledged electronically to have been read by a Orano employee. The QAPDM, procedures, manuals, etc. are also posted to the electronic Orano Business Portal where any Orano employee can access them, and they are considered controlled documents available for use unless printed.

The DCA is also responsible for developing and maintaining a hardcopy-controlled document distribution log and assigning controlled copy holder numbers for tracking. The DCA also tracks the return of controlled document transmittals for hardcopy documents and maintaining these transmittals and transmittal emails as quality records.

The team also discussed the requirements of TIP 17.1 with the DCA. The team verified that only designated staff have access to quality records. The team verified with the DCA, who also has the title of Supervisor of Records Management as described in TIP 17.1, which records are considered to be Lifetime records and which records are considered to be nonpermanent. Duplicate electronic copies of records are stored in two separate locations. All quality records are readily retrievable from Orano’s Laserfiche Enterprise Content Management imaging system and new records must be verified to be

legible upon entry into the system. Printed copies of documents automatically have "uncontrolled if printed" shown on them.

There were no concerns identified by the team in the Orano documentation control or quality records areas. The team determined that Orano's record procedures were adequate for the classification and assignment of retention times for quality records generated by Orano. Overall, the team assessed that document and records management controls at Orano were adequate.

No findings of significance were identified.

1.2.3 Conclusions

The team concluded that the CoC holder is effectively implementing its document and records control program and has adequate procedures in place to ensure compliance with the applicable regulations and QA program requirements.

The team determined a method existed to ensure that design changes initiated by the CoC holder were communicated to the licensee; the licensee was notified of the design changes in a timely manner to minimize production or operations impacts; and the licensee has reviewed and/or approved these design changes that were approved by the CoC holder.

1.3 Nonconformance Controls

1.3.1 Inspection Scope

The team determined whether any nonconforming conditions, which were resolved by design changes, have been reviewed and approved by the licensee or CoC holder (if authorized by the CoC). *(Inspection Requirement 02.03)*

The team determined whether all nonconforming conditions identified before completion of fabrication were appropriately resolved before the DCSS components affected were released to the licensee. *(Inspection Requirement 02.04)*

The team reviewed selected records and interviewed personnel to verify that Orano effectively implemented the nonconformance control program. Specifically, the team reviewed Orano's policies and the following approved implementing procedures that govern the nonconformance control program 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 21
- TIP 15.3, "Review of Supplier Nonconformances," Revision 22
- TIP 15.4, “Control of Fabrication Nonconforming Items,” Revision 3

The team discussed the nonconformance controls with the Orano staff and reviewed a sample of nonconformance reports (NCRs) and external supplier nonconformance reports (SNCRs). The team sampled NCRs and SNCRs since 2019 which consisted of a variety of component types and suppliers that included a mix of accept-as-is and repair component dispositions. Further, the team reviewed program controls for 10 CFR Part 21.

1.3.2 Observation and Findings

Overall, the team concluded that Orano had an adequate nonconformance control in place to identify, track, and resolve quality related deficiencies and deviations. The team determined that Orano appropriately dispositioned the nonconformances reviewed and closed them in a timely manner commensurate with the safety significance, in accordance with the quality procedure.

No findings of significance were identified.

1.3.3 Conclusions

The team determined that sampled nonconforming conditions, which were resolved by design changes, were reviewed and approved by the CoC holder.

The team determined that nonconforming conditions identified before completion of fabrication were appropriately resolved before the DCSS components affected were released to the licensee.

1.4 Design Control and 10 CFR 72.48

1.4.1 Inspection Scope

The team determined whether the vendor and fabricator personnel have established an effective method for tracking, evaluating, and dispositioning changes or modifications to the DCSS component design. *(Inspection Requirement 02.05)*

For selected design changes, the team determine whether the applicable documentation is complete and accurate, including relevant 10 CFR 50.59 or 72.48 evaluations. *(Inspection Requirement 02.06)*

The team reviewed selected records and interviewed personnel to evaluate Orano's design change process. The team reviewed TIP 3.1, "Design Control," Revision 28, to determine if the overall design control procedure contained adequate guidance and that Orano followed the design procedure for the sample of design documents reviewed. The team focused its review on a sample of Orano's design activities associated with Orano DCSS. Specifically, the team reviewed design reports, design criteria documents, and design review meeting reports, as applicable to the design changes being made.

