



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

January 6, 2023

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

SUBJECT: ORANO TRANSNUCLEAR AMERICAS LLC - U.S. NUCLEAR REGULATORY
COMMISSION INSPECTION REPORT NO. 72-1004/2022-203

Dear Jean-Luc Palayer:

On September 20 to September 22, 2022, the U.S. Nuclear Regulatory Commission (NRC) conducted an announced onsite team inspection at the Hitachi Zosen Corporation, Ariake Works (HZA) in Nagasu, Kumamoto, Japan. HZA was under contract with Orano Transnuclear Americas (TN) to fabricate important to safety (ITS) components of their NRC approved dry cask storage systems (DCSSs). The purpose of the inspection was to verify and assess the onsite fabrication activities at HZA of the TN ITS DCSS components, which were in various stages of fabrication, 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 enclosed report presents the results of this inspection. The team discussed the preliminary results of this inspection on September 22, 2022, and continued the inspection activities with an in-office review through October 20, 2022, after TN provided additional information. The team conducted a final exit meeting on November 28, 2022.

The inspection scope included observations of fabrication activities, documentation reviews, and interviews with personnel to determine whether the ITS DCSS fabricated by an offsite entity and used in an independent spent fuel storage installation, was being constructed in accordance with the commitments and requirements specified in the safety analysis report, the NRC's corresponding safety evaluation report, 10 CFR Parts 21 and 72 requirements, the certificate of compliance and technical specifications of the DCSS.

Based on the results of this inspection, the NRC inspection team determined that one Severity Level IV violation of NRC requirements occurred. The NRC is treating this violation as a Non-Cited Violation (NCV), consistent with Section 2.3.2 of the Enforcement Policy. The NRC inspection team described this NCV in the subject inspection report.

If you contest this violation, 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 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding."

Sincerely,



Signed by Rivera-Varona, Aida
on 01/06/23

Aida Rivera-Varona, Chief
Inspection and Oversight Branch
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

Docket No. 72-1004

Enclosure:
NRC Inspection Report No.
72-1004/2022-203

SUBJECT: ORANO TRANSNUCLEAR AMERICAS LLC - U.S. NUCLEAR REGULATORY COMMISSION INSPECTION REPORT NO. 72-1004/2022-203

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***via email**

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

Docket: 72-1004

Report.: 72-1004/2022-203

Enterprise Identifier: I-2022-203-0033

Certificate Holder: Orano Transnuclear Americas, LLC.

Facility: Hitachi Zosen Corporation Ariake Works

Location: Nagasu, Kumamoto, Japan

Inspection Dates: September 20, 2022, through September 22, 2022
October 10, 2022, through November 28, 2022 (In-Office)

Inspection Team: Marlene Davis, Senior Transportation and Storage Safety Inspector,
Team Leader
Jeremy Tapp, Transportation and Storage Safety Inspector
Matthew Learn, Transportation and Storage Safety Inspector

Approved By: Aida Rivera-Varona, Branch Chief
Inspection and Oversight 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 72-1004/2022-203

On September 20, 2022, through September 22, 2022, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an announced onsite inspection at the Hitachi Zosen Corporation Ariake Works (HZA) in Nagasu, Kumamoto, Japan. HZA was under contract with Orano Transnuclear Americas (TN) to fabricate important to safety (ITS) components associated with the EOS (72-1042) and TN-40HT (72-0010) dry cask storage systems (DCSSs).

The purpose of the inspection was to verify and assess the adequacy of TN and HZA's activities with regards to the fabrication control of DCSS components 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 observations of fabrication activities, documentation reviews, and interviews with personnel to determine whether the ITS DCSS fabricated by an offsite entity and used in an independent spent fuel storage installation (ISFSI), was being constructed in accordance with the commitments and requirements specified in the safety analysis report, the NRC's corresponding safety evaluation report, 10 CFR Parts 21 and 72, the certificate of compliance (CoC) and technical specifications (TS) of the DCSS. The team focused on the design, modification, fabrication, assembly, testing, and procurement of the EOS transfer cask and the TN-40HT fuel baskets.

