



SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. CERTIFICATE/QUALITY ASSURANCE PROGRAM (QAP) HOLDER:

Neutron Products Incorporated (NPI)
22301 Mt. Ephraim
Dickerson, MD. 20842

2. NRC/REGIONAL OFFICE

Headquarters
U. S. Nuclear Regulatory Commission
Mail Stop 3WFN 14C-28
Washington, DC 20555-0001

REPORT NUMBER(S) 72-0121/2019-201

3. CERTIFICATE/QAP DOCKET NUMBER(S)

71-0121

4. INSPECTION LOCATION

Ranson, West Virginia

5. DATE(S) OF INSPECTION

December 17 - 19, 2019

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 violation(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.

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

I. 10 CFR 71.111, "Instructions, procedures, and drawings," 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, prior to December 19, 2019, the Certificate of Compliance (CoC) holder, Neutron Products Incorporated (NPI) did not follow prescribed procedures for activities affecting quality.

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- ☐ 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	Ada Hensley Quality Assurance Manager	<i>Ada P. Hensley</i>	27 Jan 20
NRC INSPECTOR	Marlone Davis, Team Leader Sr. Storage and Transportation Safety Inspector	<i>Marlone Davis</i>	1/31/20
BRANCH CHIEF	Alayna Pearson Inspection and Operation Branch	for	

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Specifically, NPI Quality Assurance Program (QAP) Section 4.18, Audits, Steps 4.18.4.3 and 4.18.4.4 state, in part, that internal audits shall be conducted no less than every calendar year and the scope of the audit(s) conducted shall be sufficient to determine compliance and implementation of each of the eighteen elements of this QA program, respectively. The team identified that NPI did not audit all eighteen elements of their NRC-approved QAP in 2019 as required. The team noted that NPI only audited the area of procurement and commercial grade dedication. NPI entered this violation into their corrective action program as CA-2019-RT-004 for resolution.

The team assessed and dispositioned the violation in accordance with the NRC Enforcement Policy and Manual. The team characterized the violation as Severity Level IV non-cited violation.

INSPECTOR NOTES COVER SHEET

Licensee/Certificate Holder	Neutron Products, Incorporated (NPI) 22301 Mt. Ephraim Road Dickerson, MD 20842
Licensee/Certificate Holder Contact	Mrs. Ada Hensley Quality Assurance Manager 301-349-5001
Docket Nos.	71-0121
Inspection Report No.	71-0121/2019-201
Inspection Date(s)	December 17 - 19, 2019
Inspection Location(s)	300 North Preston Street Ranson, WV. 25438
Inspectors	Marlone Davis, Team Leader, Senior Storage and Transportation Safety Inspector Jon Woodfield, Storage and Transportation Safety Inspector Jeremy Tapp, Storage and Transportation Safety Inspector
Summary of Findings and Actions	During the period of December 17 through 19, 2019, the U.S. Nuclear Regulatory Commission (NRC) conducted a team inspection of the implementation of NPI's NRC approved Quality Assurance Program for compliance with the requirements of Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) Parts 21 and 71. The team discussed the preliminary results of this inspection on December 19, 2019. The team identify one violation of NRC requirements because NPI did not follow prescribed procedures for activities affecting quality. The team dispositioned the violation as Severity Level IV non-cited violation (NCV), which was consistent with Section 2.3.2 of the NRC Enforcement Policy. NPI acknowledged the information presented and documented the violation in a corrective action program for resolution.
Lead Inspector Signature/Date	Marlone Davis <i>Marlone Davis</i> 1/31/2020
Inspector Notes Approval Branch Chief Signature/Date	Alayna Pearson for

Inspector Notes

On December 17 to December 19, 2019, the U.S. Nuclear Regulatory Commission (NRC) performed an inspection at Neutron Products Incorporated (NPI) maintenance facility located in Ranson, WV. The purpose of this inspection was to verify and assess NPI's compliance with the provisions of their approved NRC Quality Assurance Program (QAP) and applicable Certificate of Compliance (CoC) for the transportation of radioactive material packages, and the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 21 and 71. Specifically, the team of NRC inspectors evaluated the adequacy of NPI's activities related to management, design, procurement and maintenance controls of their radioactive material transportation package model number 8NPI-20WC-6 MKII (USA/9215/B(U)-96). Additionally, the team reviewed and assessed the corrective actions from the violations associated with the previous team inspection conducted on December 16, 2015.

