NRC FORM 591S PART 1
(10-2013)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. CERTIFICATE/QUALITY ASSURANCE PROGRAM (QAP) HOLDER:	2. NRC/REGIONAL OFFICE
Source Production & Equipment Co., Inc. 113 Teal Street St. Rose, LA 70087	Headquarters U. S. Nuclear Regulatory Commission Mail Stop 3WFN 14C-28 Washington, DC 20555-0001
REPORT NUMBER(S) 071-0102/2018-201	

3. CERTIFICATE/QAP DOCKET NUMBER(S)	4. INSPECTION LOCATION	5. DATE(S) OF INSPECTION
9036, 9263, 9282/071-0102	St. Rose, LA	03/6-8/2018

CERTIFICATE/QUALITY ASSURANCE PROGRAM HOLDER:

The inspection was an examination of the activities conducted under your QAP as they relate to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your QAP Approval and/or Certificate(s) of Compliance. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☐ 1. Based on the inspection findings, no violations were identified.

☐ 2. Previous violation(s) closed.

☑ 3. The violations(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

2 Non-cited violation(s) was/were discussed involving the following requirement(s) and Corrective Actions(s):

1) 10 CFR 71.137, "Audits," states, in part, that audits must be performed by personnel not having direct responsibilities in the areas being audited.

Contrary to the requirements of 10 CFR 71.137, the following instance was identified by the NRC where an audit was performed by an individual having direct responsibilities in that same area:

(Continued on Next Page)

☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
CERTIFICATE/QAP REPRESENTATIVE	Kelley Richardt	Kelley Richardt	4/17/18
NRC INSPECTOR	Carla Roque-Cruz		4/17/18
BRANCH CHIEF	Meraj Rahimi		4/20/2018

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. CERTIFICATE/QUALITY ASSURANCE PROGRAM (QAP) HOLDER:	2. NRC/REGIONAL OFFICE
Source Production & Equipment Co., Inc. 113 Teal Street St. Rose, LA 70087	Headquarters U. S. Nuclear Regulatory Commission Mail Stop 3WFN 14C-28 Washington, DC 20555-0001
REPORT NUMBER(S) 071-0102/2018-201	

3. CERTIFICATE/QAP DOCKET NUMBER(S)	4. INSPECTION LOCATION	5. DATE(S) OF INSPECTION
9036, 9263, 9282/071-0102	St. Rose, LA	03/6-8/2018

(Continued)

During an internal audit performed in October 2017, SPEC assessed the internal audit and nonconformance controls areas, among others. Specifically, the individual that performed the audit was directly responsible for those two areas. Therefore, SPEC failed to perform independent audits as required by 10 CFR 71.137.

This violation was entered into SPEC's corrective action program as CPR-00115, dated March 22, 2018. The inspection team evaluated the violation in accordance with Section 2.3 of the NRC Enforcement Policy and dispositioned it as a non-cited Severity Level IV violation.

2) 10 CFR 71.107, Package design control, states, in part, that the licensee, certificate holder, and applicant for a CoC shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures, among participating design organizations, for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures must provide for verifying or checking the adequacy of design, by methods such as design reviews, alternate or simplified calculational methods, or by a suitable testing program. For the verifying or checking process, the licensee shall designate individuals or groups other than those who were responsible for the original design, but who may be from the same organization.

Contrary to, and prior to October of 2017, the following instance was identified by the NRC where SPEC did not maintain design control measures to verify and check the adequacy of engineering documents such as design and fabrication drawings.

The team noted that SPEC maintains a computer database that contain engineering documents called MQ1, which SPEC defines as a quality assurance (QA) software. This QA software database controls and maintains design workflow and records for approvals, changes and effective dates for all of SPEC's quality records. A review of the MQ1 database revealed that some of the licensing and fabrication drawings did not have engineering approval signatures captured as a part of the design process. The MQ1 database displayed the signoff status approval as "Member" with no specific name or department associated with the drawings other than the quality assurance department. The team was unable to determine if the drawings received the proper approvals in accordance with SPEC procedures and NRC requirements. The team noted that this was not an isolated case. A review of a number of other engineering documents identified the same issue.

