



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

July 13, 2023

Mike Sanchez, Vice President
& General Manager
Source Production & Equipment
Company, Inc.
113 Teal Street
St. Rose, LA 70087

SUBJECT: SOURCE PRODUCTION & EQUIPMENT COMPANY–U.S. NUCLEAR
REGULATORY COMMISSION INSPECTION REPORT NO. 71-0102/2023-201

Dear Mike Sanchez:

This letter refers to the inspection conducted by the U.S. Nuclear Regulatory Commission (NRC) on May 15–18, 2023, at the Source Production & Equipment Company (SPEC) facility in St. Rose, LA. The inspection team continued the inspection activities with an in-office review and held an exit meeting on June 1, 2023, with you and other members of your staff. The purpose of the inspection was to verify and assess the adequacy of SPEC's activities associated with the transportation of radioactive material and 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 SPEC's NRC approved Certificate of Compliances (CoC) and Quality Assurance Program (QAP). 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 two Severity Level IV violations of NRC requirements occurred. Because SPEC initiated corrective actions to address these issues, these violations are being treated as Non-Cited Violations (NCVs), consistent with Section 2.3.2 of the Enforcement Policy. These NCVs are described in the subject inspection report. If you contest the violations or significance of these NCVs, you should provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Director, Office of Nuclear Material Safety and Safeguards; and (2) the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

As discussed with you and your staff on June 1, 2023, the NRC staff plans to perform at a minimum, annual status calls to determine whether adequate and timely corrective actions are being taken as a result of the inspection findings that were identified. If the NRC staff determines that adequate or timely progress is not being made, the NRC will consider an

increased routine inspection frequency and communicate to you the decision, along with the basis. If the NRC decides to increase the routine inspection frequency, it will be performed in accordance with 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," which is consistent with our inspection program policy.

In accordance with 10 CFR Part 2 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room (PDR) or from Publicly Available Records component of the NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. The PDR is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays. 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,



Signed by Jordan, Natreon
on 07/13/23

Natreon Jordan, Acting Chief
Inspection and Oversight Branch
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

Docket No. 71-0102

Enclosure:
Inspection Report No. 71-0102/2023-201

cc w/Encl: Kristen Bonds, Regulatory
Manager & Assistant RSO

SUBJECT: SOURCE PRODUCTION & EQUIPMENT COMPANY–U.S. NUCLEAR
REGULATORY COMMISSION INSPECTION REPORT NO. 71-0102/2023-201

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

Inspection Report

Docket No.: 71-0102

Report No.: 71-0102/2023-201

Enterprise Identifier: I-2023-201-0015

Certificate Holder: Source Production & Equipment Company, Inc.

Location: St. Rose, LA

Inspection Dates: May 15–18, 2023

Inspectors: Jeremy Tapp, Transportation and Storage Safety Inspector,
Team Leader
Marlone Davis, Senior Transportation and Storage Safety
Inspector
Azmi Djapari, Transportation and Storage Safety Inspector
(Trainee)
Andres Rowe, General Engineer NRAN (Observer)

Approved by: Natreon Jordan, Acting Chief
Inspection and Oversight Branch
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

Enclosure

EXECUTIVE SUMMARY

Source Production & Equipment Company NRC Inspection Report 71-0102/2023-201

This routine inspection performed at Source Production & Equipment Company's (SPEC's) facility in St. Rose, LA from May 15–18, 2023, with additional in-office review through June 1, 2023, evaluated the ongoing activities related to the design, fabrication, and maintenance of transportation packages for radioactive materials. The purpose of the inspection was to verify and assess the adequacy of SPEC'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," SPEC's U.S. Nuclear Regulatory Commission (NRC) approved Certificates of Compliance (CoCs) and associated Safety Analysis Reports (SARs), and SPEC's NRC approved Part 71 Quality Assurance Program (QAP).

Based on the results of this inspection, the NRC inspection team assessed that overall, the implementation of SPEC's QAP was adequate. However, two Severity Level IV violations of the NRC requirements were identified by the team in the areas of package design control and instructions, procedures, and drawings. 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 overall, the quality assurance controls at SPEC, which primarily includes the Quality System Procedures Manual (QSPM), were generally adequate and implemented in a graded approach, as defined in the QAP.

