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

August 9, 2021

EA-2021-091

Mr. Mike Rose
Quality Assurance Manager
Industrial Nuclear Co., Inc.
14320 Wicks Blvd
San Leandro, CA 94577

SUBJECT: INDUSTRIAL NUCLEAR CO., INC. - NRC INSPECTION REPORT NO. 71-0062/2021-201 AND NOTICE OF VIOLATION

Dear Mr. Rose:

This letter refers to the inspection conducted on May 25 to 27, 2021, at the Industrial Nuclear Co., Inc. (INC) facility in San Leandro, CA. The inspection team continued the inspection activities with an in-office review and held an exit meeting on June 25, 2021. The purpose of the inspection was to verify and assess the adequacy of INC's activities associated with the transportation of radioactive material to determine if they were performed 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 INC's U.S. Nuclear Regulatory Commission (NRC) approved Certificates of Compliance (CoCs) and Quality Assurance Program (QAP). The inspection scope included management, design, and fabrication controls. The enclosed report presents the results of this inspection.

The inspection examined activities conducted under your NRC approved QAP as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with the conditions of the applicable CoCs. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that three Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at (http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html). The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations are being cited in the Notice because of the issues identified with INC's corrective action program (CAP) during this inspection. Specifically, it was identified that issues were not entered into the CAP and corrective actions were not performed after being identified by the NRC during previous inspection activities. In addition, not all issues identified during this inspection have been entered into the CAP, however INC has indicated each issue is being evaluated.

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/reading-rm/adams.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,

Francis Peduzzi

Francis Paul Peduzzi, Chief
Inspection and Oversight Branch
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

Docket No. 71-0062

Enclosures: 1. Inspection Report No. 71-0062/2021-201
2. Notice of Violation

Subject: INDUSTRIAL NUCLEAR CO., INC. - NRC INSPECTION REPORT NO. 71-0062/2021-201 AND NOTICE OF VIOLATION

DOCUMENT DATE: August 9, 2021

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

Inspection Report

Docket No.:	71-0062
Report No.:	71-0062/2021-201
Certificate Holder:	Industrial Nuclear Co., Inc. 14320 Wicks Blvd San Leandro, CA 94577
Inspection Dates:	May 25 - June 25, 2021
Inspectors:	Jeremy Tapp, Transportation and Storage Safety Inspector, Team Leader Marlone Davis, Senior Transportation and Storage Safety Inspector Earl Love, Senior Transportation and Storage Safety Inspector
Approved by:	Francis Paul Peduzzi, Chief Inspection and Oversight Branch Division of Fuel Management Office of Nuclear Material Safety and Safeguards

EXECUTIVE SUMMARY

Industrial Nuclear Co., Inc.
NRC Inspection Report 71-0062/2021-201

This routine inspection evaluated the on-going activities at Industrial Nuclear Co., Inc.'s (INC's) facility in San Leandro, California related to transportation of radioactive material from May 25 to 27, with additional in-office review through June 25, 2021. The purpose of the inspection was to verify and assess the adequacy of INC's activities associated with the transportation of radioactive material to determine if they were performed 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 INC's NRC approved Certificates of Compliance (CoCs) and Quality Assurance Program (QAP). The inspection scope included management, design, and fabrication controls.

Based on the results of this inspection, the NRC inspection team assessed that the implementation of INC's quality assurance (QA) program did not meet certain NRC requirements in the areas of corrective action and instructions, procedures, and drawings. This resulted in three Severity Level IV violations of NRC requirements, two of which contain multiple examples. The violations are summarized in the sections below and described in detail in the Report Details section of this inspection report.

Management Controls

The team determined that the QA controls at INC were generally adequate, however isolated issues were identified in the areas of corrective actions, documentation controls, and audit program that are discussed below and in the Report Details section. Regarding the overall QA policy, the team concluded that INC conducts its activities associated with QA organization independence and QA responsibilities in accordance with their NRC approved QAP.

The team concluded that INC effectively implemented its nonconformance control program and has adequate procedures in place to ensure compliance with the applicable regulations and QA program requirements. The team also concluded that INC has provisions in place for reporting defects that could cause a substantial safety hazard that could affect the package's ability to perform its intended safety functions, as required by 10 CFR Part 21.