This violation was entered into SPEC's corrective action program as CPR-00113, dated March 22, 2018. The inspection team evaluated the violation in accordance with Section 2.3 of the NRC Enforcement Policy and dispositioned it as a non-cited Severity Level IV violation.

INSPECTOR NOTES COVER SHEET

Licensee/Certificate Holder (name and address)	Source Production & Equipment Company, Inc. 113 Teal Street St. Rose, LA 70087
Licensee/Certificate Holder contacts and phone number	Kelley Richardt, Regulatory and Quality Manager (504) 464-9471
Docket No.	071-0102
Inspection Report No.	71-0102/2018-201
Inspection Date(s)	March 6-8, 2018
Inspection Location(s)	St. Rose, LA
Inspectors	Carla Roque-Cruz, Team Leader, Safety Inspector Marlone Davis, Senior Safety Inspector Jeremy Tapp, Safety Inspector
Summary of Findings and Actions	On March 6-8, 2018, the U.S. Nuclear Regulatory Commission (NRC) performed an announced inspection of Source Production & Equipment Company, Inc. (SPEC). The team assessed SPEC's compliance with 10 CFR Parts 21 and 71. The focus of the inspection was to determine whether SPEC activities are in accordance with their NRC-approved QA program and that the packaging(s) they use for transport of radioactive material are being properly used and maintained and the packagings that are fabricated for transportation also meet the NRC-approved QA program requirements. Overall, the team assessed that SPEC was adequately implementing their QA program. Two Non-cited Severity Level IV Violations were identified and described in the inspector notes: 1) Failure to perform independent audits; 2) Failure to maintain design control measures to verify and check the adequacy of engineering documents. SPEC acknowledged the issues and captured them in their corrective action program.
Lead Inspector Signature/Date	Carla P. Roque Cruz
Inspector Notes Approval Branch Chief Signature/Date	Meraj Rahimi

Inspection History

Source Production & Equipment Company, Inc. (SPEC) is a manufacturer of industrial gamma radiography equipment and radioactive sources, and a distributor of related radiography supplies for the nondestructive testing industry worldwide.

The last inspection at SPEC was on January 28-31, 2013 when the U.S Nuclear Regulatory Commission (NRC) performed an announced inspection. (Agencywide Documents Access and Management System (ADAMS) ML13077A120). During that inspection the team did not identify any violations of significance related to NRC requirements. The team assessed that SPEC's implementation of its NRC-approved Quality Assurance Program (QAP) was adequate for activities subject to Title 10 of the Code of Federal Regulations (CFR) Part 21 and Part 71. Prior to this inspection, SPEC was inspected in 2008 and 2004.

Inspection Purpose

The purpose of the inspection was to assess SPEC's compliance with 10 CFR Parts 21 and 71. The focus of the inspection was to determine whether SPEC activities were in accordance with their NRC-approved QAP, that the packaging(s) they use for transport of radioactive material were being properly used and maintained and the packagings that were fabricated for transportation also met the NRC-approved QA program requirements.

Primary Inspection Procedures/Guidance Documents

- IP-86001, "Design Control of ISFSI Components
- NUREG-6314, "Quality Assurance Inspections for Shipping and Storage Containers"
- Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material"

Inspection Results

INSPECTOR NOTES: APPLICABLE PORTIONS OF 02.02 THROUGH 02.10 OF IP 86001 WERE PERFORMED DURING THE INSPECTION WITH RESULTS DOCUMENTED BELOW:

02.02 Verify that the CoC holder's activities related to transportation packagings are being conducted in accordance with the CoC, as well as the NRC-approved QA Program, and that implementing procedures are in place and effective.

The team reviewed SPEC's QAP, Revision 5, dated August 20, 2001 and Quality System Procedure Manual (QSPM). The team assessed the adequacy and effectiveness of SPEC's implementation of the QAP. The team conducted reviews of SPEC's policies, procedures and work instructions and discussed portions of the reviewed documents with selected SPEC personnel to determine whether activities subject to 10 CFR Part 71 were adequately controlled and implemented under SPEC's NRC-approved QAP. The team concluded that SPEC conducts activities related to transportation packaging in accordance with their NRC approved QA program and that programs and procedures are in place and are effective to conduct activities related to packaging fabrication and testing activities.

