

February 25, 2016

Mr. William Ransohoff
Director of Operations
Neutron Products, Inc.
22301 Mt. Ephraim Road
P.O. Box 22301
Dickerson, MD 20842

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION INSPECTION REPORT
NO. 071-0121/2015-201 AND NOTICE OF VIOLATION

Dear Mr. Ransohoff:

On December 16, 2015 to December 17, 2015, the U.S. Nuclear Regulatory Commission (NRC) performed a limited-scope inspection at your Neutron Products Inc. (NPI) facility located in Ranson, WV. The purpose of the limited-scope inspection was to assess NPI's compliance with the provisions of selected portions of the NRC approved Quality Assurance (QA) Program for the transportation of radioactive material with the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 21, 71, and applicable Certificates of Compliance (CoC). The NRC inspection team discussed the preliminary results of this inspection with you and other members of your staff on December 17, 2015 and a final telephone exit on January 11, 2016.

The team of inspectors examined activities conducted under your NRC approved QA Program to determine whether NPI implemented the requirements associated with the Commission's rules and regulations and with the conditions of your CoC. The team reviewed selected procedures and records, and interviewed personnel. In addition, the team reviewed NPI's corrective actions to NRC findings from previous inspections performed on May 22, 2013 (0710121/2013-201) and November 26 through November 29, 2012 (0710121/2012-201), respectively. The enclosed report presents the results of this inspection (Enclosure 1).

Based on the results of this inspection, the NRC staff determined that the implementation of your QA program did not meet certain NRC requirements in the area of corrective action and control of purchased material. This resulted in two Severity Level IV violations of NRC requirements. The team documented the cited violations in Enclosure 2, Notice of Violation (NOV), and described the details of the violations in the subject inspection report. The team cited the violations in the NOV because they were NRC identified and the inspectors determined that the violations were repetitive as a result of inadequate corrective actions. NPI did initiate corrective action documents according to their QA Program when notified of each issue by the NRC Inspectors.

However, due to the limited scope and sample of this inspection and based on the dedication findings, the staff expects that NPI will perform and document a thorough extent of condition to evaluate for similar dedication deficiencies related to all their transportation packaging importance-to-safety components.

The NRC inspection team assessed that overall, as presently developed and implemented, NPI's QA Program and some procedures are marginal in meeting the QA requirements of 10 CFR Part 71. Specifically, the NRC staff noted programmatic weaknesses in your commercial-grade-dedication activities, which may stem from a lack of a design control procedure that you recently developed from corrective actions six years ago.

Therefore, the NRC staff continue to have concerns about the programmatic issues and violations identified in NPI's QA Program implementation. As such, the NRC will maintain NPI on an increased inspection frequency. In addition, please provide a written statement or explanation within 30 days from the date of this letter in accordance with the instructions specified in the enclosed Notice of Violation. We will consider extending the response time if you show good cause for us to do so. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that we can make it available to the Public without redaction.

Sincerely,

/RA/

Patricia Silva, Chief
Inspections and Operations Branch
Division of Spent Fuel Management
Office of Nuclear Material Safety
and Safeguards

Docket No. 71-0121

Enclosures: 1. NRC Inspection Report No. 71-0121/2015-201
2. Notice of Violation

The NRC inspection team assessed that overall, as presently developed and implemented, NPI's QA Program and some procedures are marginal in meeting the QA requirements of 10 CFR Part 71. Specifically, the NRC staff noted programmatic weaknesses in your commercial-grade-dedication activities, which may stem from a lack of a design control procedure that you recently developed from corrective actions six years ago.

Therefore, the NRC staff continue to have concerns about the programmatic issues and violations identified in NPI's QA Program implementation. As such, the NRC will maintain NPI on an increased inspection frequency. In addition, please provide a written statement or explanation within 30 days from the date of this letter in accordance with the instructions specified in the enclosed Notice of Violation. We will consider extending the response time if you show good cause for us to do so. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that we can make it available to the Public without redaction.