The team identified INC's corrective action program (CAP) as an area for improvement as evidenced by the issues identified. The team identified two violations of NRC requirements concerning the failure to (1) promptly correct a condition adverse to quality as required by 10 CFR 71.133 when Corrective Action Report (CAR) 2016-001 was not corrected during the planned 2016 internal audit or thereafter; and (2) document a condition adverse to quality identified by the NRC during the previous 2017 follow-up inspection on a CAR to enter the issue into the CAP as required by Quality Procedure (QP) 16.1, "Corrective Action," Revision 3. Due to the failure of INC to both enter issues into the CAP and perform corrective actions and close issues in a timely manner, the issues identified during this inspection are being cited in the enclosed Notice of Violation (Notice) to ensure the NRC understands the issues that have been entered into the CAP, the planned corrective actions taken, and the planned timeframe to complete those actions.

The team concluded that INC failed to establish and maintain activities associated with QA documentation controls in accordance with their NRC approved QAP. The team identified one example of a violation of NRC requirements, specifically 10 CFR 71.111 for inadequate

procedures, concerning the failure to maintain control of quality documentation and describe how to control electronic quality records and documentation. The team found that for the audits reviewed, INC conducted the audits with qualified personnel and evaluated the applicable functional areas of the QA program. The team identified an additional example of a violation of 10 CFR 71.111 for failure to follow procedures, specifically QP 18.1, "Audits and Commercial Grade Surveys," Revision 3, for the failure to perform an internal audit within a 12-month period in 2016.

Design Controls

The team assessed that overall, INC assigned design responsibilities appropriately and the engineering service contractor was effectively implementing INC's design control program. The team also assessed that implementing procedures were in place and effective in controlling activities in accordance with the applicable regulations and approved CoC.

Fabrication Controls

The team identified two examples of a violation of 10 CFR 71.111 for inadequate procedures concerning the failure to (1) adequately prescribe material testing performed by an alloy analyzer device for material dedication activities by a documented instruction or procedure; and (2) to adequately prescribe the appropriate supplier qualification methods by including an allowance in QP 7.1 for qualification of a supplier based solely on having an NRC approved QAP.

INC's implementation of fabrication controls for fabrication and assembly, including examinations and material storage, was assessed to be adequate. The team determined that welder/welding operators were appropriately qualified according to American Society of Mechanical Engineering (ASME) Code Section IX requirements and that welders met the current qualification requirements for the processes in use on the shop floor.

The team assessed that INC had adequate controls for package testing, material traceability, procurement, and receipt inspection.

The team concluded that the measuring and test equipment (M&TE) quality procedure being implemented at INC provided adequate guidance for M&TE calibration and use, and INC adequately implemented M&TE calibration, tracking, and use requirements.

REPORT DETAILS

1. Management Controls

1.1 Quality Assurance Policy

a. Inspection Scope

The team reviewed the INC QAP, "Design, Fabrication, Assembly and Testing of Type B Shipping Containers and Source Assemblies," Revision 13 and implementing Quality Procedures (QPs) to assess the effectiveness of the QA program implementation. The team conducted reviews of INC's quality program, policies, and procedures, to determine whether activities subject to 10 CFR Part 71 were adequately controlled and implemented under INC's NRC approved QAP.

The team reviewed procedures and documents regarding training, qualification, and certification of personnel involved in quality activities. The team also reviewed training records of a selection of employees in quality related positions to determine if they received the required QA indoctrination and QA program revision training.

b. Observations and Findings

The team assessed that INC had a QA program and implementing procedures in place that were generally effective in conducting activities in accordance with their transportation package CoCs as well as their NRC approved QAP. The team verified that the QA program authorities and responsibilities were clearly defined and documented, and the QA organization functioned as an independent group. The team also determined that for the sample of INC staff member training records reviewed that each staff member completed the required training. No issues of significance were identified.

c. Conclusions

The team determined that the QA controls at INC were generally adequate. The team concluded that INC conducts its activities associated with QA organization independence and QA responsibilities in accordance with their NRC approved QAP.

1.2 Nonconformance Controls

a. Scope

The team reviewed selected records and interviewed personnel to verify that INC effectively implemented a nonconformance control program in accordance with their NRC approved QAP and the requirements of 10 CFR Parts 21 and 71. Specifically, the team reviewed INC's approved procedure, QP 15.1, "Control of Nonconformances," Revision 3. The team selected several nonconformance reports (NCRs) to verify that the NCRs were identifiable, traceable, and the disposition of the nonconformance was adequate. The team reviewed NCRs since the previous 2016 routine inspection and concentrated, when possible, on issues involving important-to-safety (ITS) structures,

systems, and components (SSCs). The team reviewed these NCRs to evaluate if the disposition was appropriate, adequately performed as necessary, and properly closed out in accordance with QP 15.1.