Design Control

- The team determined that for the items selected for review the fabrication specifications were consistent with the design commitments and requirements documented in the final safety analysis report (FSAR), CoC, and TS. (Section 1.1)

Corrective Action and Non-Conformance Reports

- The team determined that HZA had an adequate nonconformance and corrective action program in place to resolve deficiencies. The team determined that HZA and TN appropriately identified issues and implemented corrective actions in a time frame commensurate with their safety significance. However, the team identified one non-cited violation of NRC requirements (10 CFR 72.150) when TN did not have adequate procedures in place to perform licensing reviews for all applicable situations. (Section 1.2)

Personnel Training and Certifications

- The team determined that HZA trained and certified individuals performing quality-related activities as required by the HZA and TN quality assurance programs. (Section 1.3)

Human Performance

- The team determined that HZA personnel were familiar with the DCSS design, performed designate fabrication techniques, testing requirements, and quality controls (QC) associated with the construction of the specific DCSS components under contract. (Section 1.4)

Procurement

- The team determined that materials, components, and other equipment received by HZA met DCSS design procurement specifications, and that the procurement specifications conform to the design commitments and requirements contained in the FSAR, CoC, and TS. (Section 1.5)

Implementing Procedures

- The team determined that HAZ generally fabricated and inspected DCSS components in accordance with 10 CFR Parts 21 and 72 requirements, quality assurance program (QAP) with the associated implementing procedures and fabrication specifications. In addition, the team concluded that HZA effectively implemented its measuring and test equipment (M&TE) control program and has adequate procedures in place to ensure compliance with the applicable regulations, industry standards and quality requirements. (Section 1.6)

10 CFR Part 21

- The team determined that HAZ conducted fabrication activities under a QAP with the associated implementing procedures that met the requirements of 10 CFR Part 21, which included the reporting and posting requirements. (Section 1.7)

Oversight and Audits

- The team determined that for the items selected for review that TN and HZA performed oversight and audits in accordance with their QAP. (Section 1.8)

REPORT DETAILS

1.0 ISFSI Component Fabrication by Outside Fabricators Inspection Procedure (IP) 60852

1.1 Design Control

1.1.1 Inspection Scope

The team determined whether the fabrication specifications were consistent with the design commitments and requirements documented in the FSAR, CoC, and TSs.

The team reviewed the fabrication specifications and fabrication drawings against the design and licensing drawings to verify the consistency of material specifications and critical dimensions as well as testing and inspection requirements to determine whether the fabrication specifications were consistent with the design. Specifically, the team focused on the translation of design commitments and requirements for the ITS Category A, B, and C components of the EOS transfer cask and TN-40HT fuel basket from the FSARs and design specifications, including associated licensing drawings, and subsequent manufacturing plans. The team reviewed the following HZA quality assurance manual (QAM) procedures and standards associated with design control during fabrication to verify proper implementation. The procedures and standards are as follows:

- QAM Section M-10-2, "Design Control," Revision 4
- QAM Section M-15-1, "Document Control," Revision 13
- QAM Section Q-30-2, "Standard for Control of Request for Design Change, Specification Change and Material Utilization," Revision 2

In addition, the team evaluated the design controls that were in place for the transmittal and handling of design drawings received from TN and how HZA transitioned from design to fabrication, as applicable. This evaluation included the process for distributing controlled drawings and verifying their location and how HZA retrieved documents to maintain the controlled versions of documentation.

1.1.2 Observation and Findings

The team did not identify any discrepancies between the design and fabrication specifications and the SAR licensing drawings from the selected records. The team noted that HZA captured all requirements that were applicable to fabrication and noted that HZA fabrication drawings contained the relevant information needed for fabrication with adequate document control and storage of Quality Assurance (QA) records. Additionally, the team did not identify any issues of concerns in the translation of design information. The team noted fabrication drawings, shop travelers, and procedures were adequately identified at various work locations with each component as necessary and that documents reflected the correct revisions, as applicable.

No findings were identified.

1.1.3 Conclusions

The team determined for the items selected for review that the design and fabrication specifications were consistent with the design commitments and requirements documented in the FSAR, CoC, and TS.

1.2 **Corrective Action and Non-Conformance Reports**

1.2.1 Inspection Scope

The team assessed whether HZA and TN had adequate corrective action and nonconformance programs for identified fabrication deficiencies related to ITS quality issues and whether HZA and TN implemented corrective actions in a time frame commensurate with their significant and initiated and resolved nonconformance reports.

The team reviewed selected records and interviewed personnel to verify that HZA effectively implemented a corrective action program (CAP) in accordance with the requirements of 10 CFR Part 72. This review included the following HZA quality manual section and related quality implementing procedures:

- Quality Manual Section M-32-1, "Corrective Action," Revision 11,
- Quality Procedure Q-32-1, "Corrective Action Standard," Revision 2, and
- Quality Procedure Q-32-2, "Implementation of Root Cause Analysis Standard," Revision 0.