Sincerely,

/RA/

Patricia Silva, Chief
 Inspections and Operations Branch
 Division of Spent Fuel Management
 Office of Nuclear Material Safety
 and Safeguards

Docket No.: 71-0121

Enclosures: 1. NRC Inspection Report No. 71-0121/2015-201
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DATE:	2/11/2016		2/18/2016		2/25/16						

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

Docket No.: 71-0121

Report No.: 71-0121/2015-201

Certificate Holder: Neutron Products, Inc.
22301 Mt. Ephraim Road, P. O. Box 68
Dickerson, MD, 20842

Inspection Location: Neutron Products, Inc.
300 North Preston Street
Ranson, WV, 25438

Inspection Dates: December 16 - 17, 2015
January 5 – 8, 2016

Inspection Team: Marlone Davis, Team Leader, Senior Safety Inspector, DSFM
Jon Woodfield, Safety Inspector, DSFM
Jeremy Tapp, Safety Inspector, DSFM

Approved by: Patricia Silva, Branch Chief
Inspections and Operations Branch
Division of Spent Fuel Management
Office of Nuclear Material Safety and Safeguards

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

EXECUTIVE SUMMARY

Neutron Products, Inc.
NRC Inspection Report 71-0121/2012-201

The U.S. Nuclear Regulatory Commission (NRC) conducted a limited scope team inspection of Neutron Products Incorporated (NPI) maintenance facility located in Ranson, West Virginia. The purpose of the limited scope inspection was to assess NPI's compliance with the provisions of selected portions of the NRC approved Quality Assurance (QA) Program for the transportation of radioactive material, the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 21, 71, and their applicable Certificate of Compliance (CoC). Specifically, the team of inspectors verified the adequacy of activities related to management controls such as nonconformances, corrective actions and audits, and maintenance controls such as material procurement of the designated NPI transportation packaging CoC.

The team examined activities conducted under the NRC approved QA Program, as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of NPI's CoC No. 071-9215. The team of inspectors reviewed selected procedures and records, and interviewed personnel. Additionally, the team reviewed NPI's corrective actions to NRC findings from previous inspections performed on May 22, 2013 (71-0121/2013-201) and November 26 through November 29, 2012 (0710121/2012-201). There were no maintenance activities to observe during this inspection period.

Nonconformance Controls

The NRC inspection team concluded that NPI effectively implemented its nonconformance control program and NPI has adequate procedures in place to ensure compliance with the applicable regulations and approved QA Program requirements. The team also 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 Part 21 postings in the NPI facility met the applicable requirements of 10 CFR Part 21 and the site-specific implementing procedure.

Corrective Action Controls

The team evaluated corrective actions taken by NPI in response to previously identified violations discovered during inspections performed from November 26 – 30, 2012 and May 22, 2013. The team also evaluated QA programmatic areas and determined that corrective actions were marginally adequate as there was one cited violation. The NRC inspection team concluded that even though NPI made improvements in the implementation of their quality program with respect to corrective actions, the team determined that the corrective action program continues to be an area that needs improvement. The team issued one Severity Level IV cited violation because NPI did not take prompt corrective actions to correct drawing deficiencies identified in 2009 and did not provide adequate justification to extend beyond its original due date. The team also identified a violation of minor safety significance because NPI did not develop a planned completion date or schedule after NPI evaluated a corrective action report in accordance with QA program implementing procedures. The team concluded that documentation of a planned completion date and associated schedule would help to drive corrective actions to completion in a timely and prompt manner.

Audits

Overall, the team noted that the internal audit reports were satisfactory in meeting the regulatory requirements in Part 71. However, the team concluded that the external surveys do not meet the requirements identified in NPI's commercial grade dedication (CGD) program procedure and CGD definitions in 10 CFR Part 21.

Design and Maintenance Controls

The NRC inspection team reviewed procedures, procurement documents, and personnel training records associated with maintenance activities. The team also reviewed corrective actions taken in response to violations identified during previous NRC inspections. The team determined that overall the implementation of maintenance controls was inadequate in the area of commercial grade dedication. As a result, the team identified violations because NPI did not adequately dedicate commercial components and services or establish adequate controls for the acceptance of these parts. Specifically, NPI did not identify and verify all the appropriate critical characteristics for a selected Category 'A' component and did not conduct some commercial-grade surveys at vendor sites. Overall, NPI's implementation of their QA Program in this area was less than adequate.