In addition, the team reviewed Orano's TIP related to the implementation instructions for 10 CFR 72.48 evaluations, which include applicability and screening reviews. Specifically, the team reviewed TIP 3.5, "Licensing Reviews," Revision 28 and a list of screenings and evaluations performed by Orano to meet regulatory requirements associated with 10 CFR 72.48 regulations. The team selected a representative sample of screenings and evaluations based on the criteria in IMC 2690, appendix E for the potential impact on safety since the last inspection in 2019.

1.4.2 Observation and Findings

Licensing Review (LR) Document No. 721042-098

Introduction

The team identified a Severity Level IV NCV of 10 CFR 72.48(c)(1), "Changes, Tests, and Experiments" because the certificate holder made changes in the spent fuel storage cask design as described in sections A.2.1.4 and A.2.4.2 of the EOS Horizontal Modular Storage System (NUHOMS), Final Safety Analysis Report (FSAR) (as updated) without meeting the requirements in the CoC. Specifically, Orano modified the Updated Final Safety Analysis Report (UFSAR) requirements for the MATRIX loading crane (MX-LC) without performing an evaluation for an accident drop as required by CoC Condition 5, "Heavy Loads Requirements" and Technical Specification (TS) 5.2.1 because the MX-LC failed to meet the "single failure proof" requirements contained in the American Society of Mechanical Engineers (ASME) NOG-1, "Rules for Construction of Overhead and Gantry Cranes," 2015 edition standard.

Description

The team reviewed the 10 CFR 72.48 LR document number (No.) 721042-098, Revisions 1-2, various sections of Revision 3 to the NUHOMS EOS UFSAR, applicable Design Change Requests, and Amendments 1-2 to the CoC No. 1042 with their corresponding NRC safety evaluation reports (SERs) to assess the proposed changes identified in the LR for the MX-LC and retractable rolling tray (MX-RRT) components.

The team performed this review to determine if Orano performed 10 CFR 72.48 reviews in accordance with their procedural guidance for proposed changes to the UFSAR that included the review and clarification of the design bases for the MX-LC and MX-RRT, a change to add contingency rigging for lowering a loaded dry shielded canister (DSC) in the event of a malfunction of the MX-LC, and a change to increase the operational sustained wind speed from 15 miles per hour (mph) to 25 mph for the MX-LC.

As stated in sections A.2.1.4.2 and A.2.4.2.4 of the NUHOMS EOS UFSAR Revision 3, "the MX-LC is the device used as part of the NUHOMS transfer equipment, designed and built to assist in loading the DSC into the horizonal storage module (HSM)-MX. The MX-LC is a Part 72 ITS related piece of transfer equipment. The MX-LC is designed, fabricated, installed, tested, inspected, and qualified in accordance with ASME NOG-1 as a Type1 gantry crane. In addition, the MX-LC is engineered as "single-failure-proof" per NUREG-0612". The UFSAR further states that the MX-LC single-failure-proof handling capability is achieved by ensuring that the applicable design factor is 200% of that required by ASME NOG-1.

For the MX-RRT, the team noted that section A.2.1.4.2 of the NUHOMS EOS UFSAR Revision 3 provides a description of the MX-RRT which consists of a pair of roller assemblies installed in their designated compartment of the HSM-MX. The MX-RRT uses hydraulic cylinders to position the rollers in the extended position for inserting or withdrawing the DSC on the front and rear support plates of the HSM-MX. The MX-RRT are ITS as the rollers provide both a structural and retrieval function. Additionally, section A.2.4.2.5 states, in part, that the MX-RRT single failure proof handling capability is achieved by ensuring that the design factor is 200% of that from ASME NOG-1.

The team assessed the screening and evaluation questions of the 10 CFR 72.48 LR using the NRC Inspection Manual Chapter 0335, "Changes, Tests, and Experiments (CTEs)," dated February 1, 2021, and industry guidance endorsed by NRC regulatory guide (RG) 3.72, "Guidance for Implementation of 10 CFR 72.48, 'CTEs'," Revision 1.