The team reviewed a selection of corrective actions reports (CARs) that HZA initiated since the last NRC inspection in 2019 and focused the review on CARs that HZA designated as significant condition adverse to quality, when possible. The team also reviewed a sample of TN CARs related to the fabrication activities at HZA.

Furthermore, the team reviewed selected records and interviewed personnel to verify that HZA effectively implemented a nonconformance control program in accordance with the requirements of 10 CFR Part 72 and approved QA procedures. Specifically, the team reviewed quality manual section M-31-1, "Nonconformance Control," Revision 9. The team reviewed a selection of nonconformance reports (NCRs) initiated since the last NRC inspection in 2019 to verify that the NCRs were identifiable, traceable, and the disposition of the nonconformance was adequate. The team focused on issues involving ITS components and NCRs with a disposition of use-as-is or repair, which generally required an engineering evaluation and subsequent 10 CFR 72.48 review. The team reviewed these NCRs to evaluate if the disposition was appropriate, adequately performed as necessary, and properly closed out in accordance with M-31-1. The team also reviewed a selection of TN supplier nonconformance reports (SNCRs) written because of issues identified by HZA or TN during fabrication. This included a review TN SNCRs written for those NCRs dispositioned as use-as-is or repair by HZA.

1.2.2 Observation and Findings

The team assessed that HZA generally resolved the issues identified in the CARs and reviewed and completed corrective actions within a time frame commensurate with its significance. The team also assessed that HZA had adequate procedures and controls

in place for identifying and writing CARs, documenting corrective action(s) taken, documenting actions taken to prevent recurrence, performing root cause analysis, performing CAR closure verification, and tracking CARs to closure.

During the inspection the team selected HZA CAR C-21-C-06 for review, the team noted that some aluminum plates supplied to HZA from Nippon Light Metal Nagoya Works (NLM) did not meet all the required American Society for Testing and Materials (ASTM) testing standard requirements. HZA communicated this issue to TN and TN performed an impact review to determine the projects this issue had the potential to affect. TN determined that none of the supplied aluminum was being used in current projects at HZA and that this issue only impacted previous completed projects and documented the issue in a TN CAR 2021-156.

The team reviewed the TN CAR to assess the adequacy of TN's corrective actions. The team noted that TN performed an adequate technical review when NLM failed to perform all required ASTM tests in accordance with ASTM B-209, a tensile strength test for all affected projects. The team identified that the ASTM B-209 material specification requirement was a licensing drawing requirement and specified in the TN FSAR for the affected ITS components. However, the team noted that there was no licensing review performed by TN for this deviation in the ASTM standard testing requirements contained in the FSAR and procurement specifications. The team held discussions with TN personnel and reviewed the following TN implementation procedures (TIPs) to assess the failure to perform a licensing review for this deviation:

- TIP 16.1, "Corrective Action," Revision 33
- TIP 15.2, "Control of Nonconforming Items," Revision 21
- TIP 15.3, "Review of Supplier Nonconformances," Revision 22
- TIP 3.5, "Licensing Reviews," Revision 31

The team noted in TIP 15.2 that the procedure requires a licensing review as part of the nonconforming item evaluation process, but the purpose and scope of the procedure limited the licensing review to those items that are under the control of the TN Quality Assurance Program Description Manual (QAPDM). Since the affected DCSS were already in use at customer facilities, which implemented their own NRC approved quality assurance programs for dry cask storage systems, this procedure did not clearly apply for this issue although it was a nonconformance to the TN FSAR, licensing drawing, and procurement specification. Additionally, TN implemented TIP 16.1 to open CAR 2021-156 to address the corrective actions related to this issue. However, the team noted that the procedure (TIP 16.1) does not contain information on performing licensing reviews or a specific step to perform one, when necessary.

The team determined this was a violation of NRC requirements. Specifically, 10 CFR 72.150, "Instructions, procedures, and drawings" requires, in part, that the certificate holder (TN) for a CoC shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances.

Contrary to the above, as of November 28, 2022, TN's quality procedures did not provide sufficient guidance to perform a licensing review for all applicable situations. Specifically, material nonconformances that are not controlled under the TN QAPDM and do not receive a supplier nonconformance are not required to have an associated

licensing review conducted under the TN quality program. A licensing review would determine if TN needed additional licensing actions such as NRC approval or an exemption to the regulations to accept the nonconformance to an approved NRC license.

