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

December 22, 2021

EA-2021-165

Mr. Franz Hilbert
Chief Operating Officer
Orano Nuclear Cargo Services, Inc.
Margarete-von-Wrangell-Strabe
Hanau Germany 63457

SUBJECT: ORANO - NUCLEAR CARGO SERVICES, INC. (FORMERLY DAHER NUCLEAR TECHNOLOGIES) - NRC INSPECTION REPORT NO. 71-0951/2021-201 AND NOTICE OF VIOLATION

Dear Mr. Hilbert:

On September 20, 2021 to September 24, 2021, the U.S. Nuclear Regulatory Commission (NRC) conducted announced onsite inspections at Eisenwerk Bassum GmbH in Peenemunde, Germany and at your Orano Nuclear Cargo Services (NCS) GmbH corporate office (formerly Daher Nuclear Technologies) in Hanau, Germany. The inspection team continued the inspection activities with an in-office review and held an exit meeting on September 30, 2021. The purpose of the inspection was to verify and assess the adequacy of NCS's activities associated with the design and fabrication of radioactive material packagings to determine if NCS performed these activities in accordance with the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71, "Packaging and Transportation of Radioactive Material," and your NRC approved radioactive material package Certificate of Compliance (CoC) No. 9362,and Quality Assurance (QA) program No. 71-00951. The inspection scope focused on your management, design, and fabrication controls for the transportation packaging model number DN30 protective structural packagings.

The NRC inspection team examined activities conducted under your QA program to determine whether NCS controlled fabrication activities associated with the Commission's rules and regulations and with the conditions of the applicable CoC. The team also reviewed and discussed the quality assurance program description and implementing procedures with you and your staff since this was the NRC's first opportunity to assess the lower level implementing procedures governing the conduct of QA activities that are important to safety. The team reviewed selected procedures, records and interviewed specific personnel. Additionally, the team discussed the preliminary results of this inspection with other members of your staff on September 24, 2021 and conducted a final exit with you on September 30, 2021. The enclosed report presents the results of this inspection.

Based on the results of this inspection, the NRC staff determined that two Severity Level IV violations of NRC requirements occurred with one violation having multiple examples. The team evaluated the violations in accordance with the NRC Enforcement Policy and Manual. The NRC's public website includes the current versions of both the Enforcement Policy and Manual

for your reference. The NRC cited these violations in the enclosed Notice of Violation (Notice) and describes the circumstances surrounding these violations in the enclosed inspection report. The violations are being cited in the Notice because the issues were NRC identified with no credit given to your corrective action program (CAP) during this inspection. Specifically, the NRC will credit a formal CAP that has been inspected and found to meet regulatory guidance, industry standards, or both. The NRC has never inspected your CAP and identified several issues associated with your overall QA program related to NRC requirements, which included the CAP. The NRC staff has concerns about the violations identified in your QA Program implementation and has plans to increase the inspection frequency in accordance with our Inspection Manual Chapter 2690, "Inspection Program for Storage of Spent Reactor Fuel and Reactor-Related Greater than Class C Waste at Independent Spent Fuel Storage Installations and for 10 CFR Part 71 Transportation Packagings".

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/NRC/ADAMS/index.html. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the Public without redaction.

Sincerely,

Hipolito J. Gonzalez

Digitally signed by Hipolito J. Gonzalez
Date: 2021.12.22 09:18:50 -05'00'

Hipolito Gonzalez, Chief
Inspection and Oversight Branch
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

Docket No. 71-0951

Enclosures: 1. Inspection Report No. 71-0951/2021-201
2. Notice of Violation

SUBJECT: ORANO NUCLEAR CARGO SERVICES, INC. (FORMERLY DAHER NUCLEAR TECHNOLOGIES) - NRC INSPECTION REPORT NO. 71-0951/2021-201 AND NOTICE OF VIOLATION

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

Inspection Report

Docket No.:	71-0951
Report No.:	71-0951/2021-201
Certificate Holder:	Orano Nuclear Cargo Services (formerly Daher Nuclear Technologies) Margarete-von-Wrangell-Strabe Hanau Germany 63457
Inspection Dates:	September 20 - 30, 2021
Inspectors:	Marlone Davis, Senior Transportation and Storage Safety Inspector, Team Leader Earl Love, Senior Transportation and Storage Safety Inspector
Approved by:	Hipolito Gonzalez, Chief Inspection and Oversight Branch Division of Fuel Management Office of Nuclear Material Safety and Safeguards

EXECUTIVE SUMMARY

Orano Nuclear Cargo Services
NRC Inspection Report 71-0951/2021-201

On September 20, 2021 to September 24, 2021, a U.S. Nuclear Regulatory Commission (NRC) team of inspectors (team) performed announced onsite inspections at Eisenwerk Bassum GmbH (EWB) in Peenemunde, Germany, and at the Orano Nuclear Cargo Services (NCS) GmbH corporate office (formerly Daher Nuclear Technologies) in Hanau, Germany. The team continued the inspection activities with an in-office review and held an exit meeting on September 30, 2021. The purpose of the inspection was to verify and assess NCS's newly established quality assurance (QA) program and implementing procedures for compliance to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71, "Packaging and Transportation of Radioactive Material," and 10 CFR Part 21, "Reporting of Defects and Noncompliance," and observe some of the initial fabrication, assembly, and testing activities associated with the new NRC approved Certificate of Compliance (CoC) number 9362. The inspection scope included the review and evaluation of NCS's management, design, and fabrication controls for the transportation packaging model number DN30. NCS contracted with EWB to fabricate the DN30.