The team concluded that SPEC effectively implemented its nonconformance control program and corrective action program (CAP) and had adequate procedures in place to ensure compliance with the applicable regulations and QAP requirements.

Overall, the team concluded that SPEC was adequately implementing its document control and records program and has adequate procedures in place to meet the applicable regulations and QA program requirements. However, the team identified this as an area for improvement. One Severity Level IV violation was identified for failure to follow procedures to adequately store quality records, so they were free from environmental threats.

The team concluded that SPEC had an adequate audit program in place to schedule, evaluate, and document the results. The team determined that SPEC appropriately identified issues and documented them in the CAP as required.

Design Controls

Although there were no design modifications that have been made, the team concluded that SPEC has adequate procedures in place to initiate design and drawing changes through a review process, and to digitally record signatures and approvals by responsible personnel in their MQ1 system. Overall, the team concluded that SPEC adequately implemented its design control program. However, the team identified this as an area for improvement. One Severity Level IV violation was identified for failure to properly categorize the sealed source capsule as an important-to-safety (ITS) Category A component as it performs the function of the primary

containment vessel, and instead, categorized it as ITS Category T, which is not equivalent to ITS Category A in procurement controls, with no documented engineering justification.

Fabrication Controls

The team concluded that materials, components, and other equipment received met the SPEC procurement specifications, and the procurement specifications conform to the design commitments and requirements contained in the packaging SARs and CoCs.

The team concluded that SPEC personnel were familiar with the designated fabrication techniques, testing requirements, and quality control associated with the fabrication, test, and inspection of the SPEC-300 packaging.

The team concluded that SPEC used suitable calibrated equipment to conduct fabrication and maintenance activities. The team also noted that SPEC identified, specified, and controlled tools and equipment in accordance with their quality implementing procedures and regulatory requirements.

Maintenance Controls

The team concluded that SPEC personnel effectively implemented a maintenance control program in accordance with their NRC approved QAP, work instructions, and requirements contained in the packaging SAR and CoC for the SPEC-150 and SPEC-300.

REPORT DETAILS

1. Management Controls

1.1 Quality Assurance Policy

a. Inspection Scope

The team reviewed the SPEC part 71 QAP, "Quality Assurance Program," Revision 5 and QSPM that contains SPEC's implementing procedures to assess the adequacy and effectiveness of SPEC's QAP implementation. The team conducted reviews of SPEC's quality program, policies, and procedures, to determine whether activities subject to 10 CFR part 71 were adequately controlled and implemented under SPEC's NRC approved QAP. The team also reviewed the QAP to determine if changes were made and if so, were performed in accordance with the requirements of 10 CFR 71.106, as applicable.

The team reviewed the QAP authorities and responsibilities to determine if they were clearly defined and documented, and the QA organization functioned as an independent group. In addition, the team reviewed the QAP to determine if commercial grade dedication activities are performed by SPEC.

The team reviewed SPEC's graded approach to quality as documented in the QAP to verify SPEC identified important-to-safety components in its packaging designs in a graded approach as described.

b. Observations and Findings

The team assessed that SPEC had a QA program and implementing procedures in place that were generally effective in conducting activities in accordance with SPEC's NRC-approved QAP and CoCs as well as part 71 requirements. The team verified that the QA organization operated in a manner sufficiently independent from cost and schedule, when opposed to safety considerations. The team determined that no changes to the NRC-approved QAP occurred since the last NRC inspection in 2018.

The team found that SPEC used a graded approach to categorize components important-to-safety in its packaging designs. The team reviewed the adequacy of the categorizations as a part of the design control review documented in section 2 of this report. The team noted that SPEC does not currently implement a commercial grade dedication program for parts or services.

No issues of significance were identified.

c. Conclusions

The team determined that overall, the QA controls at SPEC, which primarily includes the QSPM, were generally adequate and implemented in a graded approach, as defined in the QAP.