The team assessed the significance of the violation using the NRC Enforcement Policy and Enforcement Manual. The team dispositioned the violation using the traditional enforcement process in Section 2.3 of the Enforcement Policy. The team determined that the violation impacted the ability of the NRC to perform its regulatory oversight function because the TN did not evaluate whether NRC approval was required for the identified nonconforming condition to the license. The team determined that the violation was of more-than-minor safety significance because it was indeterminate if the change would require NRC approval. The team characterized the violation as a Severity Level IV violation in accordance with the NRC's Enforcement Policy, Section 6.5. TN entered the issue into its CAP under TN CAR 2022-202. The team assessed that because this violation was of low safety significance and was entered into TN's CAP, the issue was not repetitive or willful, it is being treated as an NCV, consistent with Section 2.3.2.a of the Enforcement Policy. **(72-1004/2022-203-01)**

1.2.3 Conclusions

The team concluded that HZA effectively implemented its nonconformance and corrective action control programs and has adequate procedures in place to ensure compliance with the applicable regulations and quality assurance requirements.

Overall, the team determined that HZA had an adequate CAP in place to resolve identified issues, and, in general, completed corrective actions for identified deficiencies in a technically sound and timely manner. However, the team identified one violation of NRC requirements concerning the failure by TN to have adequate procedures to ensure that personnel perform a licensing review for all applicable situations.

1.3 **Personnel Training and Certifications**

1.3.1 Inspection Scope

The team assessed and determined whether individuals performing quality-related activities were trained and certified where required. The team reviewed the records of two selected quality inspectors and two welders that performed nondestructive examinations (NDE) and welding and reviewed selected records, interviewed personnel. The following quality procedures were reviewed:

- QAM Section M-50-1, "Examination, Inspection and Test," Revision 6
- Q-01-2, "Qualification Standard for Inspector and Test Personnel," Revision 4
- Q-01,4, "NDE Personnel Qualification and Certification Standard," Revision 8

1.3.2 Observation and Findings

The team noted welder performance qualifications and welder continuity conformed to Section IX of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code. For the welding qualification records reviewed, the team noted

that HZA qualified the welders in accordance with procedures in each applicable process, and that HZA maintained welding continuity for each of the welding processes qualified as of the inspection. The team also noted that personnel performing NDE at HZA had qualifications in accordance with the American Society for Nondestructive Testing Recommended Practice No. SNT–TC-1A. This standard includes the required training, experience, medical testing, and education for NDE personnel at HZA.

No findings were identified.

1.3.3 Conclusions

The team determined that HZA had trained and certified individuals performing quality-related activities for fabrication of ITS DCSS components.

1.4 **Human Performance**

1.4.1 Inspection Scope

The team assessed and determined whether HZA personnel were familiar with the specified design, designated fabrication techniques, testing requirements, and quality controls associated with the construction of the DCSS.

The team assessed HZA's control of the fabrication process through observations, examinations of records, and personnel interviews in the areas of fabrication and assembly, test and inspection, and familiarity with measuring tools and equipment.

The team observed/witnessed the lead shielding installation on an EOS TC-125 transfer cask and examined shop travelers of a final documentation package for completed fabrication of one of the TN-40HT fuel baskets. The final documentation package review included but was not limited to TN conformance reports and completed shop travelers that contained completed NDE results, functional tests, and dimensional inspection reports, as well as NCRs.

1.4.2 Observation and Findings

The team noted that HZA personnel performed fabrication activities were adequate and that HZA staff were knowledgeable about the specified design, designated fabrication techniques, testing requirements, and QC associated with the construction of the DCSSs and TSCs. During the observations and reviews of fabrication and NDE activities the team determined that the work was well controlled, individuals were knowledgeable of the applicable fabrication process, and the work was being performed in accordance with the applicable fabrication procedures, shop travelers and weld procedure specifications.

No findings were identified.

1.4.3 Conclusions

The team determined that HZA personnel were familiar with the specified design, designated fabrication techniques, testing requirements, and QC associated with the construction of the DCSS components.

1.5 **Procurement**

1.5.1 Inspection Scope

The team assessed and determined whether HZA received materials, components, and other equipment that met the DCSS design procurement specifications and that the procurement specifications conform to the design commitments and requirements contained in the SAR, CoC, and TS.