Based on the results of this inspection, the team determined that two Severity Level IV violations of NRC requirements occurred with one violation having multiple examples. The team evaluated the violations in accordance with the NRC Enforcement Policy and Manual. This inspection report describes the circumstances surrounding the violations and examples. The team cited these violations because the team identified these issues with no credit given to the corrective action program (CAP) during the inspection. Specifically, the NRC will credit a formal CAP that has been inspected and found to meet regulatory guidance, industry standards, or both. The NRC had never inspected NCS's CAP and identified several issues associated with the overall QA program implementation of 10 CFR Parts 71 and 21 requirements. The team assessed that the underlining cause for the Notice of Violations (NOVs) was the lack of understanding of all the 10 CFR Part 71, Subpart H requirements (i.e., 10 CFR 71.101 through 71.137) in comparison to NCS's Quality Management Systems and Processes related to the International Organization for Standardization (ISO) 9001 requirements.

The team noted that there was no supplemental or gap analysis conducted to fully address all applicable 10 CFR Part 71, Subpart H requirements. The team provided NCS with information related to the NRC Regulatory Guide (RG) 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," to assist in developing applicable implementing procedures for their quality assurance program (QAP). During the debriefs and final exit meeting, the team discussed the violations and examples in detail with NCS and EWB. The team grouped the violations and provided violation examples so that NCS would address the individual issues within their CAP. Additionally, the team identified examples where NCS changed some commitments identified in the original NRC approval without sending the revised QA program into the NRC for review and approval. The team assessed that NCS has not adequately implemented its QA program.

Management Controls

Overall, the team assessed that NCS had several weaknesses regarding the implementation of their NRC approved QA program. The team assessed that NCS did not effectively implemented its nonconformance control, corrective action, and audit programs and the implementing QAP procedures lack appropriate guidance to ensure compliance with the applicable regulations in Subpart H to 10 CFR Part 71.

The team also assessed that NCS did not have adequate provisions in place for reporting defects that could cause a substantial safety hazard that could affect the transportation package and its intended safety functions, as required by 10 CFR Part 21.

Design Controls

The team assessed that NCS had an adequate design control program to develop quality project plans, specifications, calculations, safety analysis report revisions, and drawings by performing the proper quality reviews and approvals with qualified engineering staff. However, as described in Section 1.1 of this report, the team identified that NCS would need to develop procedures or implement processes that provide guidance for a graded approach to quality including commercial grade dedication guidelines as applicable.

Fabrication Controls

The team assessed that NCS provided oversight of fabrication activities performed by EWB. The team assessed that EWB had some weakness in their fabrication controls of manufacturing the DN30 packaging. However, the team determined that NCS in some instances did not impose requirements on EWB to establish measures to maintain an adequate test control and measuring and test equipment program.

REPORT DETAILS

1. Management Controls

1.1 Quality Assurance Policy

a. Inspection Scope

The team reviewed NCS Quality Assurance Program Description (QAPD) and various implementing documents to evaluate the effectiveness of their QA program implementation. This included reviews of NCS's Integrated Management System (IMS) and process procedures to determine whether NCS adequately controlled and implemented activities under their NRC approved QA program, which are subject to 10 CFR Parts 71 and 21 regulations. The team reviewed the IMS sections and process procedures to verify if NCS clearly defined and documented the quality program authorities and responsibilities and that the quality assurance organization functioned as an independent group. The team reviewed NCS procedures for the use of a graded approached for identifying important to safety (ITS) components and whether NCS applied this graded quality level to procurement documents. The team reviewed process procedures and documents regarding training, qualification, and certification of personnel involved in quality activities. Additionally, the team reviewed training records of a sample selection of employees in quality related positions to determine if they received the required QA indoctrination and QA program revision training. The team reviewed these specific documents:

- QAPD 0023-QAP-2017-001, "10 CFR 71 Subpart H," Revision 1
- IMS Manual Applicable Sections, dated August 24, 2020

b. Observations and Findings

The team assessed that the NCS QA program did not meet all the requirements delineated in 10 CFR Part 71, Subpart H. The team noted that NCS's QAPD used the quality management system associated with ISO 9001 and supplemental documents to demonstrate compliance with the 10 CFR Part 71 regulations. The team noted that the QAPD provided a table (i.e., Table 1) of QA implementing procedures and applicable quality manual sections to demonstrate implementation of the QA program. The team used the table to verify and evaluate QA program implementation. The team noted that NCS had revised the table after the original NRC approval and some of the documents did not correspond to what NCS had committed to as a part of the NRC approval. The team identified several issues with the implementing documentation identified in the table and noted that regulatory position 6 was missing from this version of the QAPD table. Regulatory position 6 corresponded to the Part 71 requirement 10 CFR 71.113, "Document control". The team captured several examples during the fabrication and corporate QA implementation inspections. The examples are in each applicable section of this inspection report. During the debrief and final exit meetings the team discussed each example of NRC requirements associated with 10 CFR Part 71 that NCS failed to meet.

The team assessed that the underlining cause for the violations was the lack of understanding of all the Subpart H requirements compared to the Quality Management

System and Processes related to ISO 9001 requirements. The team found that there was no supplemental or gap analysis conducted to fully address all applicable Subpart H regulations. Subsequently, the team wanted to group the violations as much as possible and use the individual violations as examples so that NCS would address the individual issues within their CAP. Therefore, the team determined that NCS failed to meet 10 CFR 71.105 requirements with several examples.

10 CFR 71.105, "Quality assurance program" requires, in part, that the certificate holder shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of 10 CFR 71.101 through 71.137. The certificate holder shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used.

Contrary to the above, as of September 2021, the certificate holder (NCS) failed to establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with all the requirements of 10 CFR 71.101 through 71.137. NCS also failed to document some of the quality assurance (QA) program requirements in written procedures or instructions. Specifically, NCS failed to apply all the applicable eighteen criteria (i.e., 10 CFR 71.101 through 71.137) discussed in its program description submittal into their lower level implementing procedures governing the conduct of QA activities and failed to carry out the program in accordance with those procedures in some instances.