1.2 Nonconformance and Corrective Action Controls

a. Inspection Scope

The team reviewed a sample of SPEC's nonconformance reports (NCRs) and corrective/preventive action reports (CPARs) and interviewed selected personnel to verify that SPEC effectively implemented their nonconformance control program and CAP. The review included an evaluation of how SPEC's nonconformance control program and CAP addressed materials, parts, and components that do not conform to requirements and identified quality deficiencies. The team also reviewed provisions for reporting defects that could cause a substantial safety hazard. The team reviewed the following SPEC quality procedures and work instructions:

- QSPM section 15.0, "Control of Nonconforming Product and Service," revision 9
- QSPM section 16.0, "Improvement, Corrective and Preventive Action," revision 14
- QSPM section 15.1, "Reporting and Defect Notification," revision 14
- Work Instruction No. QA51, "Root Cause Analysis," revision 2

The team reviewed NCRs and CPARs since the last NRC inspection in 2018 and reviewed two CPARs written because of issues identified during the 2018 inspection. The team discussed the nonconformances and corrective actions with the SPEC staff to understand the process. The team focused the NCR review on use-as-is and repair type dispositions to evaluate how SPEC technically justified the NCRs reviewed. The CPARs were reviewed to determine whether SPEC completed corrective actions for identified deficiencies in a technically sound and timely manner. The team also toured the SPEC facility to review the controls in place for control of nonconforming items and verified items with open NCRs were adequately controlled. In addition, the team requested a list of part 21 evaluations and notifications associated with the SPEC transportation packagings. The team also reviewed postings within the SPEC facility to determine if SPEC complied with the 10 CFR 21.6, "Posting requirements."

b. Observations and Findings

The team found that SPEC had adequate procedures and controls in place for identifying, writing, and dispositioning NCRs and for reporting defects that could cause a substantial safety hazard. The team noted that there were no part 21 reports issued since the previous inspection.

The team assessed that SPEC had adequate procedures and controls in place for identifying and writing CPARs, documenting corrective action(s) taken, performing causal analyses as necessary, documenting corrective actions and actions taken to prevent recurrence as applicable, and performing CPAR closure verification.

No issues of significance were identified.

c. Conclusions

The team concluded that SPEC effectively implemented its nonconformance control program and CAP and had adequate procedures in place to ensure compliance with the applicable regulations and QAP requirements.

1.3 **Documentation Controls**

a. Inspection Scope

The team reviewed SPEC's documentation control program to assess the effectiveness of controls established for the approval, issuance, revision, and use of quality documents. The team reviewed SPEC's instructions and procedures regarding the control of documents and quality records, and interviewed responsible personnel to verify that documents are retained and located in areas consistent with the instructions and procedures. The team reviewed the following SPEC quality procedures and work instructions:

- QSPM Section 6.0, "Document Control," revision 16
- QSPM Section 17.0, "Control of Quality Documents and Records (ISO 4.2 and 6.2)," revision 13
- Work Instruction No.: QA01, "Document Control and Security System," revision 7
- Form: QA01F1, "List of Quality Records," revision 13
- Work Instruction No. QA02, "Lost Document or Record Instruction," revision 4

The team verified that document changes and approvals are properly signed, dated, and recorded on the MQ1 system. The team also toured areas of the facility where quality documents are stored to verify the documents are being stored as required by SPEC's quality procedures and instructions.

b. Observations and Findings

That team noted that due to the effects of Hurricane Ida in 2021, storage cabinets were moved to temporary locations on site. SPEC is currently in the process of reorganizing them and will update QA01F1, "List of Quality Records," as appropriate.

SPEC also identified that external audits and approved supplier evaluation records were lost to the storm and entered the issue into their CAP. However, the team identified that prior to the storm, SPEC had not stored these records per QSPM section 17.0, which resulted in the loss of records, and this specific issue was not documented in the CAP. The filing and storage section of QSPM, section 17.0, states, in part, that quality records shall be filed in storage devices/areas free from environmental threats such as water leaks and open doors posing a threat from outside winds.