The team conducted the inspection in accordance with NRC Inspection Procedure 86001, "Design, Fabrication, Testing, and Maintenance of Transportation Packagings" and NUREG-6314, "Quality Assurance Inspections for Shipping and Storage Containers." The team reviewed selected procedures, quality assurance records, and interviewed personnel. The team performed an exit meeting on December 19, 2019 at the completion of the inspection week. The team identify one violation of NRC requirements because NPI did not follow prescribed procedures for activities affecting quality. The team dispositioned the violation as a Severity Level IV non-cited violation (NCV), which was consistent with Section 2.3.2 of the NRC Enforcement Policy. NPI acknowledged the information presented and documented the violation in their corrective action program (CAP) for resolution.

However, in general, the team assessed that NPI effectively implemented their NRC-approved QAP for activities subject to 10 CFR Parts 21 and 71.

INSPECTOR NOTES: AS DESCRIBED BELOW, THE TEAM PERFORMED APPLICABLE SECTIONS OF INSPECTION PROCEDURE (IP) 86001 AND DOCUMENTED THE INSPECTION RESULTS USING THE BASIC HEADINGS OUTLINED IN NUREG-6314

4.1 Management Controls

4.1.1 Quality Assurance Policy

The NRC inspection team reviewed Neutron Products Incorporated (NPI) quality assurance program and implementing procedures to verify how NPI conducted activities in accordance with their transportation package Certificate of Compliance (CoC) and the NRC-approved Quality Assurance Program (QAP). The team reviewed NPI's "Quality Assurance Program for the Transportation of Radioactive Materials," Revision 11. The team also reviewed a sample of personnel qualifications and indoctrination training records.

The team assessed that NPI QAP and implementing procedures in place to conduct activities in accordance with their CoC and 10 CFR Part 71 requirements. The team verified that NPI clearly defined and documented the quality program authorities and responsibilities, and that the quality assurance organization functioned as an independent group. The team noted that NPI's QAP described the eighteen quality assurance criteria such that NPI personnel could implement an effective program. The team also verified that NPI used a graded approach for identifying Important-to-Safety (ITS) components and applied this graded quality level to procurement documents.

4.1.2 Nonconformance and Corrective Action Controls

The team reviewed selected records and interviewed personnel to verify that NPI effectively implemented the nonconformance control and corrective action program (CAP). Specifically, the team reviewed NPI's approved documents and the following implementing procedures that govern the nonconformance and CAP for NPI to verify compliance with applicable requirements to 10 CFR Part 71:

- C-9008, "Compliance with 10CFR Part 21," Revision 1
- C-9011, "Documenting and Recording Non-Conformances," Revision 0
- R-5507, "Control of Nonconforming Packaging – Radioactive Material Transportation (Division 3)," Revision 5
- R-5514, "Corrective and Preventive Action – Radioactive Materials Transportation," Revision 3

The team discussed the nonconformance and CAP controls with NPI personnel and reviewed a sample of nonconformance reports (NCR)s and corrective action reports (CAR)s for appropriate disposition and correction. The team also evaluated whether NPI completed NCRs and CARs for identified nonconformances and deficiencies, respectively, in a technically sound and timely manner. The team sampled six NCRs since the last inspection in 2015 which consisted of use-as-is and process failure dispositions. The team noted that two of the NCRs were open and still awaiting disposition.

In addition, the team reviewed NPI's corrective actions associated with the two violations identified during the 2015 inspection (71-0121/2015-201), to verify the corrective actions had

