

November 6, 2006

Mr. Jack Ransonhoff  
President and CEO  
Neutron Products, Inc.  
22301 Mt. Ephraim Road, P. O. Box 22301  
Dickerson, MD 20842

SUBJECT: NRC INSPECTION REPORT NO. 71-0121/06-201 AND NOTICE OF VIOLATION

Dear Mr. Ransonhoff

This refers to the inspection conducted on September 11-13, 2006, at Neutron Products Incorporated (NPI) in Dickerson, MD and Ranson, WV. The purpose of the inspection was to determine if NPI's activities associated with the transportation of radioactive material were being performed in accordance with the requirements of 10 CFR Parts 21 and 71, applicable certificates of compliance, and the U.S. Nuclear Regulatory Commission (NRC) - approved quality assurance (QA) program. The team inspected NPI's management, design, fabrication, and maintenance activities. The enclosed report presents the results of this inspection.

Based on the results of this inspection, the NRC has determined that violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violations are being cited in the Notice because they were either identified by the NRC, or identified by NPI without corrective actions taken.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. 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 document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your

J. Ransonhoff

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response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Sincerely,

Robert J. Lewis, Chief  
Rules, Inspections and Operations Branch  
Licensing and Inspection Directorate  
Division of Spent Fuel Storage and Transportation  
Office of Nuclear Material Safety and Safeguards

Docket No. 71-0121

Enclosures: 1. NRC Inspection Report No. 71-0000121/2006201  
2. Notice of Violation

J. Ransonhoff

-2-

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Sincerely,

/RA/

Robert J. Lewis, Chief  
Rules, Inspection and Operations Branch  
Licensing and Inspection Directorate  
Division of Spent Fuel Storage and Transportation  
Office of Nuclear Material Safety and Safeguards

Docket No. 71-0121

- Enclosures: 1. NRC Inspection Report No. 71-0121/06-201
- 2. Notice of Violation

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

**Inspection Report**

Docket: 71-0121

Report: 71-000121/2006201

Certificate Holder: Neutron Products, Inc.  
22301 Mt. Ephraim Road  
Dickerson, MD

Date: September 11 -13, 2006

Inspection Team: Jim Pearson, Team Leader, SFST  
G. Michael Karmis, Safety Inspector, SFST

Approved by: Robert J. Lewis, Section Chief  
Rules, Inspections and Operations Branch  
Licensing and Inspection Directorate  
Division of Spent Fuel Storage and Transportation  
Office of Nuclear Material Safety and Safeguards

## EXECUTIVE SUMMARY

Neutron Products, Inc.  
NRC Inspection Report 71-000121/2006-201

From September 11-13, 2006, the NRC conducted an announced inspection at the Neutron Product Incorporated (NPI) facilities in Dickerson, MD, and Ranson, WV. The purpose of the inspection was to determine if NPI's activities associated with the transportation of radioactive material were being performed in accordance with the requirements of 10 CFR Parts 21 and 71, applicable certificates of compliance, and the U.S. Nuclear Regulatory Commission (NRC) - approved quality assurance (QA) program. The team inspected NPI's management, design, fabrication, and maintenance activities. The results of the inspection are summarized below and on Table 1.

### Management Controls

NPI's implementation of their QA program in this area was assessed to be adequate. However, as cited in the enclosed Notice of Violation, the team identified several instances where quality procedures were not followed or where procedural guidance was inadequate for controlling quality-related activities.

### Design Controls

NPI is not currently performing package design activities. The team reviewed the quality related procedures NPI has in place that govern design activities and identified violations to the applicable 10 CFR Part 21 and 71 regulations.

### Fabrication and Maintenance Controls

NPI is not currently performing package fabrication activities. Many of the activities reviewed under maintenance controls are also applicable to fabrication controls. NPI's maintenance controls were assessed by observing activities at NPI's Ranson, WV Maintenance Facility and associated Part 71 packagings available for inspection at that location. Overall, NPI's implementation of their QA program in this area was adequate. However, as cited in the enclosed Notice of Violation, the team identified several instances where quality procedures were not followed.