The team determined this was a violation of 10 CFR 71.111, "Instructions, procedures, and drawings," which requires, 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, in August 2021, the certificate holder (SPEC) did not follow the filing and storage section of QSPM section 17.0 and quality records were lost due to Hurricane Ida. Specifically, some quality records were not filed in storage devices/areas free from environmental threats as required.

The team dispositioned the violation using the traditional enforcement process in section 2.3 of the NRC Enforcement Policy. The team determined that the violation was of more-than-minor safety significance in accordance with Inspection Manual Chapter (IMC) 0617, "Vendor and Quality Assurance Implementation Inspection Reports," appendix E, "Minor Examples of Vendor and QA Implementation Findings," Example 17a, because actual required records were lost or damaged, and SPEC could not easily re-create the records with reasonable assurance of their accuracy. The team characterized the violation as a Severity Level IV violation in accordance with the NRC's Enforcement Policy, section 6.5. SPEC entered the issue into its CAP under CPAR #00172. Because this violation was of low safety significance, was entered into SPEC's CAP, and the issue was not repetitive or willful, this violation was treated as a NCV, consistent with Section 2.3.2.a of the NRC Enforcement Policy. **(71-0102/2023-201-01)**

c. Conclusions

Overall, the team concluded that SPEC was adequately implementing its document control and records program and has adequate procedures in place to meet the applicable regulations and QAP requirements. However, the team identified this as an area for improvement. One Severity Level IV violation was identified for failure to follow procedures to adequately store quality records, so they were free from environmental threats.

1.4 **Audit Program**

a. Inspection Scope

The team reviewed SPEC's audit program to determine if SPEC scheduled, planned, and performed internal audits in accordance with the applicable regulations and QAP requirements. The team also reviewed the qualification records to determine if they met the QAP and procedure requirements. The team reviewed SPEC's quality procedure QSPM Section 18.0, "Internal Quality Audits," revision 18.

The team reviewed a sample of audit schedules since 2018 to verify that all 18 QAP criteria were planned to be audited, as applicable, each year. The team reviewed and assessed a sample of the internal audits completed since the last inspection to determine if they were performed in accordance with quality procedures, used qualified lead auditors independent of the areas being reviewed, and if there were identified deficiencies, whether SPEC adequately addressed these deficiencies within the CAP.

The team reviewed the current procedure for the qualification of audit personnel and reviewed a sample of lead auditor qualification records to determine if they met the applicable QAP requirements.

b. Observations and Findings

Overall, the team assessed that for the audits sampled, SPEC conducted them with qualified and certified personnel, were comprehensive in nature, and covered a representative sample of SPEC's activities in the area being audited.

No findings of significance were identified.

c. Conclusions

The team concluded that SPEC had an adequate audit program in place to schedule, evaluate, and document the results. The team determined that SPEC appropriately identified issues and documented them in the CAP as required.

2. **Design Controls**

a. Inspection Scope

The team interviewed responsible personnel and reviewed selected design documentation to verify that SPEC is adequately implementing their design control program. The team reviewed the following SPEC quality procedures and work instructions:

- QSPM section 3.0, "Design Control & Product Realization," revision 16
- QSPM section 3.1, "Verification and Validation," revision 1
- EG03, "Change Requests for Engineering Documents," revision 15
- EG05, "Engineering Change Notice," revision 5

b. Observations and Findings

The team reviewed the ITS categories documented for structures, systems, and components for both the SPEC-150 and SPEC-300 packagings that SPEC holds a CoC. The team noted that the sealed source capsule, which is credited in the SAR as the primary containment vessel for both the SPEC-150 and SPEC-300 packagings, was not properly categorized as an ITS Category A component per NRC's guidance in NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety." SPEC classified the sealed source capsule as ITS Category T, which is an internal SPEC categorization and is not equivalent to ITS Category A requirements, specifically in procurement controls. In addition, the team noted that SPEC did not perform an engineering evaluation to support the assignment of the sealed source capsule as ITS Category T.