The team reviewed SPEC's documentation control program and procedures to assess the effectiveness of controls established for the approval, issuance, revision and use of quality

documents. The team reviewed QSPM 17.0, "Control of Quality Documents and Records (ISO 4.2 and 6.2), Revision 13, where it states that a list of quality records will be maintained and updated by the Quality Assurance Manager containing all records, responsible person designated, by the Quality Assurance manager, their retention periods and their approved storage locations. The procedure also contained retention periods for federal requirements. The team toured the areas where the documents are stored and obtained a copy of QA01F1, "List of Quality Records", Revision 12.

The team noted that the information on the list, document storage locations and document processing is adequate and in accordance with the procedure.

02.03 Verify that provisions are in place for reporting defects which could cause a substantial safety hazard, as required by 10 CFR Part 21.

The team reviewed SPEC's compliance to posting and reporting requirements of 10 CFR Part 21. SPEC QSPM Section 15.1, "Reporting and Defect Notification" Revision 14, describes general guidance for required notifications to regulatory bodies including Part 21. Additionally, Form No. SH09F5, "Part 21 Notification of Defect Evaluation" is use to evaluate the discovery of potential deviations or failures to comply. The team noted that work instruction No. SH09, "Returned or Reported Malfunctioning Equipment Material (EMRs), also has a reference to regulatory notifications. The team interviewed SPEC personnel and learned that SPEC uses a QA software database, MQ1, to create nonconformances and corrective actions reports. The inspectors noted that the process in the software for creating a new report has a Part 21 reference and checklist to determine if Part 21 is applicable and regulatory notification is required.

The team found one instance where engineering staff conducted an analysis for a Returned or Reported Malfunctioning Equipment/Material report (EMR's), and while completing the checklist as one of the steps in MQ1 the staff marked, "Not OK", for the question related to whether a substantial safety hazard was suspected. According to the SPEC process, marking this option would have to be followed by a Part 21 evaluation and subsequent Part 21 reporting, if applicable. None of these actions had been performed. The team interviewed the engineering and quality staff and SPEC's vice-president. SPEC staff indicated that engineering staff conducting the analysis for the EMR did not understand that this question addressed Part 21 related to a SPEC deviation in a product delivered to a customer for use. In this case the problem was not due to a SPEC product/process but a potential misuse of the product in the field. The team noted that SPEC was proactive in initiating CPR-00111 to address this error with actions to revise the checklist in MQ1 to clarify the intent of the question in the checklist and provide additional training for all personnel involved with the EMR process.

Overall, no concerns were identified with regard to SPEC's posting and process for reporting defects which could cause a substantial safety hazard, as required by 10 CFR Part 21.

02.04 Interview selected personnel and review selected design documentation to determine that adequate design controls are implemented.

The team interviewed selected personnel and reviewed selected design documentation to evaluate and determine how SPEC controls and implements all phases of their design control 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 for design activities related to Revision 9 of CoC No. 9263 for the type 'B' SPEC-150 packaging models. The team reviewed the SPEC procedures related to design development and control of modification activities. Specifically, the team reviewed the following SPEC QSPM sections associated with design control and engineering work instructions:

- QSPM 3.0, "Design Control & Product Realization," Revision. 16
- QSPM 3.1, "Verification and Validation," Revision 1
- EG03, "Change Requests for Engineering Documents," Revision 15
- EG05, "Engineering Change Notice," Revision 4
- EG07, "Engineering Documents: checking and Approval," Revision 14

The team also reviewed selected licensing drawings to verify that SPEC adequately translated the design details of the SPEC-150 models to the associated fabrication drawings.

The team assessed that overall, SPEC was effectively implementing its design control program and that implementing procedures and work instructions were in place and effective in controlling activities in accordance with the applicable regulations and their approved Certificate of Compliance (CoC). However, the team identified discrepancies in how SPEC controlled approvals, changes and effective dates for engineering documents such as licensing and fabrication drawings. The team noted that SPEC's database MQ1 also controls and maintains design workflow and records for approvals, changes and effective dates for all of SPEC's quality records. A review of the MQ1 database revealed that some of the licensing and fabrication drawings did not have engineering approval signatures captured as a part of the design process. The MQ1 database displayed the signoff status approval as "Member" with no specific name or department associated with the drawings other than the quality department. The team was unable to determine if the drawings received the proper approvals in accordance with SPEC procedures and NRC requirements. The team noted that this was not an isolated case.