been adequately completed. Specifically, the first violation was regarding NPI's failure to take prompt corrective action to develop and issue a design control procedure for licensing drawing deficiencies. The team noted that NPI did not correct the drawing deficiencies with an approved design procedure at the first available opportunity and did not provide appropriate subsequent justification to delay the corrective action for another two years. NPI wrote CAR CA-2015-007 to document NPI's corrective actions for the violation. For this issue, NPI adequately closed out the corrective actions, which had been open for almost six years. NPI revised the corrective action procedure to better define responsibilities, close-out process, and evenly perform an effectiveness verification. The team determined the corrective actions in response to the first violation were adequate. The team also reviewed CA-2015-RT-009, CA-2017-RT-002, and CA-2018-RT-001 and found they had been adequately evaluated and closed in a timely manner commensurate with their safety significance. The second violation was related to NPI's failure to develop and maintain a commercial grade dedication (CGD) program. NPI captured this issue in CARs CA-2015-RT-006 and CA-2015-RT-008. NPI revised their CGD program and document control procedures. The team also noted that NPI identified ITS components and applied a graded quality level to their procurement documents. However, the team noted that some of the quality category classifications did not match the quality category identified in the NPI "Master List of Approved Vendors" and in some instances documented as not applicable. NPI documented both issues in NCR-2019-RT-011 and CA-2019-RT-002, respectively.

The team assessed that NPI implemented its nonconformance and corrective action control programs and had adequate procedures in place to ensure compliance with the applicable regulations and QAP requirements with some exceptions. The team assessed that the quality procedures provided adequate guidance for the processing of nonconforming items and corrective actions. The team determined that NPI appropriately dispositioned the nonconformances reviewed and closed them in a timely manner commensurate with the safety significance, in accordance with the quality procedure. For the open NCRs, the team verified that NPI tagged and controlled the packaging components as required. The team also assessed the management reviews performed for 2017 and 2018 and determined that they adequately evaluated and documented the review of the quality program at NPI. However, the team identified an observation that while the 2017 and 2018 reviews met the regulatory requirements, the management review process was not documented within the QAP or implementing procedure. This observation was discussed with NPI management and entered NPI's CAP as NCR-2019-RT-009.

Part 21 Requirements

The team interviewed personnel to determine if they were familiar with the 10 CFR Part 21 implementing procedure C-9008. The team evaluated the Part 21 postings in the NPI facility to determine if they followed the 10 CFR Part 21 posting requirements. For the NCRs and CARs reviewed, the team verified during those reviews if they met the criteria of reporting under Part 21. The team noted that NPI did not issue any Part 21 reports since the last inspection in December 2015.

The team concluded that NPI has provisions in place for reporting defects that could cause a substantial safety hazard, as required by 10 CFR Part 21. The team assessed that NPI has made significant progress in improving the effectiveness of its CAP since the last inspection.

4.1.3 Documentation Controls

The team reviewed the sections of the NPI's QAP related to document control and quality records. The team also reviewed NPI procedure R-5513, "Document Control – Radioactive Materials Transportation," Revision 3 to determine if NPI was following the procedure in controlling its documentation and records.

The team reviewed the current NPI "Master List of Standard Operating Procedures (SOPs) Radioactive Materials Transportation." The team checked the revisions shown on the master list against the procedure revisions shown on the individual procedures provided in a SOP controlled copy binder provided to the team by NPI. The team determined the revisions of the SOPs in the controlled binder were the same as those on the master list. However, during this review, the team noted that SOP R-5517-006, Revision 0, had an effective date of May 9, 2017 while the SOP was approved by the NPI President and Quality Assurance Manager (QAM) on May 12, 2017. In addition, during the team's review of SOP 5517-006, it was determined that the revision of overpack drawing 240116 referenced in the SOP was not current. NPI added these two discrepancies into their CAP by writing NCR-2019-RT-006.

Upon review of the Document Control Form associated with SOP R-5517-006, the team was able to determine that SOP controlled copies 2 and 3 binders were not distributed as stated on the SOP master list. NPI wrote NCR-2019-RT-007 to add this discrepancy to their CAP.

The team also reviewed the form revisions (most SOPs have forms associated with them) shown on the "Master List of Controlled Forms Radioactive Materials Transportation," against the revisions shown on the actual controlled copy forms and determined that both agreed.

The team interviewed the document control coordinator (DCC), whom is also the QAM, and discussed all responsibilities as listed in NPI procedure R-5513. The team verified that the DCC was performing all the responsibilities as identified in the procedure. The team also verified that all the pages of the SOPs in the controlled document binder provided were stamped in red with "Controlled Document."