The team noted that NCS procedures did not use a graded approached for identifying ITS components and did not apply the graded quality level to procurement documents. The team noted that NCS was not aware that they needed to perform a graded approach for the safety categorization of materials and components. The team noted to NCS that Appendix A to Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packing used in transport of Radioactive Materials" describes an acceptable method using NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety," dated February 1996 to apply a graded approach to the DN30 packaging. The team identified that these were two more examples of violations of NRC requirements associated with the overall QAP.

10 CFR 71.105(b), "Quality assurance program," requires, in part, that the certificate holder through its quality assurance program, shall provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material.

10 CFR 71.107(a), "Package design control," requires, in part, that measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of materials, parts, and components of the packaging that are ITS.

Contrary to the above, as of September 2021, NCS did not determine the classification of components used in the DN30 packaging in accordance with a graded approach to an extent commensurate with their importance to safety.

The team noted that NCS defined and documented the quality program authorities and responsibilities and that the quality assurance organization functioned as an independent group as described in IMS Section 5, "Management". However, as discussed above, NCS changed the commitments identified in the original NRC approval and the team identified that NCS omitted the organizational chart from the table for the program authorities and responsibilities. The team also noted that the IMS did not have guidance on changes that may reduce the commitments in the QAPD previously approved by the NRC. The team assessed that this was another example of a violation of NRC requirements associated with the overall QAP.

10 CFR 71.106(b), "Changes to quality assurance program," requires, in part, that each quality assurance program approval holder may change a previously approved quality assurance program without prior NRC approval, if the change does not reduce the commitments in the quality assurance program previously approved by the NRC. Changes to the quality assurance program that do not reduce the commitments shall be submitted to the NRC every 24 months, in accordance with 10 CFR 71.1(a).

Contrary to the above, as of September 2021, NCS did not submit the quality assurance program to the NRC for changes to the QAP that reduced the commitments identified in the original NRC approval for document control and organizational charts that were not administrative in nature.

c. Conclusions

The team determined that NCS had some implementing procedures in place but did not meet the implementation of 10 CFR Part 71 regulations in all cases. The team determined that NCS developed the current procedures to satisfy ISO 9001. The team noted that there was no supplemental or gap analysis conducted to fully address all applicable 10 CFR Part 71, Subpart H requirements. The team provided NCS with information related to the NRC Regulatory Guide (RG) 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," to assist in developing applicable implementing procedures for their quality assurance program (QAP).

The team also determined that for the sample of NCS personnel training records reviewed that each staff member completed the required training.

1.2 Nonconformance Controls

a. Scope

The team reviewed selected records and interviewed personnel to verify that NCS effectively implemented a nonconformance control program in accordance with their NRC approved QA program and the requirements of 10 CFR Parts 71 and 21. Specifically, the team reviewed NCS's approved procedure, AA-0104/00-AK, "Creation and Testing of Deviation Reports and Change Certification," dated September 9, 2014.

The team asked for applicable nonconformance or deviation reports from the fabrication of the DN30 to verify if NCS or EWB had created nonconformance or deviation reports that were identifiable, traceable, and dispositioned in accordance with approved procedures. Specifically, the team asked for deviation reports since the start of fabrication activities for issues involving ITS components. The team wanted to review these reports and certification changes to evaluate if NCS or EWB dispositioned and properly closed out nonconformance or deviation reports. The team wanted to focus the review on accept-as-is and repair dispositions because generally these require a technical justification or engineering evaluation.

Additionally, the team reviewed NCS's approved procedure to determine if provisions were in place for reporting defects that could cause a substantial safety hazard from the nonconformance or deviation reports identified. This review also included an assessment for deficiencies identified for 10 CFR 71.95 Reports, as applicable. The team also reviewed if NCS or EWB posted the Part 21 postings in the NCS corporate office or at the fabrication facility, respectively.

b. Observations and Findings

The team observed that there were no nonconformance or deviation reports documented or written during the fabrication activities related to the DN30. The team interviewed personnel and noted that there were several nonconformances and EWB repaired the nonconformances or deviations following identification. However, the team noted that EWB did not disposition or provide documentation of the identified nonconformances or deviation reports. The team also noted that the IMS section stated that all non-conformities are systematically detected and presented to the responsible area manager for evaluation. However, the approved procedure did not capture how NCS personnel should review, disposition, and segregate nonconforming items. This also included how NCS would notify the affected organization and document the results of the review. The team assessed that this was another example of violation of NRC requirements associated with the overall QAP.

10 CFR 71.131, "Nonconforming materials parts, or components," requires, in part, that the certificate holder shall establish measures to control materials, parts, or components that do not conform to requirements to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

Contrary to the above, as September 2021, NCS failed to establish measures to control materials, parts, or components for identification, documentation, segregation, disposition, and notification to affected organizations for nonconforming or deviation reports. Furthermore, NCS failed to review and accept nonconforming items in accordance with documented procedures. The team noted that IMS Section 10 and AA-0104/00-AK did not capture guidance on how NCS personnel should review, disposition, and segregate nonconforming items.

In addition, the team discovered that NCS did not have a procedure or provisions in place to address the applicable regulations in 10 CFR Part 21 including the posting requirements at the corporate office.

10 CFR 21.6(a)(1), "Posting requirements," requires, in part that each individual, partnership, corporation, dedicating entity, or other entity subject to the regulations in this part shall post current copies of --

(i) The regulations in this part;
(ii) Section 206 of the Energy Reorganization Act of 1974; and
(iii) Procedures adopted pursuant to the regulations in this part.

10 CFR 21.21, "Notification of failure to comply or existence of a defect and its evaluation," requires, in part, that each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures.

Contrary to the above, NCS failed to post current copies of the regulations in part 21 and failed to adopt appropriate procedures to address the applicable regulations in 10 CFR Part 21.

c. Conclusions

The team concluded that NCS failed to have adequate nonconforming controls in place in accordance with their NRC approved QA program and the requirements of 10 CFR Parts 71 and 21.