A review of a number of other engineering documents identified the same issue.
The team assessed that this was a violation of NRC requirements. Specifically, 10 CFR 71.107, "Package design control", states in part that "the licensee, certificate holder, and applicant for a CoC shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures, among participating design organizations, for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures must provide for verifying or checking the adequacy of design, by methods such as design reviews, alternate or simplified calculational methods, or by a suitable testing program. For the verifying or checking process, the licensee shall designate individuals or groups other than those who were responsible for the original design, but who may be from the same organization..." Contrary to, and prior to October of 2017, SPEC did not maintain design control measures to verify and check the adequacy of engineering documents such as design and fabrication drawings in order to designate individuals or groups other than quality assurance organization. The team determined that this violation was more than minor because SPEC could not prove that they met design requirements. The team also noted that this affected a number of engineering documents.

The team dispositioned this violation in accordance with Section 2.3 of the NRC Enforcement Policy. The team characterized the finding as a Severity Level IV non-cited violation consistent with section 2.3.2 of the NRC Enforcement Policy. SPEC entered this issue into their corrective action program as CPR-00113.

02.05 Review selected drawings, procedures and records, and observe selected activities being performed to determine that the fabrication, test, and maintenance activities meet SARP design commitments and requirements documented in the CoC.

The team reviewed SPEC's fabrication processes by observing welding of the base to cover of a SPEC-150 package to ensure that it was controlled and verifiable from the onset of design through the approved welding process and procedure. The team reviewed randomly selected, in-process, shop travelers to ensure they were completed as required and adequately controlled the fabrication process. The team also toured the storage area where SPEC controlled quality related items. Items were segregated in a dedicated storage enclosure and identified with a color coded tagging system to ensure only acceptable items were available for use. The team did not identify any concerns with the control of fabrication process in the shop or storage of quality items, and noted that shop housekeeping was a strength.

The team observed a visual inspection (VT) of a cover to base weld on a SPEC-150 package, Serial # 2502. The team found that the VT was performed as required in the shop traveler and adequately documented. No weld issues were identified but the team noted that the calibrated lux meter was not documented on the shop traveler. This issue will be discussed further in the tools and equipment section below. In addition, the team observed a gamma scan survey of a depleted uranium shield. The team verified the survey meter was calibrated and current and the individual performing the surveying followed good health physics practices and was knowledgeable about the process. The team determined that the VT examination and gamma survey were properly performed in accordance with SPEC procedures and compliant with applicable industry standards and regulatory requirements.

The team reviewed selected measuring and test equipment (M&TE) including records and procedures to assure that equipment used in activities affecting quality were properly controlled and calibrated. The team reviewed QSPM 12.0, "Control of Inspection, Measuring, and Test Equipment," Revision 11, which prescribes activities and requirements concerning roles and responsibilities; use of measuring and test equipment; that calibration occurs to national standards; maintenance of records of various tools and equipment used; and actions to take when any piece of equipment is found out of calibration.

The team compared a sampling of M&TE in current use for fabrication and testing activities to the applicable requirements of QSPM 12.0, and determined overall compliance to the procedural requirements except in one case. As mentioned before, the team noted that the lux meter used for the VT of the base to cover weld was not documented on the shop traveler. Only the actual foot candles from the light source was documented. QSPM 12.0 states, in part, that selected equipment shall be identified in the applicable Work Instruction and/or Traveler. Therefore, the team determined this to be a violation of 10 CFR 71.111 for failure to follow procedures. This violation was determined to be of minor safety significance and not subject to formal enforcement action because it was a documentation issue and a calibrated lux meter was used to determine that the light source was adequate. SPEC entered this issue into their corrective action program as CPR-00116, dated March 22, 2018.

In addition, the team verified that if the measuring and test equipment had been sent offsite for calibration that the calibration service provider was current on the Approved Suppliers List.

The team concluded that SPEC had adequately implemented M&TE calibration, tracking, and use requirements, except in that one example of M&TE documentation on shop travelers which was identified as a violation of minor safety significance for failure to follow procedures and document the lux meter used for a VT inspection on the shop traveler.