The team reviewed the six NCRs generated since the previous 2016 routine inspection.

In addition, the team reviewed INC's approved procedure QP 19.1, "Reporting of Defects and Noncompliance," Revision 2, to determine if provisions were in place for reporting defects that could cause a substantial safety hazard from the NCRs and quality issues identified.

b. Observations and Findings

The team assessed that INC adequately dispositioned and closed each selected NCR in accordance with the requirements of QP 15.1, as applicable. In addition, the team noted that there were no Part 21 reports issued since the previous 2016 routine inspection. No issues of significance were identified.

c. Conclusions

The team concluded that INC effectively implemented its nonconformance control program and has adequate procedures in place to ensure compliance with the applicable regulations and QA program requirements. The team also concluded that INC has provisions in place for reporting defects that could cause a substantial safety hazard that could affect the package's ITS SSCs to perform their intended safety function, as required by 10 CFR Part 21. The Part 21 postings in INC's San Leandro, CA facility met the approved implementing procedure and the applicable requirements of 10 CFR Part 21.

1.3 Corrective Actions Controls

a. Scope

The team reviewed selected records and interviewed personnel to verify that INC effectively implemented a corrective action program (CAP) in accordance with the NRC approved QAP and the requirements of 10 CFR Part 71. Specifically, the team reviewed INC's approved procedure QP 16.1, "Corrective Action," Revision 3. The team reviewed corrective action reports (CARs) since the previous 2016 routine inspection and concentrated on issues involving ITS SSCs, when possible. The team reviewed selected records and interviewed personnel to verify that INC completed corrective actions for identified deficiencies in a technically sound and timely manner. Additionally, the team included a review of five CARs, 16-001 through 16-005, that were opened during the previous 2016 routine inspection, and CAR 16-006 that was opened during the previous 2017 follow-up inspection.

b. Observations and Findings

During the review of CARs generated from the issues identified in the previous 2016 routine inspection, the team identified that CAR 16-001, dated 1/28/2016 was still open

pending completion of the first 2016 internal audit. The team noted that CAR 16-001 was opened because all quality program elements were not audited in 2015 as required by INC quality procedures. The team discussed with INC why the CAR remained open and determined that no internal audits were performed in 2016, therefore, INC failed to complete the documented corrective actions in CAR 16-001 and close the issue. The team noted that INC did not close the CAR based on any internal audits performed after 2016, either. The team considered this a violation of NRC requirements. Specifically, 10 CFR 71.133, "Corrective action." The failure to perform an internal audit in 2016 is discussed in detail in Section 1.5 of this report.

10 CFR 71.133, "Corrective action" states, in part, that the certificate holder (INC) 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.

Contrary to, as of 2016, INC failed to assure that conditions adverse to quality were promptly corrected. Specifically, INC failed to promptly correct a condition adverse to quality when CAR 2016-001 was not corrected during the planned 2016 internal audit or thereafter.

The team assessed the significance of the violation using the NRC Enforcement Policy and Manual. The team determined that the violation was more than minor because of the potential for issues to remain unidentified due to the significant time the internal audit deficiencies were left uncorrected. The team characterized the violation as a Severity Level IV violation in accordance with the NRC's Enforcement Policy, Section 6.8. This violation is being cited in the enclosed Notice of Violation (Notice).

Additionally, the team requested INC provide CAR 2016-006 for review from the previous 2017 follow-up inspection. This CAR was written because INC failed to submit a license amendment request to the NRC as required when a licensing drawing referenced in the IR-100 CoC was revised without prior NRC approval. However, INC was unable to provide the team with objective evidence that the CAR was generated to enter the issue into the CAP and ensure appropriate corrective actions were taken. This includes both the CAR form and entry in the CAR Tracking Log. The team considered this a violation of NRC requirements. Specifically, 10 CFR 71.111, "Instructions, procedures, and drawings."

10 CFR 71.111, "Instructions, procedures, and drawings" states, in part, that the certificate holder (INC) shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed.