1.3 Corrective Actions Controls

a. Scope

The team reviewed selected records and interviewed personnel to verify that NCS effectively implemented a corrective action program (CAP) in accordance with their NRC approved QAPD and the requirements of 10 CFR Part 71. The team reviewed NCS's approved procedure, AA-0104/00-AK, "Creation and Testing of Deviation Reports and Change Certification," dated September 22, 2014, and the applicable IMS section. The team also reviewed one generated corrective action report (CAR) involving ITS components. The team reviewed select records and interviewed personnel to verify that NCS completed corrective actions for identified deficiencies in a technically sound and timely manner.

b. Observations and Findings

The team found that NCS did not have an adequate CAP in place to resolve conditions and, if necessary, significant conditions adverse to quality (SCAQ) based on the review of their approved procedure and applicable IMS section. The approved procedure did not provide guidance on a root-cause analysis program to determine the root causes of failures or rework events associated with SCAQ. Specifically, the team identified that NCS corrective action implementing procedure AA-0104/00-AK and IMS Section 10.0 did not provide guidance to determine the cause of SCAQ, and the corrective action necessary to preclude repetition of an SCAQ. The procedure and the IMS section

lacked specific guidance that described systematic methodology that NCS personnel could use to identify the causes of SCAQ, how to address extent of condition and extent of cause, and corrective action taken to address and preclude repetition such that there is a corrective action for each root and contributing causes. The team assessed that this was another example of violation of NRC requirements associated with the overall QAP.

10 CFR 71.133, "Corrective Action," requires, in part, that the certificate holder shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined, and corrective action taken to preclude repetition.

Contrary to requirements in 10 CFR 71.133, NCS failed to have a program in place to identify and promptly address significant conditions adverse to quality.

c. Conclusions

Overall, the team determined that NCS failed to have an adequate CAP in place to resolve and identified issues. Specifically, NCS implementing procedures did not provide guidance as to when to initiate a corrective action report or provide details on a root-cause analysis program to determine the root causes of failures or rework events associated with SCAQ. However, based on the review of the one corrective action generated, NCS entered the condition adverse to quality into the CAP and resolved the identified deficiency in a technically sound and timely manner. The team noted this was the only corrective action report generated since the start of manufacturing.

1.4 Documentation Controls

a. Scope

The team reviewed NCS's documentation and quality records control program and associated implementing documentation to assess the effectiveness of controls established for the development, review, approval, issuance, use, and revisions of quality documents. The team also reviewed the tracking, verification, and storage of quality records. The team also reviewed documents captured in the Intrexx software process. The team reviewed the following implementing documents:

- QAPD 0023-QAP-2017-001, "10 CFR 71 Subpart H," Revision 1
- IMS Manual Section 4.5, dated August 24, 2020
- IMS Manual Section 8.3, dated August 24, 2020
- AA-0147/xx-AK, "Drawing Control," dated October 1,2014
- Intrexx Software Process, "Control of Documents"
- Intrexx Software Process, "Control of Records"

b. Observations and Findings

The team noted that NCS uses IMS Section 4.5, and the Intrexx software processes to meet the requirements for document management. The Intrexx software is a

computerized system that NCS uses to create, control, release, and change quality documents. The team noted that IMS section and the Intrexx process did not provide significant details for the generation of quality records and the retention as described in 10 CFR 71.135. The team assessed that this was another example of violation of NRC requirements associated with the overall QAP.

10 CFR 71.135, requires, in part, that certificate holder shall maintain sufficient written records to describe the activities affecting quality. The records must include the instructions or procedures that establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility. The certificate holder shall retain these records for 3 years beyond the date when the certificate holder last engages in the activity for which the quality assurance program was developed.

Contrary to the above, NCS failed to maintain sufficient written records to describe the activities affecting quality and include the instructions or procedure that establish a record retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility.

c. Conclusions

The team concluded that NCS did not effectively implement its records control program and lack adequate procedures to ensure compliance with the applicable regulations and QAP requirements. This includes record procedures with adequate information for the classification and assignment of retention times for quality records generated by NCS.

1.5 Audit Program

a. Scope

The team reviewed NCS's audit program to determine if NCS scheduled, planned, and performed internal and external audits, and surveillances in accordance with their approved implementing documentation as described in the QAPD. The team selected a sample of audits from the beginning of fabrication of the DN30 focusing particularly on transportation activities. The team also reviewed the audit results to determine if NCS identified deficiencies and whether NCS addressed these deficiencies within their CAP. The team also evaluated whether NCS provided adequate supervision with quality assurance personnel for appropriate oversight of ITS activities. The team reviewed the following implementing documents:

- QAPD 0023-QAP-2017-001, "10 CFR 71 Subpart H," Revision 1
- IMS Manual Section 9.2, "Internal Audits," dated August 24, 2020
- Intrexx Software Process, "Planning Audits"
- Intrexx Software Process, "Execution of Audits"

Additionally, the team reviewed applicable processes and records to determine if individuals performing audits maintained their training qualifications and certifications. The team selected a sample of audit personnel records, including lead auditors, to determine if they met the requirements stated in Intrexx software process system. The team also reviewed external audit reports for EWB and DUNA-Corradini S.p.A.

b. Observations and Findings

Overall, the team assessed that for the external audits sampled NCS generally conducted audits with qualified and certified personnel and scheduled and evaluated applicable elements of the vendor's QA program. The team did note that the external audits lacked sufficient objective evidence to demonstrate compliance to 10 CFR Part 71 requirements and that NCS relies on ISO accreditation as a basis for material and services as the acceptance criteria although ISO accreditation does not meet all the requirements of 10 CFR Part 71, Subpart H requirements. The team also noted that NCS did not have a method in their QA program to accept ISO accreditation in lieu of performing a commercial grade survey of the vendor.

As for the internal audits, the team noted that NCS failed to perform any internal audits of their NRC approved QA program. Additionally, the team discovered that NCS changed the periodic audits of the QM system from annually to 3 years in the QAPD. The team noted that the change reduces the commitments in the quality assurance program previously approved by the NRC. The team assessed that this was another example of violations of NRC requirements associated with the overall QAP.