**Table 1  
Summary of Inspection Findings**

Regulatory Requirement 10 CFR Section	Subject of Violation or Noncompliance	Number of Findings	Type of Finding	Report Section	Issue Subject
71.105(a)	QA Program	1	Violation	2.1.2.1	Training Proficiency
71.107(c)	Package Design Control	1	Violation	2.2.2	Holes in Package
71.109	Procurement document control	1	Violation	2.4.2.1	Lead Auditor Procurement
71.111	Instructions, procedures and drawings	1	Violation	2.1.2.3	Document Control Procedure
71.115(a)	Control of purchased material, equipment and services	5	Violation	2.2.2 2.4.2.1 2.4.2.1 2.4.2.1 2.4.2.1	Package Name Stamping Improper Grade 5 Bolts Improper Grade 8 Bolts Improper Shackles Improper Gaskets
71.131	Nonconforming materials, parts or components.	1	Violation	2.1.2.4	Inadequate Nonconformance Process
71.133	Correction action	1	Violation	2.1.2.2	Inadequate Corrective Action Process
71.137	Audits	1	Violation	2.1.2.2	Inadequate Audit Process
10 CFR 21	Posting	1	Violation	2.1.2.5	No Part 21 Posting
10 CFR 21	Application to Procurement	1	Violation	2.1.2.5	No Part 21 Procedure

## REPORT DETAILS

### 1. Inspection Scope and Background

Neutron Products Incorporated (NPI) possesses a 10 CFR Part 71 (Part 71) QA Program Approval for Radioactive Material Packages, Certificate Number 71-0121, Rev. 7. The Certificates of Compliance (CoCs) currently held by Neutron Products include:

Model and Package Identification Number	COC#
NPI-20WC-6	71-9102
NPI-20WC-6 MKII	71-9215

NPI owns and maintains, for the shipment of Cobalt 60 teletherapy sources, 11 packagings fabricated to the above CoCs. Units 1 - 3 are under CoC No. 9102, Units 4 - 11 are under CoC No. 9215. Note that currently NPI is not in receipt of any shipped materials but rather only performing maintenance on the packages.

The purpose of the inspection was to determine if NPI's activities associated with the transportation of radioactive material were being performed in accordance with the requirements of 10 CFR Parts 21 and 71, applicable certificates of compliance, and the NRC - approved QA program. The team inspected NPI's management, design, and maintenance activities. The team observed selected activities; reviewed procedures and instructions; inspected selected documents, records, and drawings; verified personnel training and qualifications; and interviewed personnel responsible for various activities.

#### 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

AVL	Approved Vendors Listing
CFR	Code of Federal Regulations
CoC	Certificate of Compliance
M&TE	Measuring and Test Equipment
NRC	U.S. Nuclear Regulatory Commission
QA	Quality Assurance
SFST	Spent Fuel Storage & Transportation (Division of)

#### 1.3 Persons Contacted

The team held an entrance meeting with NPI personnel on September 11, 2006, to present the scope and objectives of the NRC inspection. On September 13, 2006, the team held an exit meeting with NPI's personnel to present the preliminary results of the inspection. The individuals present at the entrance and exit meetings are listed below in Table 2.

**Table 2  
Entrance and Exit Meetings Attendance**

NAME	AFFILIATION	ENTRANCE	EXIT
Jim Pearson	NRC	X	X
Mike Karmis	NRC	X	X
Marvin Turkanis	Neutron Products	X	X
Jack Ransonhoff	Neutron Products		X
Bill Ransonhoff	Neutron Products	X	X
Jerry Fogle	Neutron Products	X	X
Bob Nelson	State of Maryland	X	

2. Inspection Details

2.1 Management Controls

2.1.1 Scope

The inspection of management controls focused on the areas of QA policy, audit program, documentation controls, nonconformance controls, and 10 CFR Part 21 (Part 21) implementation.

2.1.2 Observations and Findings

2.1.2.1 QA Policy

The team reviewed the NPI's organizational chart and interviewed the quality assurance manager for Part 71 activities in regard to the functions and independence of the quality organization within the Neutron Product's organization. The team also reviewed selected portions of the NPI Quality Assurance Program Manual, Revision 8.