The team determined that this was a violation of 10 CFR 71.107, "Package design control," which requires, in part, that the certificate holder shall establish measures to assure that applicable regulatory requirements and the package design, as specified in the CoC for those materials and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. 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 the materials, parts, and components of the packaging that are ITS.

Contrary to the above, since May 2023, SPEC failed to establish measures to assure that appropriate quality standards were specified and included in design documents. Measures were also not established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the materials, parts, and components of the packaging that are important-to-safety. Specifically, SPEC did not perform an engineering evaluation and provide sufficient justification to support the assignment of ITS Category T to the sealed source capsule, which is defined as the primary containment vessel in the SPEC-150 and SPEC-300 SARs. The sealed source capsule was not properly classified as ITS Category A to ensure all required procurement controls are applied.

The team dispositioned the violation using the traditional enforcement process in section 2.3 of the NRC Enforcement Policy. The team determined that the violation was of more-than-minor safety significance in accordance with IMC 0617, appendix E, Example 4a because the design change requires evaluation to determine whether the component can perform its intended safety function or meet its original qualifications. The team characterized the violation as a Severity Level IV violation in accordance with the NRC's Enforcement Policy, section 6.5. SPEC entered the issue into its CAP under CPAR #00178. Because this violation was of low safety significance, was entered into SPEC's CAP, and the issue was not repetitive or willful, this violation was treated as an NCV, consistent with section 2.3.2.a of the NRC Enforcement Policy. **(71-0102/2023-201-02)**

c. Conclusions

Although there were no design modifications that have been made, the team concluded that SPEC has adequate procedures in place to initiate design and drawing changes through a review process, and to digitally record signatures and approvals by responsible personnel in their MQ1 system. Overall, the team concluded that SPEC adequately implemented its design control program. However, the team identified this as an area for improvement. One Severity Level IV violation was identified for failure to properly categorize the sealed source capsule as an ITS Category A component as it performs the function of the primary containment vessel. Instead, it was categorized as ITS Category T, which is not equivalent to ITS Category A in procurement controls, with no documented engineering justification.

3. **Fabrication Controls**

3.1 **Material Procurement**

a. Inspection Scope

The team reviewed SPEC's processes that addressed procurement, including receipt inspection, traceability of material, and commercial grade dedication, as applicable. The team reviewed selected drawings and records and interviewed personnel to verify that SPEC's procurement specification for materials, fabrication, and inspection met design commitments and requirements contained in the packaging SARs and CoCs. The team

reviewed quality system procedures, receipt inspection records, and sampled Purchase Orders (POs). The team reviewed the following documents:

- QSPM section 4.0, "Procurement Documents," revision 13
- QSPM section 7.0, "Control of Purchased Materials," revision 7
- QSPM section 8.0, "Product Identification, Traceability and Serialization," revision 15
- Drawing 15B002A, "SPEC-150 Exposure Device," revision 9
- Drawing 19B000, Sheets 1-8, "General Arrangement SPEC-300," revision 5
- Drawing B190700, Sheet 1, "DU Shield – Co-60 SPEC-300," revision 5
- Approved Suppliers List, revision 81
- PO No. 000940–SPEC-150 Source Capsule
- PO No. 000925–Byers Precision Fabricators (Enclosure Base for SPEC-300)
- PO No. 000930–Aerojet (Depleted Uranium Shields)
- PO No. 001029–Urethane Technology (Polyurethane Foam)

b. Observations and Findings

Overall, the team assessed that SPEC had adequate control of the procurement process for the ITS components selected and reviewed. The team determined that SPEC procured ITS components consistent with design requirements and their QA implementing procedures and work instructions. SPEC's material traceability, procurement, and receipt inspection controls were adequate. The team assessed that the POs were adequate and specified the applicable criteria and requirements including Part 21, as applicable based on the ITS category. The material ordered and received at the facility met the design requirements. Additionally, SPEC verified and maintained the traceability throughout the procurement and receipt process. The team also determined that SPEC purchased and applied controls based on SPEC's approved suppliers list.