The team reviewed HZA's processes that address procurement, including traceability and receipt inspection. The team reviewed selected drawings and records and interviewed selected personnel to verify that the procurement specifications for materials, fabrication, inspection, and services performed at HZA met design requirements. The team verified that TN used a graded approach for identifying ITS components during the design process and applied this graded quality to components and material procurement documents for HZA. The team selected ITS components such as the fuel compartment tubes, and the lead shielding for review. The team reviewed the following implementing procedures and procurement documents:

- QAM Section M-10-1, "Order Control," Revision 8
- QAM Section M-20-1, "Purchase Control," Revision 17
- QAM Section M-20-2, "Control of Purchased Items," Revision 6
- QAM Section M-25-1, "Material Identification and Verification," Revision 4
- Q-20-1, "Procurement Specification Standard," Revision 8
- Q-20-3, "Purchase Order Control Standard," Revision 8
- Q-20-4, "Standard for Procurement Quality Assurance Control," Revision 9
- Q-30-1, "Standard for Dedication of Commercial Grade Items," Revision 9
- F-40-2, "Marking Standard," Revision 4
- F-50-1, "Inventory Control Standard," Revision 0

The team also reviewed purchase orders and receipt inspection reports.

1.5.2 Observation and Findings

The team observed that HZA had adequate control of the procurement processes for the ITS components reviewed. Overall, HZA procured ITS components consistent with design requirements and their implementing procedures. Further, HZA's material traceability, procurement, and receipt inspection controls were adequate. The team determined that the purchase orders were adequate and specified the applicable criteria and requirements including Part 21. The material ordered and received by HZA met the design requirements, the critical characteristics if commercially dedicated and were adequate based of the receipt inspection verification. Additionally, HZA verified and maintained the traceability throughout the procurement and receipt process. The

team determined that HZA purchased the components from vendors on the HZA approved vendors list.

No findings were identified.

1.5.3 Conclusions

The team determined that materials, components, and other equipment received by HZA met the DCSS design procurement specifications, and the procurement specifications conform to the design commitments and requirements contained in the FSAR, CoC and TS.

1.6 **Implementing Procedures**

1.6.1 Inspection Scope

The team assessed whether HZA fabricated DCSS components in accordance with their QAP, fabrication specifications, and specific requirements of 10 CFR Part 21. The team evaluated HZA's control of the fabrication process through observations, examinations of records, and personnel interviews in the areas of fabrication and assembly, test and inspection, handling, and storage as well as tools and equipment.

The team reviewed the following sections of the HZA QAM and Standards for the fabrication processes, special processes (welding), and assembly processes used in transfer cask and the fuel basket fabrication:

- QAM Section M-30-1, "Process Control," Revision 6
- QAM Section M-41-1, "Welding Control," Revision 8
- F-30-1, "Fabrication Sequence Diagram Standard," Revision 3
- F-30-2, "Check Sheet Standard," Revision 4
- W-01-1, "Weld Record Form Usage Control Standard," Revision 2

The team specifically reviewed the EOS transfer cask and TN-40HT assembly fabrication sequence diagrams (FSD) to determine how HZA controlled the fabrication process. The team reviewed various weld procedure specifications and associated procedure qualification records for the fuel basket.

Secondly, the team reviewed the requirements for the handling and storage of quality equipment and materials used for TN fabrication projects, including the EOS transfer cask and the TN-40HT fuel baskets. The team reviewed the following documents:

- M-70-1, "Handling, Storage, Shipping and Preservation," Revision 6
- F-40-1, "Handling and Storage Standard," Revision 6
- F-10-1, "Welding Materials Control Standard," Revision 3
- 463-F-HD, "Handling and Storage Procedure," Revision 1

The team also toured an offsite storage warehouse that contained completed dry shielded canisters (DSCs) to determine if the storage controls were adequate and per the quality procedure requirements.

Finally, the team reviewed selected measuring and test equipment (M&TE) used in the shop, records, quality manual section M-60-1, Measuring and Test Equipment Control," Revision 8, and quality procedure Q-10-1, "Calibration Standard for Measuring and Test Equipment," Revision 13 to verify that equipment used in activities affecting quality were properly controlled and calibrated.

The team compared a sampling of measuring and test equipment in current use for fabrication activities to determine overall compliance to procedural requirements. The team reviewed calibration records, interviewed calibration personnel, and toured areas in the shop for storage and calibration of M&TE to verify compliance to the quality manual and procedure requirements.