The team reviewed training and proficiency documentation, in regard to Part 71. The Field Supervisor performs many of the activities affecting quality in regard to Part 71 transportation packaging. The required documentation of the training and proficiency program, in support of the Field Supervisor's quality affecting Part 71 activities was not found to be in place. The team reviewed a number of documents which indicated a potential basis for NPI to determine that the Field Supervisor was proficient. These documents are noted below:

“Inspection of Transfer Casks,” Rev. 1, 05-06-04, used 4/14/06, Rev. 1) 3/19/04 - Field Supervisor 4/5/05

“Visual Inspection Checklist for 9/02/9215 Packages,” Rev. 2 10/13/04  
used: 6/3/05, 6/11/05, 7/13/05, 7/19/05, 7/23/05, 8/18/05, 1/6/06

4/27/06, 9/28/05

“Annual Inspection of Wooden Inner Overpacks,” Rev. O, 12/31/03  
used: 5/4/04, 4/25/05

“Annual Inspection of Metal OP Shells,” Rev. O, 01/05/04  
used: 4/21/05, 4/8/05, 11/30/05

However, 10 CFR 71.105 (a) QA program requires that CoC holder shall provide for indoctrination and training of personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained.

Contrary to the above, NPI had not developed a procedure and method to assure proficiency training was occurring and adequately documented for personnel performing activities affecting quality.

This failure to prescribe proficiency training for personnel performing activities affecting quality is an example of the Violation cited in Enclosure 2. After identification and during the inspection, NPI identified this deficiency in Corrective and Preventive Action Reports, Division III Teletherapy Shipping #III-06-11, Proficiency Documentation Needed.

#### 2.1.2.2 Audit Program

The team reviewed the following documents:

- Audit Form for Neutron Products Inc., Internal audit for radioactive transportation activities, performed on August 4-5, 2004
- Radioactive Material Transportation Audit Report, dated August 10, 2004, Marvin Turkanis to Jack Ransonhoff
- Internal Audit of the Quality System For Teletherapy Shipping, dated September 7, 2006, Heidi Harmon to Jack Ransonhoff
- Corrective And Preventative Action Reports, Division III Teletherapy Shipping, dated 9/13/06

The inspector reviewed Quality Audit Procedure P QC 107, Rev. 2. The inspector noted QC 107 provides a listing of personnel who are required to have appropriate education and training for their assigned responsibilities. The procedure and QA program details provide adequate direction to prepare, perform, and document QA audits. (QA Programs for the Transportation of Radioactive Materials NPI, Rev. 8 dated July 17, 2001.)

The inspector noted that no audit report was available at the time of the inspection for 2005 and no other evaluative documents were provided to justify the missed audit. This lack of program evaluation is identified as a violation of 71.137. The inspector discussed the scheduling process for future audits with NPI staff. Though no schedule had been developed as of 9/11/06, the QA Manager for transportation indicated that since an audit was just performed on 9/7/06 the schedule had not yet been developed for the next audit cycle.

The inspector reviewed the internal annual audit for 2004, performed on August 4 and 5, 2004. The inspector noted that multiple major, minor noncompliances were noted, as well as a

potential problem. The inspector noted that the 2004 audit recognized that seven of nine of the recommendations from the 2003 audit were not yet addressed.

The inspector reviewed an internal audit performed on Sept. 6, 2006. The inspector noted the audit identified that a corrective action procedure was non-existent, as well as a non-conformance procedure.

This failure to evaluate the effectiveness of the NPI quality program through a planned and periodic audit is an example of the Violation cited in Enclosure 2.

### 2.1.2.3 Documentation Controls

The team reviewed the NPI QA procedures related to documentation controls, and interviewed personnel responsible for carrying out the related procedures. The team reviewed the following applicable procedures:

- NPI Procedure R-1516, Rev. 1 dated 11/18/2003, "Vendor Qualifications"
- NPI Procedure R-55402, Rev. 1, "Control of Quality Records Procedure"

The Inspector interviewed the NPI Div. III Records Clerk to determine the process used in document and record control used at Neutron Products, Inc. The records clerk described how the NPI Procedure: Control of Quality Records Procedure R-55402, Rev. 1 was used.