The team focused the review on the change to clarify the design bases for the MX-LC and MX-RRT in 10 CFR 72.48 LR document number (No.) 721042-098, Revisions 1-2, which addressed the single failure proof design requirements and the change to add contingency rigging for lowering a loaded DSC in the event of a malfunction of the MX-LC. The team noted that Orano screened these design changes proposed in the LR to a full 10 CFR 72.48 evaluation based on the changes having an adverse impact on the design functions and method of performing or controlling the design function for the MX-LC and MX-RRT. However, the team determined that Orano missed an opportunity to perform a 10 CFR 72.48 evaluation for a method of evaluation (MOE) change. For instance, Orano wanted to limit the design seismic qualification for both the MX-LC and MX-RRT to a lower seismic criterion for the zero period accelerations in the horizonal and vertical directions using a different seismic damping factor as described in the ASME NOG-1 standard, 2015 edition. Orano did not recognize that this was a change in an element of an MOE and failed to evaluate the change in the LR. The team determined that this issue was of minor significance.

Separately, as a part of the change, the team noted that Orano revised sections of the UFSAR, as stated in the LR to clarify that the new MX-LC only met applicable portions of the ASME NOG-1-2015 standard as a Type 1 gantry crane. The team noted in reviewing the LR that the MX-LC is a telescoping gantry crane, and not an overhead bridge crane or gantry crane with a top running trolley, which made most of the criteria in the ASME NOG-1 standard not applicable. The LR further listed 34 sections of ASME NOG-1 that were either not applicable or partially applied to the MX-LC design. For example, the design of the MX-LC contains additional vital lifting subcomponents such as a jacking screw and worm drives instead of a wire rope. The team noted that Orano did not provide these exceptions to the ASME NOG-1-2015 standard as a part of their original licensing application for the MX-LC. The team determined that this change was more than a clarification and that Orano departed from the standard (ASME NOG-1-2015) described in the UFSAR used in establishing the design bases Orano committed to during the original licensing of the EOS DCSS. The team determined that this change resulted in more than a minimal increase in the likelihood of occurrence of a malfunction of an SSC ITS previously evaluated because Orano must meet applicable requirements which they are committed to during licensing.

Additionally, the team determined that the change did not meet an acceptable method approved by the NRC as communicated and endorsed in NRC generic communications and RGs for control of heavy loads using single failure proof cranes. For example, the team noted that the NRC Regulatory Issue Summary (RIS) 2005-25, “Clarification of NRC Guidelines for Control of Heavy Loads,” Supplement 1, found ASME NOG-1-2004 an acceptable method for satisfying the guidelines of NUREG-0554, “Single-Failure-Proof Cranes for Nuclear Power Plants.” NUREG-0554 is the guideline described in NUREG-0612, “Control of Heavy Loads,” that establishes the single failure proof guidelines and philosophy. The RIS 2005-25, Supplement 1 further stated that the NRC staff and the ASME Cranes for Nuclear Facilities Committee has developed a comparison of ASME NOG-1 design criteria to the criteria of NUREG-0554. This comparison table serves as an aid to users that want to modify their licensing basis to use the ASME NOG-1 standard to control heavy loads in accordance with the requirements of 10 CFR 50.59 or 72.48 if the user did not submit ASME NOG-1 as a basis for their initial licensing action.

The team noted that the UFSAR states in part that the MX-LC is designed, fabricated, installed, tested, inspected, and qualified in accordance with ASME NOG-1[2015], as a Type I gantry type of crane, as per the guidance provided in NUREG-0612. As described above, NUREG-0554 is the guideline described in NUREG-0612, “Control of Heavy Loads,” that establishes the single failure proof guidelines and philosophy. The team noted that ASME NOG-1-2015 included the comparison of the ASME NOG-1 design criteria to the NUREG-0554 design criteria. The team also noted that NRC staff endorsed the comparison table in RG 1.224, “Control of Heavy Loads at Nuclear Facilities,” Revision 0 for ASME standard NOG-1-2020. After reviewing the LR and the comparison table, the team considered the changes did not meet the single failure proof criteria for ASME NOG-1 since Orano did not meet the Type 1 criteria of the ASME standard NOG-1-2015 in its entirety or provide exceptions during the initial licensing action.