Records are also addressed in SOP R-5513. The DCC is also responsible for the control of quality records. All documents, forms, and drawings are to be retained while current and once obsolete, for a period of at least the number of years required by a regulatory body and/or the QAP or three years, whichever is greater. Documents, forms, master lists and drawings are maintained by the DCC and are stored in the NPI Records Room, drafting room, or teletherapy operations facility at the discretion of the QAM. The team determined that each SOP has a section at the end of it addressing records which provides direction on any quality records associated/developed by the procedure. The DCC stated that records currently are stored in fireproof file cabinets at a location different from where the inspection was performed.

The team determined that adequate document control and records management exists at NPI. Other than the minor issues identified and documented in NPI's CAP, no concerns were identified by the team in the NPI documentation control or quality records areas.

4.1.4 Audit Program

The team reviewed the internal audit program as described in R-5510, "Internal Audits – Radioactive Materials Transportation," Revision 2. This was to verify that the program was comprehensive and that audits were scheduled and conducted periodically in accordance with approved procedures by trained and qualified audit personnel who documented the audit results and followed up deficient areas via the CAP. The team reviewed a selection of internal audits performed from 2016 to 2019 to verify that they were conducted in accordance with the program as previously defined. The team also reviewed a selection of auditor training and qualification records to assess whether those performing audits were trained and qualified as required.

The team noted that the 2018 internal audit identified that the 2016 audit was not performed until 2017, and no internal audit was performed for 2017. These issues were entered in NPI's CAP and corrected as required. The team found that for the 2018 internal audit report and checklist, the audit reviewed a representative sample of NPI's activities in the areas being audited and the audit report was written in a timely manner. The team also verified that the lead auditor was qualified as required and was independent of the areas being audited.

The team reviewed the 2019 internal audit and determined it was performed by a qualified lead auditor; the audit identified several findings and observations but was only a limited scope audit of the commercial-grade dedication and procurement areas. No additional audits were planned of the transportation quality program in 2019. The team reviewed NPI's "Quality Assurance Program for the Transportation of Radioactive Materials, Revision 11," Section 4.18, "Audits", Steps 4.18.4.3 and 4.18.4.4 which state, in part, that internal audits shall be conducted no less often than every calendar year and the scope of the audit(s) conducted shall be enough to determine compliance and implementation of each of the eighteen elements of this QA program.

Contrary to the above, in 2019 NPI did not audit all eighteen elements of their NRC-approved QA program, as required. Specifically, only commercial grade dedication and procurement were audited. This is a violation of 10 CFR 71.111, "Instructions, procedures, and drawings," for failure to follow the QAP, Steps 4.18.4.3 and 4.18.4.4. 10 CFR 71.111 requires, in part, 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. The team determined that the violation was more than minor because the failure to follow the QAP resulted in most quality areas not being assessed for compliance, which could have led to a more significant safety concern as potentially unidentified issues remain uncorrected. 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. NPI entered this issue into their CAP as CA-2019-RT-004, dated December 19, 2019.

Overall, the team assessed that NPI implemented the internal audit program by performing audits of all applicable aspects of the Quality Assurance Program on an annual basis, with trained and qualified personnel except in internal audit scope for 2019. One Severity Level IV non-cited violation was identified for failure to perform the 2019 internal audit of all areas of the QAP.

4.2 Design Controls

4.2.1 Design Development

The team reviewed the sections of the NPI QAP and the SOPs specifically related to design development, design control, and modification of design activities. The team reviewed NPI SOP R-5518, Rev. 0, "Design Control" – effective date: October 21, 2015, to determine if NPI was following the procedure in controlling its transportation packaging's initial design development and any modifications.

The team noted that there were no current design activities being performed during the time of the inspection. All the prior design/as-built issues with NPI transfer casks and overpacks identified during previous NRC inspections had been resolved.

Therefore, the team focused its review on an NPI consolidated application for renewal of CoC 9215 for transportation packaging model NPI-20WC-6 MKII. The team reviewed the consolidated SARP and drawings in detail. The only significant design change was that the overpack drawing 240116 had been made into a Computer Aided Design (CAD) Software drawing by an outside engineering company called Peterson Incorporated. The team verified that Peterson Incorporated is on the NPI "Master List of Approved Vendors" to perform engineering services as a Quality Category A vendor.