The inspector noted from his review of the NPI records procedure, Procedure R-55402, Rev. 1 that less than adequately control of document development, review, approval, issuance, and disposal/return, exists at NPI. In addition the inspector noted that the procedure does not address overall responsibility of the process detail of procedural development. The team also noted the failure to prescribe procedures for document development. This procedural weakness is identified as a violation of 71.111

The inspector discussed the quality system teletherapy shipping standard operating procedures master list, Rev 5. dated 9/5/06 with both the transportation QA manager and the field supervisor. In addition the inspector discussed the control process of master lists in general with both the Field Supervisor and the Division III Records Clerk. The Division III Records Clerk described how she controlled the NPI Documents.

The inspector reviewed procedure R-2014, Shipping/Transfer Cask Unloading and Loading Procedure, Rev. 7, dated; April 12, 2004 (Control Copy 01), the inspector noted that Attachment I was missing, but present in Control Copy 2. The Division III Records Clerk verified that the control copy 1 and copy 2 were the only copies in use. The Control Copy 1 was immediately corrected upon discovery of the missing attachment.

The inspector reviewed NPI procedure R-1516, Rev. 1 dated 11/18/2003, "Vendor Qualifications." The inspector noted that for all Part 71 parts/components a determination has generally been made that all are commercial grade items and vendor qualification is not required as long as supporting documents are acceptable and receipt inspection is acceptable, as noted in step(s) 7.4, 7.6, 7.7, 7.8, and 7.9.

The inspector also reviewed NPI procedure R-1151, Rev. 0, dated 8/25/04 "Receiving

Inspection for Parts and Materials for Teletherapy Units and Shipping Packages, DIYs Whole Body Counter, and Material For Cobalt-60 Sources.” The inspector noted that this procedure describes the use of checklist 29, Rev. 1, dated 2/24/04 (used by the NPI Field Inspector) “receiving inspection for quality sensitive parts and materials.”

The absence of an acceptable procedure to adequately control document development, review, approval, issuance, and disposal/return, as well as overall responsibility of the process detail is a violation of 10 CFR Part 71.111 and is cited in the enclosed Notice of Violation. NPI identified these deficiencies in Corrective and Preventive Action Reports, Division III Teletherapy Shipping #III-06-10 Define Development Of Docs; and in Corrective and Preventive Action Reports, Division III Teletherapy Shipping #III-06-09 Insufficient Records Handling.

#### 2.1.2.4 Nonconformance Controls

The team reviewed procedures used for the various problem reporting mechanisms, reviewed a sample of problem reports, and interviewed personnel responsible for the monitoring and trending of problem reports. The team reviewed the following applicable procedures:

- NPI Procedure R-2019, “Teletherapy Shipping Packaging Maintenance procedure - NPI Procedure R-2031, Rev 0, Repair of Teletherapy Shipping Package Components, dated August 25, 2004

Overall, the team determined that NPI needs to develop, implement, and periodically review the process on nonconformance controls. Report Section 2.1.2.2 - Audit Program, Section 2.1.2.5 - Part 21, and 2.2 - Design Controls, of this report, all identify violations which relate to implementing appropriate methods for documenting and resolving various types of nonconformances, in a timely manner. Previous audits have noted no nonconforming identification process exists for transportation activities at NPI.

The absence of a nonconformance identification process and the absence of development and implementation of corrective actions from the 2004 audit are considered violations of 10 CFR Parts 71.131 and is cited in the enclosed Notice of Violation.

#### 2.1.2.5 Part 21

At the NPI maintenance facility, the inspector found Section 206 of the Energy Reorganization Act of 1974 posted in a conspicuous place. No NPI Part 21 procedure, no Part 21 regulation or no contact information in regard to Part 21 was posted. While these were self identified violations in the 2004 audit performed of the NPI quality program, NPI could not provide proof that any corrective action had been taken to close the audit finding.

This failure to post the Part 21 regulation, a NPI Part 21 procedure, or NPI point of contact for 10 CFR Part 21 reporting is considered a violation of Part 21 and is cited in the enclosed Notice of Violation. After identification and during the inspection NPI identified this deficiency in Corrective and Preventive Action Reports, Division III Teletherapy Shipping #III-06-03 Part 21 Posting, P.O. Wording, Reference In Procedures.