Further, for lifts over 65 inches a load drop has not been analyzed, and since the system has not been demonstrated to be single failure proof, the change would affect Condition 5 and appendix A of TS section 5.2.1 to the CoC No. 1042, Amendments 1-2. The team noted that Condition 5 to CoC No. 1042 states, in part, that if a single failure proof crane is not used, the licensee must evaluate the accidental drop of the shielding components of the Transfer Cask (TC) under 10 CFR 50.59, 10 CFR 72.48, and 10 CFR 72.212, and evaluate the consequences of the accident drops. Orano did not evaluate the accidental drop under the 10 CFR 72.48 requirements. Additionally, CoC No. 1042 Amendment 2, appendix A, section 5.2.1, "TC/DSC Lifting Height and Temperature Limits" states, in part, that "the requirements of 10 CFR 72 apply to TC/DSC lifting/handling height limits outside the Fuel Building. No lift height restriction is imposed on the TC/DSC if a single-failure-proof lifting/handling system is used." The team also noted that Orano did not impose lifting and handling limits outside the fuel building for the MX-LC. The team determined that these were violations of NRC requirements.

Analysis

The team assessed the significance of the violation using the NRC Enforcement Policy and Enforcement Manual. The team determined that the violation had the potential for impacting the NRC's ability to perform its regulatory oversight function because Orano did not receive prior NRC approval for changes in licensed activities. The team determined that the violation associated with the MX-LC was more than minor because Orano did not seek prior NRC review and approval to changes that met the criteria in paragraph (c)(1) of 10 CFR 72.48. The team characterized the violation as a Severity Level IV based on Enforcement Policy example 6.1.d.2 as the change resulted in a condition having low safety significance. The team noted that there are acceptable methods to meet regulatory requirements for the control of heavy loads at nuclear facilities identified in NRC generic communications and RGs that if used correctly, can be implemented through 10 CFR 72.48 requirements or via a licensing amendment based on the results of the 10 CFR 72.48 evaluation. Orano entered this issue into their CAP as CAR 2022-073 for resolution. The team determined that because the violation was of very low safety significance, the issue was not repetitive or willful, and captured in Orano's CAP, the team is treating this issue as an NCV, consistent with section 2.3.2.a of the Enforcement Policy.

Enforcement

10 CFR 72.48(c)(1), requires, in part, that a certificate holder may make changes in the spent fuel storage cask design as described in the FSAR (as updated), […] without obtaining […](ii) a CoC amendment submitted by the certificate holder pursuant to § 72.244 (for general licensees and certificate holders) if: […] (B) change in the terms, conditions, or specifications incorporated in the CoC is not required and if the (C) change, test, or experiment does not meet any of the criteria in paragraph (c)(2) of this section.

Contrary to the above, as of December 15, 2021, the certificate holder made changes to the spent fuel storage cask design as described in the FSAR (as updated) without obtaining a CoC amendment pursuant to 10 CFR 72.244 for a change required in the terms, conditions, or specifications incorporated in the CoC. Specifically, Orano made

changes in the spent fuel storage cask design as described in sections A.2.1.4 and A.2.4.2 of the NUHOMS EOS UFSAR (as updated) without meeting the requirements in the CoC. Specifically, Orano modified the UFSAR requirements for the MX-LC without performing an evaluation for an accident drop as required by CoC Condition 5, "Heavy Loads Requirements" and TS 5.2.1 because the MX-LC failed to meet the "single failure proof" requirements in the ASME NOG-1 2015 standard. **(72-1004/2022-202-01)**

LR Document No. 721042-146

Introduction

The team identified a Severity Level IV NCV of 10 CFR 72.48(d)(1), "Changes, Tests, and Experiments" because Orano did not perform an adequate written evaluation which provided the bases for the determination that the change, test, or experiment does not require a license or CoC amendment pursuant to paragraph (c)(2) of this section. Specifically, Orano did not provide the bases for the determination that the presence of boiling water in the DSC and TC annulus does not require a CoC amendment pursuant to paragraphs (c)(2)(i) and (c)(2)(vi).

Description

The team reviewed the 10 CFR 72.48 LR document No. 721042-146, Revisions 0-1, various sections of Revision 1 to the NUHOMS EOS UFSAR, Amendment 0 to the CoC No. 1042 and the corresponding NRC SER to assess the proposed changes that revised the UFSAR to allow boiling of water within the annulus between the TC and DSC. The LR also described changes that provided additional guidance on managing the annulus water level in the operating procedure sections of the NUHOMS EOS UFSAR.