10 CFR 71.137, requires, in part, that certificate holder shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.

Contrary to the above, NCS failed to carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.

c. Conclusions

The team concluded that NCS did not effectively implement their internal audit control program and the procedures and processes lack adequate details on internal audit implementation and the use of ISO accreditation in lieu of performing a commercial grade survey of a vendor.

2. Design Controls

2.1 Design Development and Modifications

a. Scope

The team interviewed selected personnel to verify the control of all phases of the design process from the onset of the design through the fabrication activities. The team focused its review on the translation of the design specification to the fabrication drawings and the controls that NCS had in place. The team reviewed procedures and processes specifically related to design development, and control of modification activities. The team focused its review on design activities related to the initial version and Revision 1 of CoC No. 9362 for the DN30 packaging model. The team reviewed the following NCS procedures, processes, and IMS sections associated with design control

to verify that NCS properly implemented the QA program. The team also reviewed selected drawings, design specifications, and purchasing specifications to verify that design controls were in place between NCS and its fabricator (EWB). The team reviewed the following documents:

- QAPD 0023-QAP-2017-001, "10 CFR 71 Subpart H," Revision 1
- 0023-BSH-2016-002, "Safety Analysis Report of the DN30 Package," Revision 1, dated July 12, 2019
- IMS Manual Section 8.3, "Developing products and services," dated August 24, 2020
- Intrexx Software Process, "Container Development," Version 4
- Intrexx Software Process, "Selection of Material," Version 3
- Intrexx Software Process, "Creation of a Package Design Safety Report (PDSR)," Version 3

b. Observations and Findings

As discussed in Section 1.1 of this report, the team noted that NCS was unaware of developing a graded approach to quality for the safety categorization of materials and components that are ITS. The team assessed that NCS would need to develop procedures or implement processes that provide guidance for a graded approach to quality including commercial grade dedication guidelines as applicable. However, the team assessed for the most part NCS was effectively implementing their design control program.

c. Conclusions

The team concluded for the most part that NCS was effectively implementing their design control program. However, as stated above and in Section 1.1 of this report, the team assessed that NCS would need to develop procedures or implement processes that provide guidance for a graded approach to quality including commercial grade dedication guidelines as applicable.

3. Fabrication Controls

3.1 Procurement Controls

a. Scope

The team reviewed drawings and records and interviewed selected personnel to verify that the procurement specifications for materials, equipment, and services met the design requirements. This included the review of procurement documents, drawings and procedures, and receipt inspection records as applicable. The team reviewed the following NCS documents associated with procurement of the DN30 protective structural packaging (PSP):

- 0023-SPZ-2016-001, "Manufacturing Specification DN30 PSP," Revision 5
- 0023-WPB-2016-001, "Material Test Sheet," Revision 4
- 0023-STL-1000-000, "Part List," Revision 6

- 0023-ZFZ-1000-000, “DN30 PSP,” Revision 2
- 0023-ZFZ-1000-100, “Closure Device,” Revision 0
- 0023-ZFZ-1100-000, “Bottom Half,” Revision 4
- 0023-ZFZ-1200-000, “Top Half,” Revision 3
- 0023-ZFZ-1140-000, “Valve Protecting Device,” Revision 3

In addition, the team reviewed various purchase orders associated with material and components of the DN30 packaging, including but not limited to the following: (1) weld wire, (2) locking unit bolt heads, (3) bolt pins, and (4) foam. The team selected the material and components based on a review of the safety analysis report and a safety categorization that NCS prepared for another foreign regulator as a part of the review of the DN30 packaging. The team also reviewed NCS’s approved suppliers list.

b. Observations and Findings

The team noted that NCS contracted with EWB to perform the fabrication activities for the DN30. The team also noted that NCS had measures that controlled material procurement and services. For example, the team noted that the reported chemical, physical, and testing requirements depicted European National (EN) standards and cross-referenced conformance to American Society for Testing and Materials standards, as well as supplier Quality Management ISO 9001 programs, as required by NCS purchase orders. Additionally, the team had several questions on the receipt inspection program for the foam that NCS eventually answered but the team noted that the procedure and processes for the receipt inspection program lack specific details on how to review and accept procurement items. Furthermore, as a part of the material traceability for the weld wire EWB used to weld the PSP, the team noted that there was no documentation available to audit. The team noted that EWB did not document the welding sequences and processes within the manufacturing plan. The team reviewed the weld wire part number on the spool used to weld the PSP and attempted to trace the information back to the specific DN30 PSP. However, there was no weld logs generated or material test reports within the final documentation package for the DN30. The team assessed that this was another example of a violation of NRC requirements associated with the overall QAP.

10 CFR 71.117, “Identification and control of materials, parts, and components,” requires, in part, the certificate holder shall establish measures for the identification and control of materials, parts, and components. These measures must assure that identification of the item is maintained by heat number, part number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, installation, and use of the item. These identification and control measures must be designed to prevent the use of incorrect or defective materials, parts, and components.

Contrary to the above, NCS’s fabricator failed to establish measures for the identification and control of materials, parts, and components. Specifically, EWB failed to document welding sequences and processes (i.e., weld logs) within the manufacturing test plan (traveler) to assure that EWB maintained identification of the weld wire appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, installation, and use of the item. In addition, EWB failed to include weld wire material test reports within final packaging documentation packages.

c. Conclusions

The team concluded for the most part that NCS was effectively implementing their material procurement controls. However, the team determined that NCS in some instances did not impose requirements on EWB to establish measures to maintain identification of items on records traceable to the item, as required throughout fabrication and use of the item.