Table 1
Summary of Inspection Findings

Regulatory Requirement 10 CFR Section	Subject of Violation or Noncompliance	Number of Findings	Type of Finding	Report Section
71.115	Controlled of purchased material, equipment, and services	1	Level IV Violation 71-0121/2015-201-02	3.2
71.133	Corrective action	1	Level IV Violation 71-0121/2015-201-01	2.2.2

REPORT DETAILS

1.0 Inspection Scope

On December 16 - 17, 2015, the NRC conducted an announced limited-scope inspection at the Ranson, West Virginia (WV) facility of Neutron Products Incorporated (hereafter referred to as NPI). The limited-scope inspection focused on the remaining corrective actions associated with the follow-up team inspection conducted on May 22, 2013, a review of internal audits, external surveys, and a review of any ongoing maintenance activities and controls. The team reviewed NPI's CoC for the following packaging:

Model #	Package ID#	Docket #	Certificate #
8NPI-20WC-6 MKII	USA/9215/B(U)-96	71-9215	9215

1.1 Inspection Procedures Used

IP 86001, "Design, Fabrication, Testing, and Maintenance of Transportation Packagings"
 NUREG/CR 6314, "Quality Assurance Inspections for Shipping and Storage Containers."

1.2 List of Acronyms Used

CFR	Code of Federal Regulations
CoC	Certificate of Compliance
CGD	Commercial Grade Dedication
ITS	Important-to-Safety
NCR	Nonconformance Report
NOV	Notice of Violation
NPI	Neutron Products Incorporated
NRC	U.S. Nuclear Regulatory Commission
QA	Quality Assurance

1.3 Persons Contacted

The team held an entrance meeting with NPI personnel on December 16, 2015, to present the scope and objectives of the NRC inspection. The NRC inspection team discussed the preliminary results of this inspection on December 17, 2015 and a final telephone exit on January 11, 2016. Table 2 documents the individuals present at these meetings below.

Table 2

Entrance and Exit Meetings Attendees

NAME	AFFILIATION	ENTRANCE	EXIT	TELEPHONE EXIT
Marlone Davis	NRC	X	X	X
Jon Woodfield	NRC	X	X	
Jeremy Tapp	NRC	X	X	
William Ransohoff	Neutron Products	X	X	X
Keith Burns	Neutron Products	X	X	X
Jerry Fogle	Neutron Products	X	X	

2.0 Management Controls

2.1 Nonconformance Control

2.1.1 Scope

The NRC team of inspectors reviewed selected records and interviewed personnel to verify that NPI effectively implemented a nonconformance control program in accordance with the NRC approved QA Program for the transportation of radioactive material, the requirements of 10 CFR Parts 21 and 71. Specifically, the team reviewed NPI approved procedure R-5507, "Control of Nonconforming Packaging – Radioactive Material Transportation," Revision 3. The team reviewed a select number of nonconformance reports (NCRs) referenced in the previous NRC inspection report 071-0121/2013-201, which were still open at the time of this inspection. The team reviewed NPI procedure C-9008, "Compliance with 10CFR Part 21," Revision 1, to determine if provisions were in place for reporting defects that could cause a substantial safety hazard from the NCRs and condition reports identified. The team also reviewed the NPI's log of nonconforming items to verify their location at the Ranson, WV facility.

2.1.2 Observations and Findings

During the November 2012 NRC inspection of NPI, the NRC identified a number of violations. In May 2013, the NRC performed a follow-up inspection of NPI to review the corrective actions from the November 2012 inspection. Two of the NCRs written due to violations C.3 and C.4 were still open at the time of the May 2013 inspection.

For violation C.3, the team reviewed NCR 2012-003, written to address a design issue associated with the transfer cask angles and welds. The inspectors noted that NPI adequately closed this NCR on November 19, 2015. However, the team did note that the final disposition was to repair the transfer cask angles and NPI sent one transfer cask out for repair at the time of this inspection. The other two transfer casks with the same issue were awaiting repair.

For violation C.4, the team reviewed NCR 2012-004, written to address design of the overpack metal lids. The inspectors noted that NPI adequately closed the NCR on November 8, 2015. Additionally, similar to the transfer cask angles, the final disposition was to repair the overpack metal lids and NPI sent one overpack lid out for repair at the time of this inspection. The other two overpack lids with the same issue were awaiting repair.