As stated in section 4.5.11, "Thermal Evaluation for Loading/Unloading Conditions," of the NUHOMS EOS UFSAR, the water in the annulus is monitored and replenished with fresh water to prevent boiling, and to maintain the water level if excessive evaporation occurs. The presence of water within the annulus maintains the maximum DSC shell temperature below the boiling temperature of water in open atmosphere (223°F). section 4.5.11, further states, in part, that the presence of helium during blowdown and vacuum drying operations and the cooling provided by water in the annulus between the DSC and TC eliminate the thermal cycling of fuel cladding during helium backfilling of the DSCs subsequent to vacuum drying. Additionally, sections 9.1.3, 9.1.4, and 9.2.2 of the NUHOMS EOS UFSAR contain information to monitor the TC/DSC annulus water level and replenish if necessary.

The team assessed the screening and evaluation questions of the 10 CFR 72.48 LR using the NRC Inspection Manual Chapter 0335, "Changes, Tests, and Experiments (CTEs)," dated February 1, 2021 and industry guidance endorsed by NRC RG 3.72, "Guidance for Implementation of 10 CFR 72.48, 'CTEs'," Revision 1.

The team noted that Orano revised UFSAR section 4.5.11 to remove the words "to prevent boiling" in the annulus. TN also provided additional guidance on how to manage the TC/DSC annulus water level during loading and unloading. However, the team

noted that section 4.4.3, “Loading Conditions (Vacuum Drying),” of the NRC SER relied upon both the presence of helium and the cooling provided by water in the TC/DSC annulus. Furthermore, section 8.16.1, “Cladding Temperature Limits,” of the NRC SER described how the NRC staff evaluated Orano’s thermal cycling analysis and found that the presence of the annulus water during the canister draining operation would effectively mitigate thermal cycling that could lead to embrittlement from hydride reorientation.

The team determined that this change from cooling water in the annulus to boiling water had an adverse impact on the design function and MOE because the cooling water was an input parameter, determined to be an element of an MOE, based on the conservative acceptance from the NRC staff. Specifically, the team had concerns that the presence of boiling water could adversely affect the heat transfer from the DSC shell and create thermal cycling of the fuel. The team noted that Orano did not fully evaluate the change under 10 CFR 72.48 (c)(2)(viii) to determine if the change resulted in a departure from a MOE described in the UFSAR (as updated) used in establishing the design bases or in the safety analyses. Additionally, the TS Bases for B.3.1.1 assumes that the DSC/TC annulus contains water during the vacuum drying process and that the maximum DSC shell temperature of 223°F was an initial condition within the steady state thermal evaluation for transfer operation. The team also noted that Orano used the DSC shell temperature of 223°F as an assumption in calculating the maximum internal pressures within the EOS DSCs. The team determined that this change was more than a clarification as there was no discussion on what type of boiling was occurring (e.g., film or nucleate boiling) and how it would impact TS Bases and maximum internal pressure analysis.

The team noted in discussions with the Orano staff that correlations in the design basis analysis within the UFSAR bound the condition of boiling in the annulus. Specifically, the thermal analyses during transfer operations assumed that the analysis does not contain water (i.e., forced air). However, the team noted that the alternative analyses were specifically assessed for “off normal” conditions, while the vacuum drying analysis was for “normal” conditions with cooling water in the DSC/TC annulus. Therefore, utilization of these analyses to bound the boiling in the annulus would need to be evaluated under 10 CFR 72.48(c)(2)(i), to ensure they would not “result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the FSAR (as updated)”. For example, as described in the endorsed industry guidance, a change from one frequency category (normal) to another frequency category (off-normal) would result in more than a minimal increase in the frequency of occurrence of an accident. The team noted that this approach was not considered in the 10 CFR 72.48 evaluation as Orano documented, in part, that the change was to clarify the description regarding the boiling of water within the TC/DSC annulus, which has no impact on the frequency of when an accident occurs, as the frequency of an accident is independent of the variable being changed. The change itself is not an accident initiator and has no impact on failure modes or their effects as described in the UFSAR.

In addition, it is stated in the EOS UFSAR and corresponding NRC SER that the cooling provided by the water in the annulus between the DSC and TC eliminates the thermal cycling of fuel cladding. The team noted that the change from cooling water to boiling water has the potential to cause thermal cycling which would increase the likelihood of a malfunction previously thought to be eliminated based on the assumptions in the UFSAR and what the NRC staff relied upon to provide adequate assurance that no thermal cycling would occur. The team determined that this change would increase the likelihood of thermal cycling assumed to be eliminated or not to occur with the presence of helium and cooling water and that the change would create a different result than that currently described in the UFSAR and needed to be evaluated under 10 CFR 72.48(c)(2)(vi).

