

**NEUTRON PRODUCTS inc**

22301 Mt. Ephraim Road, P. O. Box 68  
Dickerson, Maryland 20842 USA  
301-349-5001 FAX: 301-349-2433  
e-mail: neutronprod@erols.com

January 5, 2007

Mr. Robert J. Lewis, Chief  
Rules, Inspections and Operation Branch  
Licensing and Inspection Directorate  
Division of Spent Fuel Storage and Transportation  
Office of Nuclear Material Safety and Safeguards  
United States Regulatory Commission  
Washington, D.C., 20555-0001

Re: NRC Inspection Report No. 71-0121/06-201 and Notice of Violation, dated November 8, 2006

Your e-mail dated November 16, 2006

VIA FAX: 301-415-8555 (Original by UPS Overnight)

Dear Mr. Lewis:

This is Neutron's timely response to the referenced Notice of Violation, using the format of the Notice.

A. VIOLATION

*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.*

RESPONSE

Neutron has posted on the bulletin boards at our Ranson, WV, and Dickerson, MD,

offices the current copies of:

- the 10CFR21 regulations;
- Section 206 of the Energy Reorganization Act of 1974; and,
- Neutron's procedures implementing 10CFR21.

A draft Neutron Products Division III Training Module, Part 21, has been prepared and was first used during Neutron's Annual Source Handler's training on October 13, 2006.

B. VIOLATION

*10 CFR Part 21.31 requires, in part, that procurement documents specified, when applicable, that the provisions 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 10 CFR 21.31.*

RESPONSE

The purchase order form used for all purchases for Neutron's cobalt-60 division has been modified to include the legend:

*“ With respect to the supply of goods, relating to a facility regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, the provisions of Title 10 Code of Federal Regulations, Part 21 (10CFR21) are applicable to this order. No changes shall be made to specifications, including material or process.”*

The old purchase order forms have been destroyed in accordance with corporate Procedure C 9001, Document and Data Control, Revision 2, dated October 19, 2001.

Training for those involved in the use and maintenance of radioactive packaging on Procedure C 9001 will be completed before January 31, 2007.

C. VIOLATION

*10 CFR Part 71.105 (a) requires, in part 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, proficiency documentation for personnel performing activities affecting quality was not provided during the inspection.*

RESPONSE

A new Procedure "Training for Radioactive Material Shipments," R-5509, Revision 0, has been written and approved.

Training was provided and documented during Neutron's Annual Source Handler's training on October 13, 2006.

Additional training on R-5509 will be completed before January 31, 2007.

Documentation of the maintenance of the proficiency of the Manager, Radioactive Shipping Packages will be completed in accordance with the procedure before June 26, 2007, when the annual Radiation Protection Program Report is due.

D. VIOLATION

*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 nameplates, which have subsequently been replaced by new name plates, installed in a new location on both overpacks.*

RESPONSE

To meet the package marking regulations that resulted from harmonization, Neutron added two new permanent labels to the outside of the packages approved by CoC USA/9215/B(U) and removed the two old labels from these packages. This left eight 1/4-

inch diameter holes in the steel shell where the rivets held the labels.

We believe that the best corrective action is to replace the rivets that held the old labels with solid steel rivets.

Neutron will discuss alternative corrective actions and necessary approvals, if any, with the NRC before selecting and implementing a corrective action for the extra eight 1/4-inch diameter holes in the steel shell. As a temporary measure, we have covered them with waterproof tape as required for by the CoC for the 1/2-inch diameter holes in the shell.

We will talk to the NRC and, if desirable, schedule a meeting before January 22, 2007.

E. VIOLATION

*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 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.*

RESPONSE

The qualifications of the contracted lead auditor who performed the audit referenced in the violations is well known to NPI's management through his years of consulting with NPI.

He has been added to the list of approved vendors.

All future contracts for quality services shall be in accordance with procedure "Purchasing - Radioactive Transportation Packages," R-5508.

Training on Procedure R-5508 will be completed before January 31, 2007.

F. VIOLATION

*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.*

#### RESPONSE

Our review of existing corporate procedures subsequent to the referenced inspection determined that corporate Procedure C-9001, Document and Data Control, Revision 2, dated October 19, 2001 should apply to use and maintenance of radioactive packaging.