Contrary to, as of February 2017, INC failed to follow quality related procedure QP 16.1, "Corrective Action," Revision 3, Step 6.2 that states, in part, in cases where the adverse condition is not identified and being corrected by some other form of documentation, the Quality Assurance Manager shall identify the adverse condition on a CAR. Specifically, INC failed to document a condition adverse to quality identified by the NRC during the previous 2017 follow-up inspection for failure to receive prior NRC approval for an IR-100 CoC change on a CAR to enter the issue into the CAP.

The team assessed the significance of the violation using the NRC Enforcement Policy and Manual. The team noted that the license amendment request to revise the IR-100 CoC was submitted for approval to the NRC after identification of the issue, but the issue was considered to have minor safety significance because it was understood to have been entered into INC's CAP. The team determined that the violation was more than minor because of the potential for repetitive issues due to the issue not being entered into and assessed by INC's CAP. The team characterized the violation as a Severity Level IV violation in accordance with the NRC's Enforcement Policy, Section 6.8. This violation is being cited in the enclosed Notice as an example of the violation of 10 CFR 71.111 for failure to follow procedures.

c. Conclusions

The team identified INC's CAP as an area for improvement as evidenced by the issues identified and described above. The team identified two violations of NRC requirements concerning the failure to (1) promptly correct a condition adverse to quality when CAR 2016-001 was not corrected during the planned 2016 internal audit or thereafter; and (2) document a condition adverse to quality identified by the NRC during the previous 2017 follow-up inspection on a CAR to enter the issue into the CAP. Due to the failure of INC to both enter issues into the CAP and perform corrective actions and close issues in a timely manner, the issues identified during this inspection are being cited in the enclosed Notice to ensure the NRC understands the issues that have been entered into the CAP, the planned corrective actions taken, and the planned timeframe to complete those actions.

1.4 Documentation Controls

a. Scope

The team reviewed INC's documentation control program and quality procedures to assess the effectiveness of controls established for the approval, issuance, use and revisions of quality documents. The team reviewed a sample of INC documents (instructions, procedures, records, drawings, and specifications) to verify that INC developed and controlled quality related activities. The team reviewed the following documents:

- QP 6.1, "Document Control," Revision 5, and
- QP 17.1, "Quality Assurance Records," Revision 3

The team also interviewed QA personnel regarding documentation controls.

b. Observations and Findings

The team identified a violation of 10 CFR 71.111 because INC did not prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and failed to include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished. Specifically, INC did not maintain control of quality documentation, describe how to control electronic quality records in instructions or

procedures and did not generate quality documentation such that the documents were readily retrievable.

The team reviewed the INC QPs for control of documents and records. Specifically, QP 6.1, "Document Control," Revision 5 and QP 17.1, "Quality Assurance Records," Revision 3 establish the methods for the control of documents and requirements for the classification, filing, storage, retention, and disposition of quality records generated by INC. The team identified that INC failed to maintain control of documents and establish a system of storing and filing quality records associated with ITS activities. The team noted the loss of quality records such as audits and receipt inspections, the lack of detail on how INC would control electronic records, and the generation and issuance of all documents and any changes were readily retrievable. The team considered this a violation of NRC requirements. Specifically, 10 CFR 71.111, "Instructions, procedures, and drawings."

10 CFR 71.111, "Instructions, procedures, and drawings" states, in part, that the certificate holder (INC) shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

Contrary to, as of May 27, 2021, INC failed to prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished. Specifically, INC failed to maintain control of quality documentation such as audits and receipt inspections and describe how to control electronic quality records and other generated quality documentation in QP 6.1 and QP 17.1, respectively, such that the documents were readily retrievable.

The team assessed the significance of the violation using the NRC Enforcement Policy and Manual. The team determined that the violation was more than minor because there were repetitive occurrences with no documentary evidence in some instances. The team characterized the violation as a Severity Level IV violation in accordance with the NRC's Enforcement Policy, Section 6.8. The team noted this issue was entered into INC's CAP as CAR 21-001, but as described in Section 1.3, is being cited in the enclosed Notice as an example of the violation of 10 CFR 71.111 for inadequate procedures.

c. Conclusions

The team concluded that INC failed to establish and maintain activities associated with QA documentation controls in accordance with their NRC approved QAP. The team identified one example of a violation of NRC requirements concerning the failure to maintain control of quality documentation and describe how to control electronic quality records and documentation.

1.5 Audit Program

a. Scope

The team reviewed selected records and interviewed personnel to verify that INC effectively implemented an internal audit program in accordance with the NRC approved QAP and the requirements of 10 CFR Part 71. Specifically, the team reviewed INC's approved procedure QP 18.1, "Audits and Commercial Grade Surveys," Revision 3.