The team determined that NPI adequately dispositioned and closed each selected NCR in accordance with the requirements of procedure R-5507, as applicable. The team noted that NPI adequately controlled all items at Ranson, WV facility as required by the procedure.

In addition, the team noted that there were no Part 21 reports issued for the past three years.

2.1.3 Conclusions

The team concluded that NPI effectively implemented its nonconformance control program and NPI has adequate procedures in place to ensure compliance with the applicable regulations and approved QA Program requirements. The team also 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 Part 21 postings in the NPI facility met the applicable requirements of 10 CFR Part 21 and the site-specific implementing procedure.

2.2 Corrective Action Program

2.2.1 Scope

The NRC team of inspectors reviewed selected records and interviewed personnel to verify that NPI effectively implemented a corrective action control program in accordance with the NRC approved QA Program for the transportation of radioactive material, and the requirements of 10 CFR Part 71. The team reviewed selected records and interviewed selected personnel to verify that NPI effectively implemented their corrective action program, and that NPI completed corrective actions for identified deficiencies in a technically sound and timely manner. Specifically, the team reviewed NPI approved procedure R-5514, "Corrective and Preventive Action – Radioactive Material Transportation," Revision 1. The team reviewed corrective action reports referenced in the previous NRC inspection report 2013-201. The team selected three corrective action reports from the May 2013 NRC inspection, CA-2013-RT-001, CA-2013-RT-002, and CA-2013-RT-003.

2.2.2 Observations and Findings

The team noted that during the review of the corrective actions for CA-2013-RT-001, the corrective action original due date for issuance of a new design control procedure was September 2013. The new design control procedure was going to provide guidance to aid NPI in resolving licensing drawing deficiencies. However, NPI did not issue the procedure until October 21, 2015. The team's review of the corrective action file noted a revised schedule to issue the new design control procedure but the new schedule did not document the completion until October 15, 2015. This was about a week before NPI issued the procedure. The revised schedule also discussed the justification for missing the original due date of September 2013. The justification cited a change in direction of the procedure and other operational activities to justify the delay of over two years.

Due to the two-year delay, the team reviewed other related documentation and noted that the design control procedure was actually a corrective action from licensing drawing deficiencies originally identified in 2009 (CA-2009-RT-001). The drawing deficiencies were originally planned to be corrected during the certificate renewal process in the early 2013 timeframe, but the lack of a procedure and resources to make the necessary changes resulted in a delay until after NPI completed the renewal work. NPI completed the renewal work in 2012 and the NRC issued the renewed certificate on May 16, 2013.

However, the team of inspectors noted that after completing the certificate renewal activities, NPI did not take prompt corrective actions on CA-2013-RT-001 to develop and issue a design control procedure to support correction of the licensing drawing deficiencies identified in 2009. Specifically, NPI delayed the original schedule over two years, from September 2013 to October 2015, without appropriate justification. NPI cited other operational activities or normal work activities and a change in direction of the procedure, but the team determined the significance of these reasons was not appropriate to justify a delay of over two years, as well as the additional four years when NRC inspectors first identified the licensing design drawing deficiencies. The inspectors noted that NPI did not document the justifications for delaying the schedule until October 2015 or provide corrective actions until six years after NRC inspectors identified this as a violation.

The team determined that this was a violation of 10 CFR 71.133, Corrective action. 10 CFR 71.133 requires, in part, that the licensee, certificate holder, and applicant for a CoC shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. The team determined that NPI did not promptly develop and issue a design control procedure to correct licensing drawing deficiencies. The team determined that the violation was more than minor because NPI did not correct the drawing deficiencies at the first available opportunity and did not provide appropriate subsequent justifications to delay the corrective action for another two years. The team assessed and dispositioned the violation in accordance with the NRC Enforcement Policy. The team characterized the finding as a Severity Level IV violation. The team documented the cited violation in Enclosure 2, Notice of Violation (NOV). The team cited the violation because it was NRC identified and the inspectors determined that the violation was repetitive based on a review of previous inadequate corrective actions. NPI captured this issue in condition report CA-2015-RT-007.