Training for those involved in the use and maintenance of radioactive on Procedure C-9001 will be completed before January 31, 2007.

#### G. VIOLATION

*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.*

## RESPONSE

At a programmatic level, Procedure "Purchasing - Radioactive Shipping Packaging," R-5508, Revision 0, has been written and approved.

Corrective actions for the referenced items follows:

### G.1. SHACKLES

The non-conforming shackles have been removed from the packages, segregated and marked "NOT FOR USE ON R.A.M. PACKAGES."

New conforming shackles have been ordered, received, inspected and accepted.

### G.2. CERTIFICATIONS

Certification for the gasket material purchased under the purchase order referenced in the Notice of Violation has been ordered, received, evaluated and conformance with the material specification verified.

The purchase order form used for all purchases for Neutron's cobalt-60 division has been modified to include the legend:

"Please supply a Certificate of Compliance/Calibration when shipping goods or services designated "Q" in the DQMS column."

### G.3. MANUFACTURERS IDENTIFICATION LABELS

Corrective action has been initiated and upper and lower manufacturer's stamped name and date will be added to:

- all overpacks, except OP 9, prior to their use by Neutron;
- OP 9 overpack after it is returned from Colombia (if it is returned) and before it is used,
- all OP's in Neutron's possession that do not have the manufacture's stamped name and date on both the upper and lower half of the shell have been segregated and marked as "NONCONFORMING PART - DO NOT USE."

### G.4. SUSPECT/COUNTERFEIT CLOSURES

The non-conforming bolts have been discarded in a metal recycling roll-off scrap

container. No nonconforming bolts remain in the Ranson facility where the shipping packages are maintained.

Procedure "Purchasing - Radioactive Shipping Packaging," R-5508, Revision 0, has been written and approved.

All purchase orders forms now include the legend: "Fasteners shall not have head marking that are on the U.S. Customs Service list of suspect/counterfeit fasteners."

Training on Procedure R-5508 will be completed before January 31, 2007.

H. VIOLATION

*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 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.*

RESPONSE

Procedure "Control of Nonconforming Packaging - Radioactive Materials," R-5507 has been written and approved.

The two nonconforming packages referenced in the Notice of Violation have been made conforming, except for the extra label holes, which have been temporarily covered with water proof tape, as CoC specifies for the eight 1/2-inch diameter holes.

Training on Procedure R-5507 will be completed before January 31, 2007.

I. VIOLATION

*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 towards 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.*

#### RESPONSE

A new position, Quality Assurance Manager for Radioactive Transportation, has been created and filled.

Procedure "Corrective and Preventative Action Radioactive Material Transportation," R-5506 Revision 0, has been written and approved.

Training on Procedures R-5506 will be completed before January 31, 2007.

#### J. VIOLATION

*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.*

#### RESPONSE

A new position, Quality Assurance Manager for Radioactive Transportation, has been created and filled.

Procedure "Training for Radioactive Shipments," R-5509, Revision 0, has been written and approved, which, in part, provides that:

- individuals responsible for quality procedures will provide the records clerk the schedule for the Corporate Calendar of training for which they are responsible; and,
- the records clerk is responsible for maintaining the Corporate Calendar and notifying the individuals responsible for required actions on a timely basis, and their supervisors when action is not taken, including audits.

Training on Procedure R-5509 will be completed before January 31, 2007.

We have noted several minor errors in the referenced report, including:

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1. NPI receives cobalt-60 sources at off-sites under its MD-31-025-03 license, and ships and transfers them to an approved licensee.

1.3. Ransohoff is the correct spelling of Jack and Bill's last name.

2.1.2.3. R-5502 is the correct number for NPI's Control of Quality Records Procedure.

Thank Messrs. Pearson and Karmis for the professionalism with which they performed their inspection and we look forward to your response.

Although I primarily telecommute, I can always be reached through my office and often at home. I would appreciate it if all e-mails were sent to both my office and home.

Regards,



Marvin M. Turkanis  
Special Assistant to the President for Division III

telephone: 301 929 9318 (Home)  
                  301 580 2596 (Cell)  
fax:            301 929 1957 (Home)  
e-mail:        marvintur@comcast.net (Home)