The team reviewed the qualifications, training records, and annual evaluations for INC's Lead Auditor to determine if they met the requirements stated in QP 18.1.

The team reviewed selected internal audits since the previous 2016 routine inspection to determine if they were performed in accordance with QP 18.1, if INC identified deficiencies, and whether INC addressed these deficiencies within their CAP.

b. Observations and Findings

For the 2021 internal audit reviewed, the team assessed that the audit was adequately performed per QP 18.1, assessed current INC activities, and contained appropriate objective evidence of the information and activities audited. The team noted that INC could not provide the quality records that documented the 2017, 2018, and 2019 internal audits. This issue is captured as part of the QA documentation control issue described in Section 1.4 of this report.

The team also identified, as noted in Section 1.3 of this report, that an internal audit was not performed in 2016 as required by QP 18.1, Step 6.1.1, that states, in part, that all elements of the QA program shall be audited within a 12-month period. The team considered this a violation of NRC requirements. Specifically, 10 CFR 71.111, "Instructions, procedures, and drawings."

10 CFR 71.111, "Instructions, procedures, and drawings" states, in part, that the certificate holder (INC) shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed.

Contrary to, between January 1 and December 31, 2016, INC failed to follow quality related procedure QP 18.1, Step 6.1.1. Specifically, INC failed to perform an audit within a 12-month period by not performing an internal audit of the QA program in 2016.

The team assessed the significance of the violation using the NRC Enforcement Policy and Manual. The team determined that the violation was more than minor because of the potential for issues to remain unidentified and uncorrected due to the missed audit. The team characterized the violation as a Severity Level IV violation in accordance with the NRC's Enforcement Policy, Section 6.8. This violation is being cited in the enclosed Notice as an example of the violation of 10 CFR 71.111 for failure to follow procedures.

c. Conclusions

The team found that for the audits reviewed, INC conducted the audits with qualified personnel and evaluated the applicable functional areas of the QA program. The team identified a violation of NRC requirements concerning the failure to perform an internal audit in 2016 as required by quality procedures.

2. Design Controls

2.1 Design Development

a. Scope

The team reviewed the design control section of the INC QAP and applicable implementing quality procedures associated with design control to verify that INC properly implemented their design control program. The team reviewed selected design development, changes and interviewed INC personnel that provided oversight of the design control process.

The team reviewed design documents and interviewed selected personnel to verify that INC had 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 were in place. The team reviewed the INC implementing quality procedures specifically related to design development, and control of modification activities. The team also reviewed the qualifications of selected engineering personnel as applicable because INC contracted most of their design control activities to an engineering contractor.

The team focused its review on INC design activities related to Revision 1 of CoC No. 9360 for the Part 71 Ten Hole Source Changer (THSC) package. The team reviewed the following INC QPs and QAP sections associated with design control. The procedures are as follows:

- QAP, Section 3.0, “Design Control,” Revision 13
- QP 3.1, “Design Control,” Revision 9
- QP 3.2, “Commercial Grade Item Dedication,” Revision 1

The team reviewed selected drawings, design specifications, purchasing specifications and other design control records to verify that materials, equipment, and engineering services met design requirements. The team reviewed the INC THSC package safety analysis report, Revision 1, to assure that INC complied with the acceptable methods, drawings and specifications described in the NRC Safety Evaluation Report.

The team also reviewed two selected licensing drawings to verify that INC provided adequate oversight of engineering services and that the engineering contractor had adequately translated the design details of the THSC models to the associated fabrication drawings. Specifically, the team reviewed licensing drawings THSC-MP-1, Revision 0 and THSC-BB-1, Revision 0, and compared the licensing drawing to the related fabrication drawings.

b. Observations and Findings

The team assessed that overall, INC assigned design responsibilities appropriately and the engineering service contractor was effectively implementing INC's design control program. The team also assessed that implementing procedures were in place and effective in controlling activities in accordance with the applicable regulations and approved CoC. No issues of significance were identified.

c. Conclusions

The team concluded that INC was effectively implementing their design control program.

3. Fabrication Controls

3.1 Procurement Controls

a. Scope

The team reviewed INC's procurement of ITS, Category A materials and services, which included the review of procurement documents, material traceability, drawings and procedures, and receipt inspection records. The team reviewed INC's procedure, QP 7.1, "Control of Purchased Items, Materials and Services," Revision 5, associated with procurement, including commercial grade dedication for both materials and services to verify if they were being properly implemented. The team also reviewed INC's approved suppliers list (ASL) to determine if materials and services were being procured from qualified suppliers and the suppliers were being acceptably qualified.