The team noted from the review of a sample of purchase orders (Listed in 2.4.2.1 of this report), that procurement documents are not specifying, when applicable, that the provisions of

Part 21 apply. NPI self identified this violation, but did not complete corrective action in a timely manner.

This failure to apply the provisions of Part 21, when applicable, in procurement documents/purchase orders is considered a violation of 10 CFR Part 21 and is cited in the attached Notice of Violation. After identification and during the inspection NPI identified this deficiency in Corrective and Preventive Action Reports, Division III Teletherapy Shipping #III-06-02 Part 21 Training and Reference.

### 2.1.3 Conclusions

The team assessed that overall, NPI's implementation of the QA program in these areas requires increased emphasis on identification of nonconformances; implementation of both a nonconformance and corrective action process; and timely corrective action. The team identified areas requiring improvement in identification of nonconforming conditions, corrective action, training, documentation, and records. Also identified was the failure to follow the requirement to accomplish scheduled audits and accomplish associated corrective actions. The absence of a nonconformance identification process and the absence of development and implementation of a corrective action process identified in an 2004 NPI audit are considered violations of Part 71.131 and 133 as both elements are essential in the implementation of any quality program and are cited in the enclosed Notice of Violation along with weaknesses in training, audits and procedures.

## 2.2 Design Controls

### 2.2.1 Scope

The team reviewed the NPI quality-related procedures that govern design control.

### 2.2.2 Observations and Findings

The team reviewed NPI's QA procedures related to design development and modifications. The team reviewed the following procedures:

- NPI Procedure R-2019, "Teletherapy Shipping Packaging Maintenance procedure"
- NPI Procedure R-2031, Rev 0, "Repair of Teletherapy Shipping Package Components," dated August 25, 2004

The following drawings were reviewed:

NPI-20WC-6  
Drawing Number 240116 Rev. G  
240010 Rev. C

NPI-20WC-6 MKII  
Drawing Number 240122 Rev H

NPI is not currently performing design development or modification activities subject to 10 CFR Part 71. The team reviewed the procedure controls in effect for these activities to

assess their adequacy in the event NPI engages in such activities relative to use and maintenance of the transportation packages.

The team inspected two sample overpacks (OP-8 & OP-11) noting that both have eight, 1/8" holes in addition to the required twelve, 1/2" vent holes. The holes appear to have been previously used for older name plates which have subsequently been replaced by new name plates, installed in a new location on both overpacks.

This failure to subject design changes to design control measures commensurate with the original design is considered a violation of 10 CFR 71.107© and is cited in the enclosed Notice of Violation. After identification and during the inspection, NPI documented this deficiency in Corrective and Preventive Action Reports, Division III Teletherapy Shipping #III-06-05 Additional Holes In Metal Shells.

Both OP 8 and OP 11, 20WC-6 MKII Overpacks are missing the manufacturers stamped name and date on the lower half of the component. This stamp is required by CoC Dwg. 240116, Rev. G, dated 8/15/02.

This failure to meet the requirements for a stamp per the CoC drawing is considered a violation of 10 CFR 71.115(a) and is cited in the enclosed Notice of Violation. After identification and during the inspection, NPI documented this deficiency in Corrective and Preventive Action Reports, Division III Teletherapy Shipping #III-06-04 ID Tags Missing.

The team also identified three different Grade 5 and 8 bolts bearing head markings on the Suspect/Counterfeit Part Headmarks List, DOE Quality Alert, Issue Number 92-4, in use during the inspection of Units 8 and 11. This failure to assure counterfeit parts were not in use is considered another example of a violation of 10 CFR 71.115(a) and is cited in the enclosed Notice of Violation. After identification and during the inspection, NPI documented this deficiency in Corrective and Preventive Action Reports, Division III Teletherapy Shipping #III-06-08 Counterfeit Hardware Found.

### 2.2.3 Conclusions

Overall, the team assessed that NPI's procedures related to design development and modification were adequate in addressing related requirements of 10 CFR 71, Subpart H. However, the team identified several instances where the transportation packages deviated from the CoC drawings.