3.2 Fabrication and Assembly

a. Scope

The team reviewed records and observed fabrication activities associated with the DN30 packaging. The team observed three batches of the fabrication process that included welding, assembly, inspections, and testing. The team reviewed the manufacturing sequence test plan, fabrication documentation, and test procedures. Specifically, the team reviewed the following NCS's documents:

- 0023-BSH-2016-002, "Safety Analysis Report DN30 Package," Revision 1
- 0023-BPP-2016-001, "Manufacturing Test Plan," Revision 1
- 0023-PA-2015-016, "Inspection Criteria for Regular and Periodical Inspections of the DN30 Package," Revision 3.

The team also reviewed applicable welder qualification and certification records in accordance with the applicable ISO standards. The team interviewed selected personnel and reviewed various weld procedure specifications and qualifications. The team also observed both manual and automatic welding of DN30 components.

b. Observations and Findings

The team noted that EWB fabricated the DN30 PSP in accordance with a welding program that was specific to ISO EN standards as opposed to American Society of Mechanical Engineers standards as described in the safety evaluation report (SER) for the DN30 package. The team assessed that the welder qualification and certification records met the applicable ISO standards although it was different than what was approved in the SER. The team assessed that EWB personnel assembled material and components based on the manufacturing plans.

c. Conclusions

Except for EWB's failure to document welding sequences and processes (i.e., weld logs) within the manufacturing test plan (traveler) to assure that EWB maintained identification of the weld wire (refer to Section 3.1 of this report), the team determined that EWB controlled the assembly and welding of material and components for the DN30 PSP. EWB had approved procedures to control the fabrication and assembly processes.

3.3 Test and Inspection

a. Scope

The team reviewed records associated with the test and inspection plans for the DN30 packaging to verify that NCS properly controlled and implemented the applicable test and inspection processes. The team observed visual weld examinations, liquid penetrant examinations, upper and lower enclosure pressure tests (bubble leak) and load weight test of various subassemblies and the final assembled PSP. The team also reviewed applicable quality control inspector qualification and certification records. The team reviewed the manufacturing sequence test plan, fabrication documentation, and test procedures, which included 0023-BSH-2016-002 and EN ISO 1593 standard titled, "Non-destructive Testing – Bubble Emission Techniques."

b. Observations and Findings

The team noted EWB's compliance to fabrication drawing requirements, manufacturing test plans, and applicable test instructions. The team noted EWB's accepted individual certification for Level III and II NDE examiners based on ISO EN requirements for principles and for the qualification and certification of personnel who performed industrial non-destructive testing. However, when the team observed the bubble leak test for the thermal plugs, the team identified that the manufacturing test plan did not include all the requirements from the testing standard DIN EN 1593 as required in the safety analysis report and manufacturing specification, 0023-BSH-2016-002 and 0023-SPZ-2016-001, respectively. The testing standard included surface temperature and visual examination limits, required pressure maintained for a specified time, and required calibration of vacuum and pressure gages. The team noted that NCS did not include all the requirements listed above into the bubble leak test examination for the thermal plugs. The team assessed that this was another example of a violation of NRC requirements associated with the overall QAP.

10 CFR 71.123, "Test control," requires, in part, that the certificate holder shall establish a test program to assure that all testing required to demonstrate that the packaging components will perform satisfactorily in service is identified and performed in accordance with written test procedures that incorporate the requirements of this part and the requirements and acceptance limits contained in the package approval. The test procedures must include provisions for assuring that all prerequisites for the given test are met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. The certificate holder shall document and evaluate the test results to assure that test requirements have been satisfied.

Contrary to the above, NCS failed to assure that all testing required to demonstrate that the packaging components will perform satisfactorily in service is identified and performed in accordance with written test procedures that incorporate the requirements of this part and the requirements and acceptance limits contained in the package approval. Specifically, NCS failed to incorporate all the requirements captured in EN ISO 1593 into the manufacturing test plan to demonstrate that the thermal plugs would perform satisfactorily in service.

c. Conclusions

The team concluded that NCS did not provided adequate oversight of EWB test control program such that all testing required to demonstrate that the packaging components incorporated the requirements contained in the package approval.

3.4 Tools and Equipment

a. Scope

The team reviewed the control of measuring and test equipment (M&TE) to evaluate how NCS and their fabricator EWB identified, specified, and controlled tools and equipment in accordance with applicable standards and regulatory requirements. The team selected a sample of the M&TE used during the fabrication of the DN30. The sample included a scale (EWB169), vacuum and pressure gages, and welding machines. The team reviewed the calibration records and certifications to verify calibration dates, testing standards, and traceability of the associated M&TE. The team also reviewed NCS's NRC approved QA program to verify if NCS had a method to use laboratory accreditation by Accreditation Bodies that are a part of the International Laboratory Accreditation Cooperation (ILAC) in lieu of performing commercial grade surveys for procurement of calibration and testing services.

b. Observations and Findings

Overall, the team assessed that NCS and EWB had a program to control M&TE. However, the team identified several discrepancies with the EWB M&TE program and identified that EWB and NCS did not describe a method to use laboratory accreditation in lieu of performing commercial grade surveys for procurement of calibration and testing services. Both NCS and EWB received calibration service in accordance with ISO/International Electrotechnical Commission (IEC) 17025:2017 "General Requirements for the Competence of Testing and Calibration Laboratories." If the vendor maintained appropriate certification through IEC than NCS and EWB did not perform surveys of the vendors.

As a part of the review, the team identified these discrepancies at EWB: (1) instances where there was no ISO/IEC accreditation with no corresponding survey, (2) that the calibration list was not up to date with the latest information, (3) M&TE used to perform the leak test for the thermal plugs were not calibrated and not maintained on the calibration list, and (4) tools and equipment were not traceable back to the specific jobs and date of use. The team assessed that this was another example of a violation of NRC requirements associated with the overall QAP and general oversight of the NCS fabricator.

10 CFR 71.125, "Control of Measuring and Test Equipment," requires, in part, that the certificate holder shall establish measures to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified times to maintain accuracy within necessary limits.