The team selected a sample of qualified suppliers and ITS, Category A materials and services for review.

b. Observations and Findings

The team reviewed procurement controls associated with an ITS, Category A THSC Mounting Plate and reviewed shop traveler, S/N 002, dated 4/24/21. This included INC's verification of conformance to the procurement documents by receipt inspection and commercial grade dedication of the ITS, Category A, MP-1/Mounting Plate (heat no. E38963) and noted the critical characteristic for independent verification as 1) material grade and 2) dimensions (e.g., thickness, diameter, and threads). INC verified the material grade to a standard specification for chromium and chromium-nickel stainless steel plate (e.g., American Society for Testing and Materials (ASTM) A240, Type 304) using an alloy analyzer device. The team requested the procedure INC used to perform the material grade test, however, INC stated that a documented procedure was not used for this test. The team also noted that an alloy analyzer has been used to perform material testing internally to INC without a documented instruction or procedure since 2011. The team considered this a violation of NRC requirements. Specifically, 10 CFR 71.111, "Instructions, procedures, and drawings."

10 CFR 71.111, "Instructions, procedures, and drawings" states, in part, that the certificate holder (INC) shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and

shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

Contrary to, as of 2011, INC failed to prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished. Specifically, INC failed to adequately prescribe material testing performed by an alloy analyzer device by a documented instruction or procedure when the device was used as a method to verify and dedicate material property conformance to the approved requirements.

The team assessed the significance of the violation using the NRC Enforcement Policy and Manual. The team determined that the violation was more than minor because of the potential for a material test being performed improperly due to the lack of a quality procedure to adequately control the process. The team characterized the violation as a Severity Level IV violation in accordance with the NRC's Enforcement Policy, Section 6.8. The team noted this issue was entered into INC's CAP as CAR 21-002, but as described in Section 1.3, is being cited in the enclosed Notice as an example of the violation of 10 CFR 71.111 for inadequate procedures.

The team also reviewed the design engineering services INC procured from AREVA Federal Services (AFS), now known as Orano Federal Services, for THSC design qualification, test unit fabrication, and testing/licensing support. Specifically, the team reviewed INC's purchase order (No. 56) and scope of work and noted that all AFS' services were performed under the controls of INC's NRC approved QAP, except for testing services which were subcontracted. The team also noted that the responsibility for final products of the projects (e.g., drawings, documents, test units, safety analysis report) resided with INC in that INC invoked and implemented numerous purchase order/contract conditions requiring INC approval (e.g., ITS drawings, calculations, and analysis reports) in support of contracted services. However, the team identified during the review of the ASL that INC's basis for acceptance of AFS' thermal and shielding calculations as part of the design services provided from AFS for the THSC, was based on QA program review, history of use (e.g., performance), and that AFS had an NRC approved QAP.

The team identified that INC failed to perform an adequate supplier audit of AFS to assess and verify adequate implementation of their QA program in support of engineering services and testing provided to INC for quality work performed for the THSC packaging due to the fact that INC qualified AFS because it has an NRC approved QAP. The team noted that INC procedure, QP 7.1, "Control of Purchased Items and Services," Revision 5, Step 6.4 allows a supplier to be approved based solely on the supplier's NRC approved QAP, which is not an adequate supplier qualification method that meets the requirements of 10 CFR 71.115 for control of purchased material, equipment, and services. The team considered this a violation of NRC requirements. Specifically, 10 CFR 71.111, "Instructions, procedures, and drawings."

10 CFR 71.111, "Instructions, procedures, and drawings" states, in part, that the certificate holder (INC) shall prescribe activities affecting quality by documented

instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

Contrary to, as of 2011, INC failed to prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished. Specifically, INC failed to adequately prescribe the appropriate supplier qualification methods by including an allowance in QP 7.1 for qualification of a supplier based solely on having an NRC approved QAP.