### 2.3 Fabrication Controls

NPI is not currently performing package fabrication activities. However, many of the activities reviewed under maintenance controls, as discussed in the following section, are also applicable to fabrication controls. Though no work was in progress at the time of inspection, the team verified that suppliers of fabricating, welding, and testing of steel, that could be used for fabrication activities, were audited and listed on the NPI approved vendors list, entitled, "Master List of Approved Vendors For Parts and Materials For Radioactive Shipping Packages, In Vivo Counting Services Group, and Teletherapy Parts and Unit Re-manufacture," dated 8/30/06.

## 2.4 Maintenance Controls

### 2.4.1 Scope

The inspection of maintenance controls focused on the implementation of the NPI QA program, (e.g., material control, documentation control, nonconformance control, and implementation) in regard to control and performance of maintenance of activities performed on transportation packagings subject to 10 CFR Part 71.

### 2.4.2 Observations and Findings

#### 2.4.2.1 Procurement Controls

NPI's maintenance program was assessed by observing activities at the Ranson, West Virginia Maintenance Facility and associated Part 71 packagings and spare parts that were available for inspection. The team performed an inspection of two CoC No. 9215, NPI-20WC-6 MKII transportation packages.

The following applicable procedures were reviewed:

- NPI Procedure R-2019, "Teletherapy Shipping Packaging Maintenance Procedure"
- NPI Procedure R-2031, Rev 0, dated 8/25/04, "Repair of Teletherapy Shipping Package Components"

The team verified NPI's procurement quality through an inspection of spare parts and components and their associated markings and categorizations. The team also verified, through review of a sample of purchase orders, that the NPI approved vendors list, entitled, "Master List of Approved Vendors For Parts and Materials For Radioactive Shipping Packages, In Vivo Counting Services Group, and Teletherapy Parts and Unit Re-manufacture," dated 8/30/06; listed vendors associated with suppliers of materials, components, equipment and services, and other equipment manufacturers (OEMs). The team noted that the NPI approved vendors list is very stable and the performance of vendors over time has been acceptable for the quality level of items provided by each vendor. The following Purchase Orders were reviewed:

- Purchase Order 2002-399, dated 8/21/06, To McMaster Carr, P.O. Box 440, New Brunswick, NJ 08903, For Galvanized Alloy Steel Forged Anchor Shackle W/Screw Pin, 5/8" Material Dia, 10,000LB WLL
- Purchase Order 2002-505, dated 11/15/02, To McMaster-Carr, P.O. Box 440, New Brunswick, NJ 08903, For Grade 5 and 8 Bolts and Nuts
- Purchase Order 2002-506, dated 11/19/02, To Phelps Industrial Products, 6300 Washington Blvd, Elridge, MD 21075 For Black and Red Silicon Rubber Gasket requiring ASTM D-2000-70 and D-2000-80 respectively
- Purchase Order 2005-214, dated 7/08/05, To Phelps Industrial Products, 6300 Washington Blvd, Elridge, MD 21075 For Black and Red Silicon Rubber Gasket requiring ASTM D-2000-70 and D-2000-80 respectively

The team reviewed a sample of parts listed on CoC drawings for the Model No. 9215, NPI-20WC-6 MKII transportation package/shipping Cask. The sampled items were then used as the basis for reviewing the associated NPI's purchase orders.

The team verified that material requirements for components identified on CoC drawings were transferred to the purchase order.

The inspector reviewed the audit plan and the audit report for an audit of the NPI QA program for transportation packaging, dated 8/4-6/03. The inspector noted that this audit was performed by a contracted lead auditor - NPI provided a letter of agreement dated 11/13/97 to support the contracted lead auditor's procurement. The QA manager has authority to appoint lead auditors (per the NPI QAP).

The team noted that no procurement documents were generated for the contracted services of a lead auditor (letter of agreement did exist). This failure to prescribe requirements for lead auditor services is considered a violation of 10 CFR 71.109 and is cited in the enclosed Notice of Violation. After identification and during the inspection, NPI documented this deficiency in Corrective and Preventive Action Reports, Division III Teletherapy Shipping #III-06-01 Vendors Not On List.

The shackles used on Transfer Casks 1 and 4 (2 of 4 samples) were found to not comply with CoC DWG 240122, Rev. H, dated 8/15/02, shipping/transfer cask model S/TCMKII in that the shackle pins did not allow use of cotter pins.