No issues of significance were identified.

c. Conclusions

The team concluded that materials, components, and other equipment received met the SPEC procurement specifications, and the procurement specifications conform to the design commitments and requirements contained in the packaging SARs and CoCs.

3.2 **Fabrication and Assembly**

a. Inspection Scope

The team reviewed selected drawings, procedures, and records, and observed selected activities related to the SPEC-300 fabrication and assembly to determine if the fabrication, testing, and any maintenance activities met SAR design commitments and the requirements documented in the CoC. The team selected the enclosure base and cover assembly activity for the SPEC-300 to observe because those fabrication activities occurred during the onsite inspection. The team reviewed and observed the following documents and activities:

- QSPM section 5.0 “Instructions, Procedures, and Engineering Documents,” revision 10
- QSPM section 9.0, “Control of Special Processes,” revision 15
- Drawing 19B000, Sheets 1-8, “General Arrangement SPEC-300,” revision 5
- Manufacturing Traveler, “Final Assembly, SPEC-300 (190601),” revision 38
- Gas Tungsten Arc Welding (GTAW) of the enclosure base to the enclosure cover
- Liquid penetration and visual nondestructive examinations (NDEs) of the welding activity

b. Observations and Findings

Based on the sample selected and observed, the team assessed that SPEC established appropriate means to control the SPEC-300 fabrication activities and special processes that met the SAR design commitments and requirements documented in the CoC. The team examined SPEC’s fabrication specification, design and fabrication drawings, work control procedures, and travelers and confirmed that the fabrication and testing activities were adequate. The team noted that the shop manufacturing travelers identified the applicable drawings, part numbers, work instructions, and qualified personnel applicable to the fabrication and assembly activities.

No issues of significance were identified.

c. Conclusions

The team concluded that SPEC personnel were familiar with the designated fabrication techniques, testing requirements, and quality control associated with the fabrication of the SPEC-300 packaging.

3.3 **Test and Inspection**

a. Inspection Scope

The team observed activities for the test and inspection of the SPEC-300 of the enclosure base and cover to verify that SPEC performed these tasks in accordance with approved methods, procedures, and specifications. The team reviewed the test and inspection process through observations of welding, assembly, and NDEs, and personnel interviews of the activities as described above. The team reviewed the following quality procedures and work instructions:

- QSPM section 9.0, “Control of Special Processes,” revision 15
- QSPM section 11.0, “Testing,” revision 10
- QA27, “Visual Weld Inspection,” revision 10
- QA28, “Liquid Penetrant Procedure for Solvent Removable Visible,” revision 10
- QA63, “Written Practice for the Qualification and Certification of NDE Personnel,” revision 1
- PR22, “GTAW – Welding Procedure Specification,” revision 7

b. Observations and Findings

The team assessed that the SPEC established appropriate means to control the SPEC-300 fabrication and special processes for test and inspection activities. The team noted that SPEC implemented their QAP, quality procedures, and special processes with qualified personnel, using approved procedures for assembly, welding, and testing. The team also assessed that SPEC provided the appropriate information on shop manufacturing travelers in accordance with approved quality procedures.

No issues of significance were identified.

c. Conclusions

The team concluded that SPEC personnel were familiar with the designated fabrication techniques, testing requirements, and quality control associated with the test and inspection of the SPEC-300 packaging.

3.4 **Tools and Equipment**

a. Inspection Scope

The team reviewed the control of measuring and test equipment (M&TE) program to evaluate how the SPEC identified, specified, and controlled tools and equipment in accordance with their QAP, implementing standard procedures, and regulatory requirements. Specifically, the team reviewed the following quality standard procedure:

- QSPM section 12.0, "Control of Inspection, Measuring, and Test Equipment," revision 13

The team selected a sample of the M&TE used during the assembly and testing of the SPEC-300 packaging. The sample included a review of travelers that identified the use of specific M&TE that the team selected such as a light meter, thread gauge, and caliper. The team reviewed the calibration records to verify calibration dates, testing standards, and traceability of the associated M&TE.

b. Observations and Findings

The team determined that there the M&TE being used was within the calibration dates for use, and for the items selected the team noted that the M&TE were properly labeled with calibration history recorded per quality procedures.