02.06 Observe activities affecting safety aspects of the packaging (such as maintenance and/or testing) to verify that they are performed in accordance with approved methods, procedures, and Specifications.

The team reviewed selected records and interviewed personnel to verify that SPEC effectively implemented a maintenance control program in accordance with their NRC approved QA Program, CoC conditions, and the requirements of 10 CFR Part 71 for the transportation of radioactive material. The team performed a review on maintenance activities related to the SPEC-150 packaging for a period of five years including assessing and verifying the results of the visual and liquid penetrant weld inspections of the SPEC-150 packaging shell. The team also observed fabrication and maintenance activities conducted at SPEC fabrication shop on site. The team reviewed maintenance requirements identified in the Safety Analysis Report (SAR) and CoC; fabrication and maintenance instructions; completed maintenance records and travelers; and personnel qualification training records.

The team reviewed the following quality implementing procedures, fabrication travelers and maintenance instructions:

- QA27, "Visual Weld Inspection," Revision 9,
- QA28, "Liquid Penetrant Procedure for Solvent Removable Visible," Revision 10,
- QA63, Written Practice for the Qualification and Certification of NDE Personnel, Revision 1,
- PR18, "AWS/ASME – Welding Procedure Specification (WPS)," Revision 6
- SH12, "RAM Package Shipping Preparations (including package labeling/marking)," Revision 23, and
- QA55F2, "ASM/Lock Module Inspection Checklist, QA camera w/short," Revision 15.

Based on the review of the maintenance instructions and completed maintenance records and travelers, the team assessed that SPEC used appropriate materials, tools and equipment to perform fabrication and conduct maintenance activities for the SPEC-150 packaging. The team verified that the inspections were comprehensive and met acceptance criteria identified in the travelers and maintenance instructions. The team also noted that SPEC conducted the fabrication and maintenance activities with qualified personnel.

02.07 Review selected drawings and records, and interview selected personnel, to verify that the procurement specifications for materials, equipment, and services received by the QA Program holder meet the design requirements.

The team reviewed SPEC procedures QSPM 4.0, "Procurement Documents," Revision 13 and QSPM 7.0, "Control of Purchased Materials," Revision 7 associated with the procurement of materials for the SPEC-150 packaging to verify if they were being properly implemented.

The team determined that there were no Important-to-Safety (ITS) Category A components for the SPEC-150 package. Therefore, no Commercial Grade Dedication activities are performed by SPEC. The team selected three components from the SPEC-150 for review of the applicable procurement records: 1) depleted uranium shield, 2) lock end plate button head socket bolts, and 3) titanium weld wire used for the cover to base welds. The team reviewed the drawings, specifications, purchase orders or requisition, receiving inspection reports, receiving travelers, certificates of conformance, and certified material test reports, as applicable. The team verified

whether the procurement specifications and purchase orders or requisition met the design and applicable quality procedure and regulatory requirements.

Additionally, for the depleted uranium shield, the team specifically reviewed the receiving gamma scan survey report and verified the shield met the license drawing requirement for its weight, density, and purity. For the titanium weld wire, the team specifically verified that it was the correct material, size, length, and the chemical composition was in accordance with American Welding Society (AWS) A5.16 specifications, as required per the applicable SPEC approved Welding Procedure Specification (WPS). For the socket bolts, the team specifically verified the bolt material was as specified in the license drawings and modified at the SPEC shop to meet the requirements of the applicable drawing.

The team noted that procurement specifications and activities were adequate and all results were found to be acceptable.

02.08 Review selected records and interview selected personnel to verify that a nonconformance control program is effectively implemented, and that corrective actions for identified deficiencies are technically sound and completed in a timely manner.

The team reviewed QSPM Section 15.0, "Control of Nonconforming Product and Services", Revision 9; Section 16.0, "Improvement, Corrective And Preventive Action", Revision 14; Work Instruction QA32, "Control of Non-conforming Material"; QA50, "How to Process a Corrective/Preventive Action Report (CPR) and SH09, "Returned or Reported Malfunctioning Equipment/Material (EMR's)". These documents define the requirements for identification, segregation, documentation and close-out of nonconforming items as well as the procedure for opening, processing and closing corrective actions and use of MQ1 for this purpose.