Drawing number 240122, Rev. H, dated 8/15/02, for overpacks identifies ASTM std. D2000-80 for gasket materials. An associated PO 2005-14 for the purchase of gasket material describes specifically ASTM D-2000-70 based material, yet the checklist 29 completed for this Purchase Order was marked N/A as matching spec. requirements.

The failure to assure shackle specifications are met and gasket material specifications are met, are considered a violation of 10 CFR 71.115(a) and are cited in the enclosed Notice of Violation. NPI had identified these deficiencies in Corrective and Preventive Action Reports, Division III Teletherapy Shipping #III-06-07 Shackles Not To Spec; and Corrective and Preventive Action Reports, Division III Teletherapy Shipping #III-06-06 Gasket Receipt Checklist Needed

#### 2.4.2.2 Measuring and Test Equipment Controls

The team reviewed procedures, inspected M&TE documents, and discussed implementation of the process with the Neutron Products Part 71 Quality Assurance Manager. The following documents were reviewed:

- Certificate of Calibration #38950, OHAUS Scale, Model I-20W, S.N. 12976, Dated 2/02/06, American Scale and Equipment Company, Baltimore MD

- Certificate of Calibration #1000111057, Torque Wrench Model DT250A, Calibration Date 9/26/2005, Gerber Scale and Calibration

The team noted the small amount of calibrated equipment required to support Part 71

operations. The torque wrench and scale used for respectively tightening bolts and weighing the shipping cask were reviewed and found acceptable and current.

### 2.4.3 Conclusions

Overall, NPI's implementation of their QA program in the areas of maintenance controls requires more emphasis on documentation and formality of implementation. In the specific areas of maintenance, measuring and test equipment, implementation was adequate. In the area of procurement, corrective actions are required to assure implementation of Part 21 requirements and to assure procurement to specifications and maintenance to the requirements and specifications of CoC Drawings is occurring. As cited in the enclosed Notice of Violation, the team identified several instances where quality procedures were not followed or where procedural guidance was inadequate for controlling quality-related activities.

### 3. Exit Meeting

An exit meeting was conducted by the team with NPI personnel on September 13, 2006. The team's preliminary findings and assessments were presented at the meeting. NPI personnel at the meeting acknowledged the team's findings and did not state any disagreement with the preliminary findings and their characterization. The team verified that no proprietary information was discussed at the exit nor provided to the team during the inspection.

## NOTICE OF VIOLATION

Neutron Products  
Dickerson, MD 29210

Docket No. 71-0121

During an NRC inspection conducted on September 11-13, 2006, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violations are listed below:

- A. 10 CFR Part 21 requires, in part, that posting of Part 21 occurs in the workplace.

Contrary to the above, the team noted that only partial posting of Part 21 requirements at both the Dickerson and Ranson facilities existed. The team noted that only Section 206 of the Energy Reorganization Act was posted at both locations. The team noted that no 10 CFR Part 21 regulation was posted and no NPI Part 21 procedure or NPI point of contact for 10 CFR Part 21 reporting was posted.

This is a Severity Level IV violation (Supplement V).

- B. 10 CFR Part 21.31 requires, in part, that procurement documents specified, when applicable, that the provisions of 10 CFR Part 21 apply.

Contrary to the above the inspector identified the following completed procurement under the following purchase orders in the transportation area occurred without regard to application of Part 21:

- Purchase Order 2002-399, dated 8/21/06, alloy steel forged anchor shackle
- Purchase Order 2002-505, dated 11/15/02, Grade 5 and 8 bolts and nuts
- Purchase Order 2002-506, dated 11/19/02, black and red silicon rubber gasket material
- Purchase Order 2005-214, dated 7/08/05, black and red silicon rubber gasket material

NPI self Identified this violation, but did not complete corrective action as required in 10 CFR 21.31.

This is a Severity Level IV violation (Supplement VI)

- C 10 CFR Part 71.105 (a) requires, in part, that CoC holders shall provide for indoctrination and training of personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained.

Contrary to the above, proficiency documentation for personnel performing activities affecting quality was not provided during the inspection.

This is a Severity Level IV violation (Supplement V).