1.6.2 Observation and Findings

The team observed that HZA fabricated DCSS components in accordance their quality procedures. The team observed for the items selected that the procedures contained the appropriate quantitative and/or qualitative acceptance criteria for determining that ITS activities have been satisfactorily accomplished. The team observed that staff performing ITS activities were adequately following procedures based on the limited fabrication activities assessed during the inspection. The team verified during a visit to an offsite storage facility that HZA stored components indoors with secured tarps and coverings and partitioned the storage area with ropes that contained an authorized access list of personnel.

The team verified that HZA stored weld wire used for quality applications on the TN projects as required by procedure and HZA personnel stored stainless steel and carbon steel tools separately with the appropriate markings.

The team assessed that HZA established controls on M&TE in accordance with their quality requirements, industry standards and regulatory requirements. The team assessed that HZA personnel provided the appropriate information on shop travelers in accordance with approved procedures. The team verified that personnel used M&TE within their rated capacities and sensitivities as documented in calibration records.

In addition, the team verified that HZA stored as required by procedure the weld wire used in quality applications for the TN projects, that HZA stored stainless steel and carbon steel tools separately and marked and used them as appropriate for the current work in the shop, and HZA covered all DSC fuel baskets and shells with all materials and components off the ground and covered, as required.

No findings were identified.

1.6.3 Conclusions

The team determined that HZA fabricated and inspected DCSS components in accordance with their QAP, 10 CFR Part 21 implementing procedures and fabrication specifications. In addition, the team concluded that HZA effectively implemented its M&TE control program and has adequate procedures in place to ensure compliance with the applicable regulations, industry standards and quality requirements.

1.7 10 CFR Part 21

1.7.1 Inspection Scope

The team reviewed the 10 CFR Part 21 quality procedure, Q-20-2, "Reporting Standard of Defects and Noncompliance," Revision 6, to verify if provisions were in place for reporting defects that could cause a substantial safety hazard and completed the required notification in a timely manner. The inspectors requested a list of 10 CFR Part 21 evaluations and notifications associated with the fabrication activities and interviewed personnel to verify if they were familiar with the implementing procedure. The team also verified if HZA complied with 10 CFR 21.6, "Posting requirements."

1.7.2 Observation and Findings

The team assessed that HZA and TN has provisions in place for evaluating deviations and reporting defects that could cause a substantial safety hazard and for design or fabrication deficiencies that could affect the DCSSs ITS structures, systems, and components to perform their intended safety function, as required by 10 CFR Part 21 and 72.242(d), respectively. The team noted that the 10 CFR Part 21 posting at the HZA facility met the approved implementing procedure and the applicable requirements of 10 CFR Part 21.

No findings were identified.

1.7.3 Conclusions

The team determined that HAZ conducted fabrication activities under an approved supplier QAP and included the provisions of 10 CFR Part 21 within purchase order contracts and quality implementing procedures. The team also determined that HAZ personnel were familiar with the reporting requirements of 10 CFR Part 21 and HZA complied with 10 CFR 21.6, "Posting requirements."

1.8 Oversight and Audits

1.8.1 Inspection Scope

The team assessed and determined the following: (1) whether TN audited HZA; (2) if inspection findings from these QAP audits or surveillances were appropriately handled with corrective actions implemented in a time frame commensurate with their safety significance, and (3) if HZA management and HZA QC/QA personnel performed appropriate oversight during fabrication activities.

The team reviewed the TN and HZ audit programs to determine if both entities scheduled, planned, and performed audits in accordance with their QAP. The team focused on the audits or surveillances TN performed of the fabricator (HZA). The team selected a sample of audits and surveillances from the time of the last NRC inspection to the present. The team reviewed the audit results to determine if TN identified deficiencies and HZA addressed these deficiencies within their CAP. The team also evaluated whether TN and HZA provided adequate supervision with QC/QA personnel for appropriate oversight during fabrication activities.

The team also reviewed the external audits of HZA suppliers of ITS materials, equipment, and services. The team selected a sample of internal and external audits from the time of the last NRC inspection to the present. This included a sample of lead auditor and auditor certifications and qualifications. The team focused on activities related to HZA fabrication of the EOS transfer cask and TN-40HT fuel basket.