Contrary to this, NCS failed to provide oversight of their contractor EWB to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified times to

maintain accuracy within necessary limits. Specifically, EWB did not properly control calibrate, and adjust M &TE (i.e., pressure gages and scales) at specified times to maintain accuracy and within necessary limits. EWB used these M&TE in activities affecting quality of the DN30 packaging. Further, the EWB M&TE logs contained discrepancies and used equipment that had no ISO/IEC accreditation without a corresponding survey. In addition, the team assessed that NCS had to perform a survey of the contractor and could not just reply on the ISO accreditation.

10 CFR 71.115, "Control of purchased material, equipment, and services, "states, in part, that the certificate holder shall establish measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products on delivery.

Contrary to the above, NCS relied strictly on the vendors ISO accreditation as a basis to accept material and services. There were no measures established to include provisions, as appropriate for source evaluation and selection, objective evidence of the quality furnished, or inspection at the source.

c. Conclusions

The team concluded that NCS did not provided adequate oversight of EWB to ensure EWB properly controlled, calibrated, and adjusted M&TE within specified times to maintain accuracy within necessary limits. The team also noted if NCS plans on replying on ISO/IEC accreditation with no corresponding survey than NCS must capture this commitment within their QA program.

4. Entrance and Exit Meeting

The team held an entrance meeting with NCS and EWB personnel on September 20, 2021, to present the purpose and scope of the NRC inspection activities. On September 21 and 24, 2021, the team held briefings to discuss the primarily results of the inspection based on the fabrication activities at EWB and quality assurance program implementing procedures at NCS. On September 30, 2021, the team conducted the final exit meeting with Mr. Franz Hilbert, Chief Operating Officer, and other members from the NCS staff. The attachment to this report documents the individuals present at the entrance, debriefs, and exit meeting.

ATTACHMENT

LIST OF ATTENDEES FOR ENTRANCE AND EXIT MEETINGS

The team held an entrance meeting with NCS and EWB personnel on September 20, 2021, to present the purpose and scope of the NRC inspection activities. On September 21 and 24, 2021, the team held briefings to discuss the primarily results of the inspection based on the fabrication activities at EWB and quality assurance program implementing procedures at NCS. On September 30, 2021, the team conducted the final exit meeting with Mr. Franz Hilbert, Chief Operating Officer, and other members from the NCS staff. The table below documents the individuals present at the entrance, debrief, and exit meeting.

Table
Entrance and Exit Meetings Attendees

NAME	AFFILIATION	ENTRANCE	(DEBRIEF) September 21	(DEBRIEF) September 24	TEAMS (Exit)
Marlone Davis	NRC/DFM	X	X	X	X
Earl Love	NRC/DFM	X	X	X	X
Yara Van Wijk	NCS	X	X	X	X
Wolfgang Haker	NCS	X	X	X	X
Andreas Kiep	EWB	X	X		
Markus Bernhard	EWB	X	X		
Franz Hilbert	NCS				X

LIST OF INSPECTION PROCEDURES USED

1. Inspection Procedure 86001, “Design, Fabrication, Testing, and Maintenance of Transportation Packagings” issue date January 16, 2008.
2. Regulatory Guide 7.10, “Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material,” Revision 3.
3. NUREG/CR-6407, “Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety”
4. NUREG/CR 6314, “Quality Assurance Inspections for Shipping and Storage Containers”

LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description
71-0951/2021-201-01	Opened	NOV	71.105 Quality Assurance Program
71-0951/2021-201-02	Opened	NOV	10 CFR 21.6 Posting and 10 CFR 21.21 Notification

LIST OF ACRONYMS USED

ADAMS	Agencywide Documents Access and Management System
ASME	American Society of Mechanical Engineers
CAP	Corrective Action Program

CFR	Code of Federal Regulations
CoC	Certificate of Compliance
EN	European National
EWB	Eisenwerk Bassum GmBH
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
IMS	Integrated Management System
ISO	International Organization for Standardization
ITS	Important to Safety
M&TE	Measuring and Test Equipment
NCR	Nonconformance Report
NCS	Nuclear Cargo Services
NOV	Notice of Violation
NRC	Nuclear Regulatory Commission
PSP	Protective Structural Packaging
QA	Quality Assurance
QAP	Quality Assurance Program
QAPD	Quality Assurance Program Description
SER	Safety Evaluation Report

DOCUMENTS REVIEWED

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

NOTICE OF VIOLATION

Orano Nuclear Cargo Services
Hanau Germany 63457

Docket No. 07100951
EA-2021-165

During an NRC inspection conducted on September 20 to September 24, 2021, an NRC inspection team identified two violation of NRC requirements with one violation having multiple examples. In accordance with the NRC Enforcement Policy, the violations and examples are listed below:

A. 10 CFR 71.105, "Quality assurance program" requires, in part, that the certificate holder shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of 10 CFR 71.101 through 71.137. The certificate holder shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used.

Contrary to the above, as of September 2021, the certificate holder (NCS) failed to establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with all the requirements of 10 CFR 71.101 through 71.137. NCS also failed to document some of the quality assurance (QA) program requirements in written procedures or instructions. Specifically, NCS failed to apply all the applicable eighteen criteria (i.e., 10 CFR 71.101 through 71.137) discussed in its program description submittal into their lower level implementing procedures governing the conduct of QA activities and failed to carry out the program in accordance with those procedures in some instances. The team captured ten examples during the fabrication and corporate QA implementation inspections. The examples are as follows:

1. 10 CFR 71.101(b) "Quality assurance requirements," states, in part, that the certificate holder shall execute the applicable criteria in a graded approach to an extent that it is commensurate with the quality assurance requirements importance to safety.

   10 CFR 71.107(a), "Package design control," requires, in part, that measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of materials, parts, and components of the packaging that are ITS.

   Contrary to the above, NCS did not determine the classification of components used in the DN30 packaging in accordance with a graded approach to an extent commensurate with their importance to safety.