No issues of significance were identified.

c. Conclusions

The team concluded that SPEC used suitable calibrated equipment to conduct fabrication and maintenance activities. The team also noted that SPEC identified, specified, and controlled tools and equipment in accordance with their quality implementing procedures and regulatory requirements.

Maintenance Controls

a. Inspection Scope

The team reviewed selected records and interviewed personnel to verify that SPEC personnel effectively implemented a maintenance control program in accordance with their NRC approved QAP and requirements contained in the packaging SAR and CoC for the SPEC-150 and SPEC-300. The team performed a review of maintenance records related to the packagings and observed an operational test of the lock cap and device lock. The team reviewed the following quality implementing procedures and maintenance instructions:

- QSPM section 10.0, "Inspection," revision 14
- QA45, "Model #7 Connector and G-60 Pigtail Inspections," revision 20
- SH09, "Returned or Reported Malfunctioning Equipment/Material," revision 18

b. Observations and Findings

Based on a review of the maintenance records and procedures, the team assessed that SPEC used appropriate maintenance materials, tools, and equipment to conduct the annual maintenance activities for the SPEC-150. The team verified that the inspections were comprehensive and met acceptance criteria for tests identified in the maintenance records and procedures. The team verified that SPEC appropriately inspected attributes of the lock cap and device lock. The team also verified that maintenance personnel and technicians recorded the proper information on the applicable forms and data sheets as defined and required in the SPEC quality and maintenance instructions. The team assessed that the maintenance tests satisfied the requirements identified in the SPEC-150 SAR and CoC.

No issues of significance were identified.

c. Conclusions

The team concluded that SPEC personnel effectively implemented a maintenance control program in accordance with their NRC approved QAP, work instructions, and requirements contained in the packaging SAR and CoC for the SPEC-150 and SPEC-300.

4. Entrance and Exit Meeting

On May 15, 2023, the NRC inspection team discussed the scope of the inspection during an entrance meeting with Mike Sanchez and other members of the SPEC staff. On May 18, 2023, the NRC inspection team presented the inspection results and observations during an onsite debrief. On June 1, 2023, the NRC inspection team conducted a final telephone conference exit with Mike Sanchez and other members of SPEC staff. 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	Onsite Debrief	Exit
Jeremy Tapp	Inspection Team Leader	NRC	X	X	X
Marlone Davis	Inspector	NRC	X	X	X
Azmi Djapari	Inspector (Trainee)	NRC	X	X	X
Andres Rowe	Observer	NRC		X	
Mike Sanchez	Vice President & General Manager	SPEC	X	X	X
Kristen Bonds	Regulatory Manager & Assistant RSO	SPEC	X	X	X

2. INSPECTION PROCEDURES AND OTHER NRC DOCUMENTS 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

<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
71-0102/2023-201-01	Opened and Closed	NCV	Failure to adequately store records per procedure
71-0102/2023-201-02	Opened and Closed	NCV	Failure to properly classify and justify sealed source capsule quality category

4. LIST OF ACRONYMS USED

ADAMS	Agencywide Documents Access and Management System
CAP	Corrective Action Program
CFR	Code of Federal Regulations
CoC	Certificate of Compliance
CPAR	Corrective/Preventive Action Report
DFM	Division of Fuel Management
GTAW	Gas Tungsten Arc Welding
IMC	Inspection Manual Chapter
IP	Inspection Procedure
ITS	Important-to-Safety
M&TE	Measuring and Test Equipment
NCR	Nonconformance Report

NCV	Non-Cited Violation
NDE	Nondestructive Examination
NRC	Nuclear Regulatory Commission
PDR	Public Document Room
PO	Purchase Order
QA	Quality Assurance
QAP	Quality Assurance Program
QSPM	Quality System Procedure Manual
SAR	Safety Analysis Report
SPEC	Source Production & Equipment Company, Inc.

5. DOCUMENTS REVIEWED

Certificate holder documents reviewed during the inspection were specifically identified in the report details above.