In addition, the team reviewed CA-2013-RT-002, and noted it was still open. However, NPI could not resolve this issue since the corrective actions required a design control procedure. The team also noted that NPI did not document a planned completion date or schedule for the corrective action, as required by procedure R-5514. The team determined this constituted a violation of minor safety significance. NPI entered this issue into NPI's corrective action program as condition report CA-2015-RT-009. The team also noted during discussions with NPI management on this issue, that documentation of a planned completion date and associated schedule would help to drive corrective actions to completion in a timely and prompt manner.

2.2.3 Conclusions

The NRC inspection team concluded that even though NPI made improvements in the implementation of their quality program with respect to corrective actions, the team determined that the corrective action program continues to be an area that needs improvement. The team issued one Severity Level IV cited violation because NPI did not take prompt corrective actions to correct drawing deficiencies identified in 2009 and did not provide adequate justification to extend beyond its original due date. The team also identified a violation of minor safety significance because NPI did not develop a planned completion date or schedule after NPI evaluated a corrective action report. The team concluded that documentation of a planned completion date and associated

schedule would help to drive corrective actions to completion in a timely and prompt manner.

2.3. Audit Program

2.3.1 Scope

The team of inspectors reviewed the NPI audit program and implementing procedure to determine if NPI scheduled and performed internal audits and external surveys in accordance with approved procedures. Specifically, the team reviewed Section 4.18, "Audits," from the most recent NPI QA program, NPI procedures R-5510, "Internal Audits-Radioactive Materials Transportation," Revision 2, and R-5509, "Training and Proficiency Assessments – Radioactive Materials Transportation," Revision 3. The team sampled the last two internal audits from 2015 and 2014, respectively. The team also reviewed NPI procedure R-5511, "Vendor Qualification – Radioactive Materials Transportation." The team reviewed this procedure to determine how NPI performed its external surveys. The team sampled two external surveys related to Important to Safety (ITS) Category 'A' vendor supplied equipment. The team also reviewed the internal audit results to determine if NPI identified deficiencies and resolved those deficiencies in a timely manner.

2.3.2. Observations and Findings

The team noted that NPI did not adequately implement the external survey program in accordance with their CGD Program Procedure R-5517, Commercial Grade Dedication – RMT, Revision 0. The NRC inspection team noted NPI did not conduct commercial-grade surveys on most of their ITS category A commercial vendor suppliers for items and services used in the dedication process as required in procedure R-5517. NPI relied on their inadequate receipt inspection that did not verify all critical parameters of important to safety components. In one instance, NPI took credit for an NRC audit conducted six years ago as the justification on why they did not have to perform the survey.

The team determined that this was a violation of 10 CFR 71.111, "Instructions, Procedures, and Drawings". The NRC inspection team noted that this was a part of a larger issue with NPI's CGD program. The team elected to capture this procedure violation as a part of the design and maintenance control section of this report.

2.3.3 Conclusions

Overall, the team noted that the internal audit reports were satisfactory in meeting the regulatory requirements in Part 71. However, the team concluded that the external audits do not meet the requirements identified in NPI's CGD program procedure.

3.0 Design and Maintenance Controls

3.1 Scope

The NRC team of inspectors reviewed selected records and interviewed personnel to verify that NPI effectively implemented a maintenance control program in accordance

with the NRC approved QA Program for the transportation of radioactive material, and the requirements of 10 CFR Part 71. The inspection of maintenance controls focused on a review of the maintenance requirements under the CoC and the procedures used to perform maintenance on the overpack and transfer cask of transportation packaging NPI-20WC-6 MKII. The team reviewed applicable NPI maintenance procedures such as those used in the procurement of spare and consumable parts in its evaluation of the maintenance process. Specifically, the team reviewed NPI implementing procedure R-2019, "Maintenance and Storage Procedure for USA/9215/B(U) Package," Revision 9. The team reviewed the NPI Master List of Approved Vendors for Radioactive Materials Transportation equipment and ITS Categories for the materials supplied by the various vendors.