The team reviewed a representative sampling of EMRs, Nonconforming reports (NCRs) and CPRs. The team focused their reviewed on EMR 0268, related to a SPEC -150 locking ball that appeared to be damaged or non-conforming; EMR 0260 related to a camera with apparent above normal readings, NCR 8733 for a hole orientation out of specification, NCR 22175 for a camera not working with a new inventory lock, CPR 00102 related to SPEC personnel not notifying international customers that SPEC was not allowed to receive non-US origin sources from an international customer, and CPR 00107 related to verification of welding requirements and oven temperatures.

The team noted that the resolution of issues documented in the various reports was appropriate, with the reports closed in a timeframe commensurate to their importance. No concerns were identified with the Nonconformance and Corrective Action processes as controlled by SPEC's quality assurance program.

02.09 Review selected records and procedures, interview selected personnel, and observe selected activities affecting the safety aspects of the packaging to verify that individuals performing activities affecting quality are properly trained and qualified, and to verify that management and QA staff are cognizant and provide appropriate oversight.

The team reviewed work instruction AD25, "Indoctrination, Training, Qualification and Certification", Revision 20 and personnel qualification training records for staff working in fabrication and maintenance activities and selected engineering personnel. The team also reviewed a selection of auditor training and qualification records to assess whether those performing audits were trained and qualified as required by SPEC's approved procedures.

The team determined that SPEC was adequately controlling qualification activities and records in accordance with its procedures and NRC approved QA program.

02.10 Verify that audits of the QA Program and activities affecting the safety aspects of the packaging are scheduled, have been performed as scheduled, and that identified deficiencies have been satisfactorily resolved in a timely manner.

The team reviewed the internal and external audit programs as defined in QSPM 18.0, "Internal Quality Audits," Revision 18 and work instruction QA41, "Qualification of Suppliers," Revision 7, respectively. This review was done to verify that the programs were comprehensive and that audits were scheduled and conducted periodically in accordance with approved procedures. Additionally, the team assessed that audit were performed by trained and qualified audit personnel who documented the audit results and followed up deficient areas via the corrective action program. The team reviewed a selection of internal audits performed in 2016 and 2017 as well as the 2016 to 2018 internal audit schedule to verify that they were conducted in accordance with the program as previously defined. Due to the small number of external audits performed to qualify a vendor to provide ITS Category A items, the team reviewed one external audit from both 2016 and 2017.

The team found that SPEC performed annual audits of all applicable quality criteria since 2016 and planned to perform audits of all applicable criteria in 2018. The team also determined that for the internal audits and checklists reviewed, the audits covered a representative sample of SPEC's activities in the area being audited and the audit reports were written in a timely manner. However, during review of the audit report and checklist for Audit No. 990, dated October, 26, 2017 that reviewed the internal quality audit and nonconformance control programs, the team noted that the individual directly responsible for these program areas also performed the audit. The team determined that this issue was a violation of 10 CFR 71.137, "Audits", which requires that audits be performed by personnel not having direct responsibilities in the areas being audited. The team determined this violation to be more than minor because audit independence was not maintained. The team evaluated the violation in accordance with Section 2.3 of the NRC Enforcement Policy and characterized it as a non-cited Severity Level IV violation. SPEC entered this issue into their corrective action program as CPR-00115, dated March 22, 2018.

The team determined that for the external audits reviewed of Aerojet Rocketdyne and Manufacturing Sciences Corporation, they were comprehensive in nature, used a detailed checklist to perform the audit, and were performed by a lead auditor who was qualified to the requirements of SPEC's approved procedure. The team also verified that the Approved Supplier List was current for both suppliers.

Overall, the team assessed that the internal audit program was adequately implemented by performing audits with trained and qualified personnel of all applicable aspects of the Quality Assurance Program on an annual basis, except in the area of auditor independence for internal audits. One Severity Level IV non-cited violation was identified for failure to perform independent audits of the internal audit and nonconformance control programs. External audits were found to be adequately implemented by performing comprehensive audits with trained and qualified personnel at least every 3 years for ITS Category A suppliers.