The team made the following observations associated with design controls to NPI. The NPI SARP was not identified as a controlled document either under design control or document control programs. The team noted that the SARP was not shown on the NPI "Master List of Controlled Documents." Additionally, drawing number 240122, "Shipping/Transfer Cask Model S/TC MKII" did not include dates and initials of NPI approvers. The team noted that the NPI "Master List of Approved Drawings," Revision 2, did not list the latest revision for drawing number 240116, "Overpack USA/9215(BU) Package." The team also identified that the current revision to CoC 9215, Revision 15, has the incorrect revision for drawing number 240122 sheet 1 of 2. NPI entered these issues into their CAP for resolution as CA-2019-RT-001.

The team assessed that overall, NPI was minimally effective in implementing its design control procedure. Due to the small amount of design activities occurring, there was an excessive number of observations made by the team in this area. However, other than the observations noted, no significant concerns were identified by the team in the design control area.

4.2.2 Modifications

There were no current NPI transportation packaging modifications for the team to review and evaluate during this inspection period.

4.4 Maintenance Controls

4.4.1 Maintenance Activities

The team reviewed selected records and interviewed personnel to verify that NPI effectively implemented a maintenance control program in accordance with their NRC approved QAP, 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 NPI Type (B) transportation package for a period of four years on the 8NPI-20WC-6 MKII (CoC 9215). The team evaluated annual maintenance activities conducted at NPI and other facilities. The evaluation included a review of maintenance requirements identified in the Safety Analysis Report (SAR) and CoC, inspection and maintenance procedures, completed maintenance records, and personnel and qualification training records.

The team reviewed the following quality and maintenance implementing procedures:

- R-2014-G, "Unloading and Loading Procedure for USA/9215/B(U) Package," Revision 3
- R-2019-G, "Maintenance and Storage Procedure for USA/9215/B(U) Package," Revision 2
- R-2031, "Repair of Shipping Package Components," Revision 2

Based on a review of the maintenance records and procedures the team assessed that NPI used appropriate maintenance materials, tools and equipment to conduct the annual maintenance activities for the NPI transport package. The team verified that the inspections were comprehensive and met acceptance criteria for tests identified in the maintenance records and procedure. The team assessed and verified the results of the visual weld inspection defects in the wooden protective jacket. 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 NPI quality and maintenance records. The team verified that NPI appropriately inspected attributes of the transfer cask, wooden protective jacket, and outer steel shell. The team assessed that the maintenance satisfied the requirements identified in the 8NPI-20WC-6 MKII SAR and CoC.

4.4.2 Tools and Equipment

The team reviewed sections of the NPI QAP specifically related to the control of measuring and test equipment. The team also reviewed NPI procedure R-5515, Rev. 2, "Control of Inspection, Measuring and Test Equipment – Radioactive Materials Transportation" – effective date: June 9, 2016, to verify if NPI followed the procedure for controlling the calibration and maintenance of measuring and test equipment (M&TE) used to perform maintenance on its transportation packaging.

During the inspection no actual transportation packaging maintenance was being performed, therefore, the team selected M&TE from the current NPI master "Radioactive Material Transportation Tools and Equipment Calibration List" to review calibration records.

From the list of calibration records, the team selected to review a torque wrench, a length measuring rod, thread plug gage, an electronic scale, and a durometer measuring instrument. The team reviewed the calibration records for each of these devices as provided by NPI's QAM because the QAM is responsible for the M&TE calibration program. Vendor Garber Metrology performed M&TE calibration services for NPI except for the electronic scale. NPI contracted with an outside source to conduct the electronic scale calibration. The QAM is responsible for scheduling M&TE calibration by qualified vendors; reviewing and approving quality control and quality assurance checklists and forms used to document calibrated M&TE; removing from service, tagging, and segregating any M&TE that is not within the acceptable tolerance for the item; and maintaining calibration records for each calibrated M&TE item per the procedure.

The team assessed that NPI completed all the calibration records in accordance with the procedure. The team also verified that each of the selected items had identification numbers, last calibration dates, and next calibration due dates on stickers attached to them or on the protective box they were in. Procedure R-5515 provides guidance on actions to be taken if any M&TE is found to be out of calibration during recalibration. The QAM will initiate measures to validate previous inspection and test results for the last known correct calibration date for the as-found out of calibration M&TE.

The calibration of each M&TE instrument/device sampled was current and traceable to a recognized standard. The team determined that NPI was controlling M&TE calibration activities and records in accordance with its QAP and M&TE calibration procedure with no concerns.