The team determined that the licensee failed to include an adequate written evaluation which provides the bases for the determination that the change does not require a license or CoC amendment pursuant to paragraph 10 CFR 72.48(c)(2) in accordance with NRC requirements.

Analysis

The team assessed the significance of the violation using the NRC Enforcement Policy and Enforcement Manual. The team determined that the violation had the potential for impacting the NRC's ability to perform its regulatory oversight function because Orano did not receive prior NRC approval for changes in licensed activities. The team determined that the violation was more than minor because the licensee did not seek prior NRC review and approval to changes that require a CoC amendment pursuant to paragraph (c)(2) of 10 CFR 72.48. The team characterized the violation as a Severity Level IV based on Enforcement Policy example 6.1.d.2. Specifically, the team evaluated the potential consequences of boiling occurring during vacuum drying operations. The team reviewed the thermal analyses and corresponding operational controls that were put in place to help reduce the likelihood of boiling. The team assessed that the peak cladding and ITS component temperatures described in the UFSAR were still bounding of nucleate boiling. Orano entered this issue into their CAP as CAR 2022-073 for resolution. The team determined that because the violation was of very low safety significance, the issue was not repetitive or willful, and captured in Orano's CAP, the team is treating this issue as an NCV, consistent with section 2.3.2.a of the Enforcement Policy.

Enforcement

10 CFR 72.48(d)(1) requires, in part, that the licensee and certificate holder shall maintain records of changes in the facility or spent fuel storage cask design, of changes in procedures, and tests and experiments made pursuant to paragraph (c) of this section. These records must include a written evaluation which provides the bases for the determination that the change does not require a CoC amendment pursuant to paragraph (c)(2) of this section.

Contrary to the above, as of September 30, 2021, the certificate holder did not maintain adequate records of changes in the spent fuel storage cask design made pursuant to

paragraph (c) of 10 CFR 72.48 that included a written evaluation that provided the bases for the determination that the change does not require a CoC amendment pursuant to 10 CFR 72.48(c)(2). Specifically, Orano did not include an adequate written evaluation which provided the bases for the determination that the change from water not boiling to allowing boiling of water in the DSC/TC annulus does not require a CoC amendment pursuant to 10 CFR 72.48 (c)(2)(i) and (c)(2)(vi). **(72-1004/2022-202-02)**

LR Document No. 721004-1702

Introduction

The team identified a Severity Level IV NCV of 10 CFR 72.146, "Design Control," because the certificate holder did not subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Specifically, Orano supported a field change for a general licensee and did not properly analyze for tornado events in accordance with original UFSAR requirements.

Description

The team reviewed the corrective action report No. 2019-115 initiated during the previous NRC inspection to close an Unresolve Item (URI) associated with 10 CFR 72.48 LR No. 721004-1702, Revision 1. The LR evaluated the temporary removal of end-shield walls to expand a Standardized NUHOMS System (CoC No. 1004), HSM array at a general licensee's ISFSI facility. The NRC inspection team at the time noted that the temporary modification would allow the general licensee to lift and remove the end-shield walls, one at a time, and install large ¾-inch steel plates to temporarily protect the DSCs from adverse weather including tornado wind pressures and generated missiles. The team had identified three concerns with the LR, one being an assumption that Orano made about the temporary steel plates because of the steel plates close proximity to the empty HSM, Orano did not consider the negative tornado wind pressures in their analysis.

The team noted that Orano revisited the analysis and determined that the assumption did not have a technical justification basis and failed to meet procedural guidance contained in section 5.2.E of TIP 3.2, "Calculations," Revision 17. Orano revised Calculation 11213-0204 to evaluate the tornado wind pressures on the steel plates and concluded that the negative pressure from the tornado winds would have pulled the ¾-inch steel plates away from the loaded DSCs and exposed the interior sides of the HSMs and the vent openings to tornado-generated missiles. Orano then used the MOE in the UFSAR to demonstrate that the DSC would not have lost confinement and would have continued to perform all design functions from a tornado event.