3.2 Observations and Findings

The team of inspectors reviewed the NPI Master list of Approved Vendors to determine how NPI controlled the purchase of some items used to conduct maintenance activities. The team focused its selection sample on ITS Category A components. One of the ITS Category A components was the transfer cask end cap screws (also referred to as bolts). The approved vendors listed stated, in part, that the listed vendor for the bolts is a commercial vendor and items purchased must be dedicated through the CGD process. A review of the dedication plan for the bolts, the team noted that the bolts shall be grade eight (8) bolts. The team noted that there was no strength sample of the commercial grade bolts performed by a testing lab with a QA program and that there was no commercial grade survey performed by NPI of this vendor. Additionally, the team noted that the dedication plan for the bolts, Commercial Grade Dedication Process for Fasteners and Hardware Used on USA/9215/B(U) Packaging," Revision 1 had no reviewer to verify or check the adequacy of the dedication plan. Based on this review, the team determined that NPI did not perform an independent review or approve the CGD plan. Due to the improper CGD plan for the cap screws (bolts), NPI did not verify all critical characteristics of the bolts prior to making them available for use.

The NRC inspection team determined that this was a violation of 10 CFR 71.115, Control of Purchased Material, Equipment, and Services. 10 CFR 71.115 requires, in part, that the licensee, certificate holder, and applicant for a CoC shall establish measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor, and examination of products on delivery. The team determined that NPI did not establish adequate source evaluations, objective evidence of quality furnished, and perform a complete examination of the products on delivery. The team determined that the violation was more than minor because NPI did not demonstrate that the transportation packaging met applicable requirements. The team assessed and dispositioned the violation in accordance with the NRC Enforcement Policy. The team characterized the finding as a Severity Level IV violation. The team documented the cited violation in Enclosure 2, NOV. The team cited the violation because it was NRC identified and the inspectors determined that the violation was programmatic. NPI captured this issue in condition report CA-2015-RT-008.

3.3 Conclusions

The NRC inspection team concluded that overall the implementation of maintenance controls activities in the area of commercial grade dedication was less than adequate. The team identified violations because NPI did not adequately dedicate commercial components and services or establish adequate controls for the acceptance of these parts through NPI's CGD program. Specifically, NPI did not identify and verify all the appropriate critical characteristics for some Category 'A' components and did not conduct commercial-grade surveys of commercial grade vendors, as applicable.

4.0 **Exit Meeting**

On December 16, 2015, the NRC inspection team discussed the scope of the inspection during an entrance meeting with Mr. William Ransohoff and other members of the NPI staff. On December 17, 2015, the NRC inspection team presented the inspection results and observations during an on-site preliminary exit meeting. On January 11, 2016, via a telephone conference the NRC inspection team conducted a final exit with Mr. William Ransohoff and Keith Burns. Table 2 of this report, shows the attendance for all entrance and exit meetings.

NOTICE OF VIOLATION

Neutron Products, Inc.
22301 Mt. Ephraim Road
Dickerson, MD 20842

Docket No.: 71-0121
Report Number 2015-201

During an NRC inspection conducted on December 16, 2015 through December 17, 2015, a team of inspectors identified two Severity Level IV violations of NRC requirements. In accordance with the NRC Enforcement Policy, dated February 4, 2015, the violations are listed below:

- A. 10 CFR 71.133, "Corrective action," requires, in part, that the licensee, certificate holder, and applicant for a CoC shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected.

Contrary to the above, from October 2009 to October 2015, NPI did not take prompt corrective action to develop and issue a design control procedure for licensing drawing deficiencies. Specifically, 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.

This is a Severity Level IV violation (Section 6.0)

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

Contrary to the above, as of December 2015, NPI did not establish adequate source evaluations, objective evidence of quality furnished, and perform a complete examination of the products on delivery. Specifically, NPI did not identify and verify all the appropriate critical characteristics for some Category 'A' components and did not conduct commercial-grade surveys of commercial grade vendors, as applicable. This included NPI not adequately dedicating commercial components and services or establishing adequate controls for the acceptance of these parts through NPI's CGD program in accordance with procedures.

This is a Severity Level IV violation (Section 6.0)

Pursuant to the provisions of 10 CFR 2.201, Neutron Products, Inc., is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Chief, Inspections, and Operations Branch, Division of Spent Fuel Management, Office of Nuclear Material Safety and Safeguards within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results

achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

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

Your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21. If Classified Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR Part 95.

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

Dated this 25th day of February 2016.