- D, 10 CFR Part 71.107© requires in part, that CoC holders shall establish measures to assure that applicable regulatory requirements and the package design. These measures must include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled.

Contrary to the above, the team inspected two sample overpacks (OP-8 & OP-11) - noting that both have 8 holes in addition to the required ½" vent holes. The holes appear to have been previously used for older name plates which have subsequently been replaced by new name plates, installed in a new location on both overpacks.

This is a Severity Level IV violation (Supplement V).

- E. 10 CFR 71.109 requires, in part, that the CoC holder shall establish measures to assure adequate quality is required for procurement of services.

Contrary to the above, procurement documents and associated quality assurance/qualification specifications, were not developed for the control of the procurement of contracted services. No Purchase Order was used to procure the services of the contracted lead auditor for an audit performed on August 4-5, 2004. The inspector did note that a letter of agreement did exist between NPI and the auditor.

This is a Severity Level IV violation (Supplement V).

- F. 10 CFR 71.111 requires, in part, that the CoC holder shall prescribe activities affecting quality by documented procedures. The procedures must include appropriate qualitative and quantitative acceptance criteria to determine its activities have been satisfactorily accomplished.

Contrary to the above, Procedure R-5502, Rev. 1 does not adequately address control of document development, review, approval, issuance, and disposal/return as well as overall responsibility of the process detail.

This is a Severity Level IV violation (Supplement V).

- G. 10 CFR 71.115 (a) requires, in part, that the CoC holder shall establish measures to assure that purchased material, equipment and services conform to procurement documents (resulting from CoC basis) and (b) that material conform to procurement specifications.

Contrary to the above, Control of purchased material - Shackles, Transfer Casks 1 and 4 (2 of 4 samples) were found to not comply with DWG 240122, Rev. H, dated 8/15/02, shipping/transfer cask model S/TCMKII in that the shackle pins did not allow use of cotter pins.

Contrary to the above Drawing number 240122, Rev. H, dated 8/15/02, for overpacks identifies ASTM std. D2000-80 for gasket materials. An associated Purchase Order 2005-14 for the purchase of gasket material describes, specifically, ASTM D-2000-70 based material yet the Checklist 29 completed for this Purchase Order was marked N/A as matching spec. requirements.

Contrary to the above, both OP 8 and OP 11, 20WC-6 MKII Overpacks are missing the manufacturers stamped name and date on the lower half of the component. This stamp is required by CoC Dwg. 240116, Rev. G, dated 8/15/02.

Contrary to the above, the team also identified three different Grade 5 and 8 bolts

bearing head markings on the Suspect/Counterfeit Part Headmarks List, DOE Quality Alert, Issue Number 92-4, in use during the inspection of Units 8 and 11.

This is a Severity Level IV violation (Supplement V).

- H. 10 CFR 71.131 requires, in part that the CoC holder shall establish measures to control materials, parts and components that do not conform to requirements to prevent inadvertent use or installation. These measures must include as appropriate procedures for identification, documentation, segregation, disposition and notification to affected organization. Nonconformances must be reviewed and accepted or rejected, repaired or reworked.

Contrary to the above, previous audits have noted no nonconforming identification process exists for transportation activities at NPI. As a result, the NRC inspector identified 2 packagings which were non-conforming, but still in use.

This is a Severity Level IV violation (Supplement V).

- I. 10 CFR 71.133 requires, in part, that the CoC holder shall establish measures to assure conditions adverse to quality are promptly identified and corrected.

Contrary to the above, previous audits have identified no corrective action process exists for transportation activities at NPI. The team noted that corrective actions toward the development of a nonconformance process and a corrective action process have not been completed and therefore have not been timely, since identified in a 2004 audit.

This is a Severity Level IV violation (Supplement V).

- J. 10 CFR 71.137, requires, in part, that the CoC holder shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program.

Contrary to the above, the team noted that NPI did not perform an internal audit for 2005.

This is a Severity Level IV violation (Supplement V).

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, with a copy to Robert J. Lewis, Chief, Rules, Inspections and Operations Branch, Licensing and Inspection Directorate, Division of Spent Fuel Storage and Transportation, Office of Nuclear Material Safety and Safeguards. 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, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document 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 deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

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

Dated this 6th day of November, 2006.