The team also reviewed the last two management reviews of the HZA QAP to determine whether that HZA performed the reviews per procedure and assess if it was an effective tool to use for the overall health of the HZA QAP. The team reviewed the following QAM sections and quality procedure:

- QAM Section M-04-01, "Control of QA Manual," Revision 4
- QAM Section M-90-1, "Audits," Revision 7
- Q-01-3, "Audit Personnel Qualification Standard," Revision 8

1.8.2 Observation and Findings

Overall, the team assessed that for the audits and surveillances sampled, as applicable that TN and HZA generally conducted oversight with qualified and certified personnel, scheduled and evaluated the applicable quality elements of HZA's QA program associated with fabrication activities. The team assessed that, in most cases, HZA and TN appropriately identified issues and implemented corrective actions in a time frame commensurate with their safety significance.

No findings were identified.

1.8.3 Conclusions

The team determined, for most of the items selected for review that TN and HZA are performing oversight and audits in accordance with their QAP.

2.0 **Entrance and Exit Meeting**

On September 20, 2022, the NRC inspection team discussed the scope of the inspection during an entrance meeting with Kevin O'Connor and other members of the TN and HZA staff. On September 22, 2022, the NRC inspection team discussed the preliminary results and observations during an onsite debrief meeting with Kevin O'Connor and other members of the TN and HZA staff. The team continued the inspection activities with an in-office review and held another debrief on October 20, 2022, after TN provided additional information. The team conducted a final exit meeting on November 28, 2022. Section 1 of the attachment to this report shows the attendance for the entrance and exit meetings.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES AND INDIVIDUALS INTERVIEWED

<u>Name</u>	<u>Title</u>	<u>Affiliation</u>	<u>Entrance</u>	<u>Debrief</u>	<u>Debrief</u>	<u>Exit</u>
Marlone Davis	Inspection Team Leader	NRC/DFM	X	X	X	X
Jeremy Tapp	Safety Inspector	NRC/DFM	X	X		X
Matthew Learn	Safety Inspector	NRC/DFM	X	X		
Jean-Luc Palayer	Chief Operating Officer	Orano TN			X	
Brian O'Campos	Director Quality Assurance	Orano TN			X	X
Kevin O'Connor	QA Specialist	Orano TN	X	X	X	
Gerardo Deniega	QA Specialist	Orano TN	X			X
Marlin Stoltz	Manager	Orano TN			X	X
Prakash Narayana	Director	Orano TN			X	X
Doug Yates	Licensing	Orano TN			X	X
Glenn Mathues	Licensing	Orano TN			X	X
Don Shaw	Director	Orano TN				X
Akinori Murakami	QA Manager	HZA	X	X		X
Atsushi Higashiiwa	Manager of QA Department	HZA		X		
Hitoshi Tobita	General Manager Design Department	HZA	X			
Hitoshi Ihara	General Manager Project Execution Department	HZA	X			X
Yoshihiro Hashimoto	Manager Nuclear Equipment QA	HZA	X			X
Naoki Yamashita	Manager Project Engineering Section No. 2	HZA	X			X
Hiroshige Kikumoto	Quality Assurance Section	HZA	X			X

2. INSPECTION PROCEDURES USED

IP 60852	ISFSI Component Fabrication by Outside Fabricators
NUREG/CR-6407	Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety
NUREG/CR-6314	Quality Assurance Inspections for Shipping and Storage Containers

LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
72-1004-2022-203-01	Closed	NCV	Inadequate supplier audit

3. LIST OF ACRONYMS USED

ASME	American Society of Mechanical Engineers
CAP	Corrective Action Program
CAR	Corrective Action Report
CFR	Code of Federal Regulations
CoC	Certificate of Compliance
DCSS	Dry Cask Storage System
DFM	Division of Fuel Management
DSC	Dry Shielded Canister
FSAR	Final Safety Analysis Report
HZA	Hitachi Zosen Corporation Ariake Works
IP	Inspection Procedure
ISFSI	Independent Spent Fuel Storage Installation
ITS	Important to Safety
M&TE	Measuring and Test Equipment
NCR	Nonconformance Report
NCV	Non-Cited Violation
NDE	Nondestructive Examination
NRC	Nuclear Regulatory Commission
QA	Quality Assurance
QAM	Quality Assurance Manual
QAP	Quality Assurance Program
QC	Quality Control
TIP	TN Implementation Procedure
TS	Technical Specifications

4. DOCUMENTS REVIEWED

Certificate holder and fabricator documents reviewed during the inspection were specifically identified in the Report Details above.