The team assessed the significance of the violation using the NRC Enforcement Policy and Manual. The team determined that the violation was more than minor because of the potential for not identifying supplier issues during implementation of their QAP applicable to the procured services because adequate supplier audits were not performed at the required intervals. The team characterized the violation as a Severity Level IV violation in accordance with the NRC's Enforcement Policy, Section 6.8. This violation is being cited in the enclosed Notice as an example of the violation of 10 CFR 71.111 for inadequate procedures.

c. Conclusions

The team identified two examples of a violation of NRC requirements concerning the failure to (1) adequately prescribe material testing performed by an alloy analyzer device for material dedication activities by a documented instruction or procedure; and (2) to adequately prescribe the appropriate supplier qualification methods by including an allowance in QP 7.1 for qualification of a supplier based solely on having an NRC approved QAP.

3.2 Fabrication and Assembly

a. Scope

The team reviewed records associated with fabrication (welding) and visual examinations as well as material storage controls to verify that all phases of the fabrication, inspection and storage processes were properly controlled and implemented. The records reviewed included Welding Procedure Specification and Procedure Qualification Record 17-98-001 and PQR-THC-001, "Gas Tungsten Arc Welding (GTAW)," Revision 0, dated 12/17/98 used in production welding of IR-50 device changers and IR-100 exposure devices. Route cards were reviewed to verify that fabrication and test activities were accomplished and appropriately documented according to controlled drawings, work instructions and quality procedures. The team also reviewed qualification and certification records of an INC visual weld examiner and a welder.

b. Observations and Findings

No issues of significance were identified.

c. Conclusions

INC's implementation of fabrication controls for fabrication and assembly, including examinations and material storage, was assessed to be adequate. The team determined that welder/welding operators were appropriately qualified according to ASME Code Section IX requirements and that welders met the current qualification requirements for the processes in use on the shop floor.

3.3 Test and Inspection

a. Scope

The team reviewed INC processes and procedures that address testing of the THSC packaging, and traceability and receipt inspection of ITS, Category A material used in fabrication of IR-100 and THSC packagings. The team selected various components including, but not limited to, depleted uranium shields; a THSC body sub-assembly and package assembly; various mounting plate assemblies; weld wire; IR-100 exposure device manufacturing travelers; and an alloy analyzer calibration standard.

b. Observations and Findings

The team reviewed the AFS Test Procedure for the THSC, No. TPR-3019210 specific to free and puncture drop tests for qualifying the THSC to the requirements of 10 CFR Part 71. The results of the tests were utilized in supporting documentation for the THSC application for an NRC Part 71 CoC. Testing was utilized to demonstrate shield integrity after normal and hypothetical accident conditions including free drop and puncture tests. The team also determined that the purchase orders associated with the inspection records reviewed were adequate and specified the applicable criteria and requirements including Part 21. No issues of significance were identified.

c. Conclusions

The team assessed that INC had adequate controls for package testing, material traceability, procurement, and receipt inspection.

3.4 Tools and Equipment

a. Scope

The team reviewed selected measuring and test equipment (M&TE) including interviews of responsible personnel and review of records and procedures to assure that equipment used in activities affecting quality were properly controlled and calibrated. The team reviewed QP 12.1, “Control of Measuring and Test Equipment,” Revision 1, which prescribes activities and requirements concerning use of M&TE; calibration occurs to

higher accuracy standards; equipment identification; maintenance of records of various tools and equipment used; and actions to take when M&TE is found out of calibration.

The team compared a sampling of M&TE used for quality activities to the applicable requirements of QP 12.1. The M&TE selected consisted of a digital caliper, micrometer, and torque wrench. In addition, the team verified that if the M&TE had been sent offsite for calibration that the calibration service providers were current on INC's ASL.

b. Observations and Findings

No issues of significance were identified.

c. Conclusions

The team concluded that the M&TE quality procedure being implemented at INC provided adequate guidance for M&TE calibration and use, and INC adequately implemented M&TE calibration, tracking, and use requirements.

4. Entrance and Exit Meeting

On May 25, 2021, the NRC inspection team discussed the scope of the inspection during an entrance meeting with Mr. Mike Rose and other members of the INC staff. On May 27, 2021, the NRC inspection team presented the inspection results and observations during an onsite preliminary exit meeting. On June 25, 2021, the NRC inspection team conducted a final telephone conference exit with Mr. Mike Rose. 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

Name	Title	Affiliation	Entrance	Exit	Re-exit
Jeremy Tapp	Inspection Team Leader	NRC/DFM	X	X	X
Marlone Davis	Inspector	NRC/DFM	X	X	
Earl Love	Inspector	NRC/DFM	X	X	X
Mike Rose	QA Manager	INC	X	X	X
Ron Monteforte	Quality Management Consultant	INC	X	X	X