2. 10 CFR 71.106(b), "Changes to quality assurance program," requires, in part, that each quality assurance program approval holder may change a previously approved quality assurance program without prior NRC approval, if the change does not reduce the commitments in the quality assurance program previously approved by the NRC. Changes to the quality assurance program that do not reduce the

commitments shall be submitted to the NRC every 24 months, in accordance with 10 CFR 71.1(a).

Contrary to the above, NCS did not submit the quality assurance program to the NRC for changes to the QAPD that reduced commitments identified in the original NRC approval of the QAPD for area in document control, missing organizational charts, and moving from 1 to 3 years for periodic audits. The team determined that these changes were not administrative in nature.

3. 10 CFR 71.115, "Control of purchased material, equipment, and services, "states, in part, that the certificate holder shall establish measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products on delivery.

   Contrary to the above, NCS relied strictly on the vendors ISO accreditation as a basis to accept material and services. There were no measures established to include provisions, as appropriate for source evaluation and selection, objective evidence of the quality furnished, or inspection at the source.

4. 10 CFR 71.117, "Identification and control of materials, parts, and components," states, in part that the certificate holder shall establish measures for the identification and control of materials, parts, and components. These measures must assure that identification of the item is maintained by heat number, part number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, installation, and use of the item. These identification and control measures must be designed to prevent the use of incorrect or defective materials, parts, and components.

   Contrary to the above, NCS fail to provide oversight of their fabricator to document welding sequences and processes (e.g., weld logs) within the manufacturing test plan. In addition, NCS's fabricator fail to include weld wire material test reports within final packaging documentation packages.

5. 10 CFR71.123, "Test control," states, in part that the certificate holder shall establish a test program to assure that all testing required to demonstrate that the packaging components will perform satisfactorily in service is identified and performed in accordance with written test procedures that incorporate the requirements of this part and the requirements and acceptance limits contained in the package approval. The test procedures must include provisions for assuring that all prerequisites for the given test are met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. The licensee, certificate holder, and applicant for a CoC shall document and evaluate the test results to assure that test requirements have been satisfied.

   Contrary to the above, NCS failed to provide oversight of their contractor EWB to include appropriate testing requirements and failed to incorporate the requirements and acceptance limits contained in the packaging approval.

6. 10 CFR 71.125, “Control of Measuring and Test Equipment,” states, in part, that the certificate holder shall establish measures to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified times to maintain accuracy within necessary limits.

   Contrary to the above, NCS failed to provide oversight of their contractor EWB to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified times to maintain accuracy within necessary limits. Specifically, EWB did not properly control calibrate, and adjust M &TE (i.e., pressure gages and scales) at specified times to maintain accuracy and within necessary limits. EWB used these M&TE in activities affecting quality of the DN30 packaging. Further, the EWB M&TE logs contained discrepancies and used equipment that had no ISO/IEC accreditation without a corresponding survey. NCS’s fabricator fail to ensure that the M&TE (e.g., pressure gages and scale) was calibrated, adjusted, and maintained at prescribed intervals or before use.

7. 10 CFR 71.131, “Nonconforming materials parts, or components,” requires, in part that the certificate holder shall establish measures to control materials, parts, or components that do not conform to requirements to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

   Contrary to the above, NCS failed to establish measures to control materials, parts, or components for identification, documentation, segregation, disposition, and notification to affected organizations for nonconforming or deviation reports. Furthermore, NCS failed to review and accept nonconforming items in accordance with documented procedures including dispositioning of use-as-is, repair, or reject nonconforming items. The team noted that IMS Section 10 and AA-0104/00-AK did not capture guidance on how NCS personnel should review, disposition, and segregate nonconforming items.

8. 10 CFR 71.133, “Corrective Action,” requires, in part, that the certificate holder shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined, and corrective action taken to preclude repetition

   Contrary to the above, NCS failed to have a program in place to identify and promptly address significant conditions adverse to quality.

9. 10 CFR 71.135, “Quality Assurance Records,” requires, in part that the certificate holder shall maintain sufficient written records to describe the activities affecting quality. The records must include the instructions or procedures that establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility. The licensee, certificate holder, and applicant for a CoC shall retain these records for 3

years beyond the date when the licensee, certificate holder, and applicant for a CoC last engage in the activity for which the quality assurance program was developed.

Contrary to the above, NCS failed to establish a records retention program that is consistent with applicable regulations. Further, NCS does not describe the duration of retaining quality records in any implementing procedure or process.

10. 10 CFR 71.137, "Audits," requires, in part, that the certificate holder shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.

    Contrary to the above, NCS failed to carry out a comprehensive system of planned and periodic internal audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.

This is a Severity Level IV violation (Section 6.5.d.1)

B. 10 CFR 21.6(a)(1), "Posting requirements," requires, in part that Each individual, partnership, corporation, dedicating entity, or other entity subject to the regulations in this part shall post current copies of

(i) The regulations in this part;
(ii) Section 206 of the Energy Reorganization Act of 1974; and
(iii) Procedures adopted pursuant to the regulations in this part.

10 CFR 21.21, "Notification of failure to comply or existence of a defect and its evaluation," requires, in part, that each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures

Contrary to requirements in 10 CFR 21.6(a)(1) and 10 CFR 21.21, as of September 2021, NCS failed to post current copies of the regulations in 10 CFR Part 21 and failed to adopt appropriate procedures to address the applicable regulations in 10 CFR Part 21

This is a Severity Level IV violation (Section 6.5.d.5)

Pursuant to the provisions of 10 CFR 2.201, Orano Nuclear Cargo Services (formerly Daher Nuclear Technologies) is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to Hipolito Gonzalez, Chief, Inspection and Oversight Branch, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation, EA-2021-165" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued requiring information as to why the license should not be modified, suspended, or revoked, or why such other action as

may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS), http://www.nrc.gov/NRC/ADAMS/index.html to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated 22 of December 2021.