The team assessed that this was a violation of NRC requirements related to 10 CFR 72.146, "Design control," because Orano did not subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Specifically, Orano supported a field change for a general licensee and did not properly analyze for tornado wind pressures without considering all assumptions from the original design.

Analysis

The team assessed the significance of the violation using the NRC Enforcement Policy and Enforcement Manual. The team determined that the violation was of more than minor safety significance in accordance with IMC 0612, appendix E, Example 3.g. Specifically, Orano had to re-perform an analysis to assure that design basis accident analysis requirements were met. The team characterized the violation as a Severity Level IV based on Enforcement Policy example 6.5.d.1. Specifically, based upon further analysis the DSC and the interior of the HSM would not have been significantly damaged by the postulated tornado missile if the plate(s) were to be removed during the tornado accident. The DCSS would have maintained confinement and all other safety functions such as thermal, criticality, and shielding. Orano entered the issue into their CAP as CAR 2022-075 for resolution. Orano revisited the Calculation 11213-0204 and determined that the assumption did not have a technical justification basis and failed to meet procedural guidance contained in section 5.2.E of TIP 3.2, "Calculations," Revision 17. Orano revised the Calculation to account for tornado wind pressures and used the MOE in the UFSAR that accounted for wind pressures. This demonstrated that the exposed loaded DSCs in the HSMs would maintain confinement and would have continued to perform all design functions following a tornado event based on the removed end shield wall configuration. The team determined that because the violation was of very low safety significance, the issue was not repetitive or willful, and captured in Orano's CAP, the team is treating this issue as an NCV, consistent with section 2.3.2.a of the Enforcement Policy.

Enforcement

10 CFR 72.146, "Design control," requires, in part, that the certificate holder shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design.

Contrary to the above, prior to September 28, 2018, Orano did not subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Specifically, Orano supported a field change for a general licensee to remove end shield walls from a HSM that contained loaded DSCs and did not properly analyze for tornado wind pressures and consider all assumptions from the original design. **(72-1004/2022-202-03)**

1.4.3 Conclusions

The team determined that generally the CoC holder had established an effective method for tracking, evaluating, and dispositioning changes or modifications to the DCSS component design. The team identified one issue associated with the design control process. This resulted in one Severity Level IV NCV of 10 CFR 72.146.

For selected design changes reviewed, the team determined that, generally, applicable documentation was complete and accurate, including relevant 10 CFR 50.59 or 72.48 evaluations. The team identified two issues associated with the design changes. This resulted in two Severity Level IV NCVs of 10 CFR 72.48.

2.0 Exit Meeting

The team presented the results of the inspection to Brian Ocampos, Director of Quality Assurance and Safety, and other members of the Orano staff at an exit meeting on June 1, 2022. The CoC holder acknowledged the results presented and did not identify any of the information discussed as proprietary.

SUPPLEMENTAL INFORMATION

INSPECTION PROCEDURES USED

IP 60851 Design Control of ISFSI Components

ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description
72-1004/2022-202-01	Opened	NCV	72.48 Violation
72-1004/2022-202-02	Opened	NCV	72.48 Violation
72-1004/2022-202-03	Opened	NCV	72.146 Violation
72-1004/2019-201-01	Closed	URI	HSM Missile Protection

PARTIAL LIST OF DOCUMENTS REVIEWED

The team identified the documents reviewed during the inspection in the report details above.

LIST OF ACRONYMS USED

ASME	American Society of Mechanical Engineers
CAP	Corrective action program
CAR	Corrective action reports
CoC	Certificate of compliance
DCA	Document Control Administrator
DCSS	Dry cask storage system
DSC	Dry shielded canister
ELS	Electronic learning system
FSAR	Final Safety Analysis Report
HSM	Horizonal storage module
ISFSI	Independent Spent Fuel Storage Installation
ITS	Important to safety
LR	Licensing review
MOE	Method of evaluation
NCV	Non-Cited Violation
NIAC	Nuclear Industry Assessment Committee
NRC	Nuclear Regulatory Commission
NUHOMS	Horizontal Modular Storage System
QA	Quality Assurance
QAP	Quality assurance program
QAPDM	Quality Assurance Program Description Manual
RG	Regulatory guides
SER	Safety Evaluation Reports
TC	Transfer Cask
TIP	Transnuclear Implementing Procedures
TN	Transnuclear
TS	Technical Specification
UFSAR	Updated Final Safety Analysis Report
URI	Unresolved item