2. INSPECTION PROCEDURES USED

IP 86001	Design, Fabrication, Testing, and Maintenance of Transportation Packagings
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

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description
71-0062/2021-201-01	Opened	NOV	Failure to promptly correct and close CAR 2016-001
71-0062/2021-201-02	Opened	NOV	Failure to follow corrective action and audit procedures to enter a violation in the CAP and perform the 2016 internal audit
71-0062/2021-201-03	Opened	NOV	Failure to have adequate procedures in document control of quality records, material testing with an alloy analyzer, and allowable supplier qualification methods

4. LIST OF ACRONYMS USED

ADAMS	Agencywide Documents Access and Management System
AFS	AREVA Federal Services
ASL	Approved Suppliers List
ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
CAP	Corrective Action Program
CAR	Corrective Action Report
CFR	Code of Federal Regulations

CoC	Certificate of Compliance
IP	Inspection Procedure
ITS	Important-to-Safety
M&TE	Measuring and Test Equipment
NCR	Nonconformance Report
NOV	Notice of Violation
NRC	Nuclear Regulatory Commission
QA	Quality Assurance
QAP	Quality Assurance Program
QP	Quality Procedure
SSCs	Structures, Systems, and Components
THSC	Ten Hole Source Changer

5. DOCUMENTS REVIEWED

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

NOTICE OF VIOLATION

Industrial Nuclear Co., Inc.
San Leandro, CA

Docket No. 07100062
EA-2021-091

During an NRC inspection conducted on May 25 to June 25, 2021 three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 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.

Contrary to the above, as of 2016, INC failed to establish measures to assure that a condition adverse to quality was promptly corrected when required QA program areas not reviewed during the 2015 internal audit and documented in CAR 2016-001 were not corrected during the planned 2016 internal audit or thereafter.

This is a Severity Level IV violation (Section 6.8).

B. 10 CFR 71.111, “Instructions, procedures, and drawings” states, in part, that the certificate holder shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed.

Contrary to the above, as of 2016, INC failed to follow quality related procedures as evidenced by the following examples:

1. QP 16.1, “Corrective Action,” Revision 3, Step 6.2 states, in part, in cases where the adverse condition is not identified and being corrected by some other form of documentation, the Quality Assurance Manager shall identify the adverse condition on a CAR. Specifically, INC failed to document a condition adverse to quality on a CAR to enter it into their CAP, in which the issue was identified by the NRC during the previous 2017 follow-up inspection for failure to receive prior NRC approval for an IR-100 CoC change.

2. QP 18.1, "Audits and Commercial Grade Surveys," Revision 3, Step 6.1.1, states, in part, that all elements of the QA program shall be audited within a 12-month period. Specifically, INC failed to perform an audit within a 12-month period by not performing an internal audit of the QA program in 2016.

This is a Severity Level IV violation (Section 6.8).

C. 10 CFR 71.111, “Instructions, procedures, and drawings” states, in part, that the certificate holder (INC) shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

Contrary to the above, as of 2011, INC failed to prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished as evidenced by the following examples:

1. QP 6.1, “Document Control,” Revision 5 and QP 17.1, “Quality Assurance Records,” Revision 3 establish the methods for the control of documents and requirements for the classification, filing, storage, retention, and disposition of quality records generated by INC. Specifically, INC failed to maintain control of quality documentation such as audits and receipt inspections and describe how to control electronic quality records and other generated quality documentation in QP 6.1 and QP 17.1, respectively, such that the documents were readily retrievable.

2. INC failed to adequately prescribe material testing performed by an alloy analyzer device by a documented instruction or procedure when the device was used as a method to verify and dedicate the material property conformance to the approved requirements.

3. INC failed to adequately prescribe the appropriate supplier qualification methods by including an allowance in QP 7.1, “Control of Purchased Items and Services,” Revision 5, Step 6.4, for qualification of a supplier based solely on having an NRC approved QAP, which is not an adequate supplier qualification method that meets the requirements of 10 CFR 71.115 for control of purchased material, equipment, and services.

This is a Severity Level IV violation (Section 6.8)

Pursuant to the provisions of 10 CFR 2.201, Industrial Nuclear Co., Inc., 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 Francis Paul Peduzzi, 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-2021-091” 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 in the NRC’s Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-

rm/adams.html. To the extent possible, your response 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 this 9 day of August 2021.