

NEUTRON PRODUCTS inc

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February 5, 2008

ATTN: Document Control Desk,
Director, Spent Fuel Project Office
Office of Nuclear Material Safety and Safeguards
United States Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, Maryland 20852-2738

Re: Reply to Notice of Violation

Mr. David W. Pstrack letter and Notice of Violation, dated January 10, 2008
NRC Inspection Report No. 71-0121/2007-201 dated August 28-30, 2007

VIA FAX: 301-492-3350 (Original by UPS Overnight)

Dear Sir or Madam:

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

GENERAL CONCERN

Though some improvement has been made in the implementation of the NPI QA Program since the previous NRC inspection in 2006, the NRC is concerned that many of the violations identified in the 2007 inspection indicate continuing programmatic weaknesses. Specifically the NRC is concerned that NPI may not be providing the necessary resources needed to improve implementation of its NRC approved QA Program. To verify that timely and effective corrective action has been taken by NPI in response to these concerns, the NRC will conduct another inspection of NPI in 2008.

GENERAL CONCERN RESPONSE

The Corporate structure and organization of Neutron Products is being reviewed by the President and the Board of Directors with the intent of making changes that address the concern that has been raised and to ensure a continued record of safe operations involving the shipment of radioactive material. The review is being driven by a number of forces, including a recognition by the management that additional top management attention and

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resources are needed to improve implementation of our quality assurance programs, including our NRC Quality Assurance Program for the Transportation of Radioactive Materials. While the Corporate structure and organization are reviewed and changed, attention is being focused on reviewing, updating and harmonizing our procedures for the transportation of radioactive materials.

As part of this review:

- the President has appointed a new Quality Assurance Manager for Radioactive Transportation;
- the previous Quality Assurance Manager for Radioactive Transportation is assisting the new QA manager in his new responsibilities; and,
- the Quality Assurance Manager for Radioactive Transportation has appointed a new Manager, Radioactive Shipping Packages, thereby adding an individual to the quality system.

VIOLATION 1

10 CFR 71.1 05(d) requires, in part, that the CoC holder shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained.

Contrary to the above, the inspection team identified that some NPI personnel (at a minimum, the RSO-03 and the NPI Division III Records Clerk/Document Control Clerk/Document Control Coordinator), who had responsibilities for performing activities affecting quality for Division III, had not been adequately trained and the QAMRT for NPI Division III had only evaluated one of the persons performing activities affecting quality as associated to 10 CFR Part 71 transportation activities at NPI and therefore NPI cannot be certain that proficiency is achieved and maintained for all NPI personnel performing activities affecting quality under Part 71.

RESPONSE: VIOLATION 1

As part of the review of procedures referred to above:

- Procedure R-5509, Revision 0, Training for Radioactive Material Shipments is being extensively expanded and renamed Procedure R-5509, Revision 1, "Training and Proficiency Assessments for Radioactive Material Shipments" which will provide for:

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- the evaluation of proficiency to be performed annually; and,
- the QAMRT to provide the Records Clerk with the records of the proficiency assessments for all quality personnel; and,
- existing and draft procedures have been reviewed and tables of:
 - Personnel by Job Titles;
 - Responsibility in Quality Procedures by Job Position; and,
 - Training Requirements by Job Position

have been drafted as a basis of assuring that all personnel performing activities affecting quality have been identified, trained and evaluated for proficiency on a documented schedule.

Implementation of procedure R-5509, Revision 1, and the tables referenced above is scheduled to be completed by February 29, 2008.

VIOLATION 2

10 CFR 71.111, requires, in part, that the CoC holder shall prescribe activities affecting quality by documented instructions, procedures, or drawings ...

Violation 2, Part 1

Contrary to the above, a newly developed procedure, "Corrective and Preventative Action for Radioactive Material Transportation," R-5506, Revision 0, was written to implement a process for the subject area, as none existed for Division III previous to the 2006 inspection. The newly developed 5506 procedure was identified during the 2007 inspection as inadequate for the following reasons:

R -5506, Revision 0, does not indicate any responsible party for the capture and maintenance of records completed from the implementation of the procedure.

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The RSO has been assigned responsibilities in the body of the 5006 procedure, but the responsibilities of the RSO were not addressed in Section 4, "Personnel" of the procedure where other responsibilities were described.

RESPONSE: VIOLATION 2, PART 1

Procedure R-5506, Revision 0, "Corrective and Preventive Action for Radioactive Material Transportation," had been made obsolete; and had been replaced by our Corporate procedure C-9003 "Corrective and Preventive Action" prior to the August 2007 Inspection, per our letter to Mr. Robert J. Lewis dated October 1, 2007.

Our Corporate procedure C-9003 "Corrective and Preventive Action" is being revised as part of the improvement of our QA Programs referred to in our response to your general concern, and to harmonize with our procedures for the transportation of radioactive materials.

Implementation of the revised procedure C-9003 is scheduled to be completed by February 29, 2008.

Violation 2; Part 2

Contrary to the above, the CoC holder has indicated that assigned responsibility exists for the RSO under NPI procedure, "Control of Nonconforming Packaging, Radioactive Material Transportation," R-5507, Revision 0, through a current statement found in NPI procedure "Teletherapy Shipping Packaging Maintenance Procedure," R-2019, Revision 3 yet the responsibility is not evident in the R-5507 procedure.

RESPONSE: VIOLATION 2, PART 2

Procedure R-2019 "Teletherapy Shipping Packaging Maintenance" is being revised so that the QAMRT instead of the RSO-03 is notified in the event of maintenance issues, such as a weight/gain loss of the wooden jacket or nonconformances including damage to the TC, wooden jacket, steel shell or assembled package/package. Similarly, the evaluation and implementation of corrective and preventive action will be the responsibility of the QAMRT instead of the RSO-03.

Procedure R-5507, Revision 0, "Control of Non-Conforming Packaging for Radioactive Material Transportation," is being revised to require that:

- all nonconformances/nonconforming packaging are reported to the QAMRT; and,

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- all personnel involved with radioactive materials transportation are responsible for reporting nonconformances to the QAMRT.

Implementation of procedure R-2019, Revision 4, "Teletherapy Shipping Packaging Maintenance Procedure" and procedure R-5507, Revision 1 "Control of Non-Conforming Packaging for Radioactive Material Transportation," is scheduled to be completed by February 29, 2008.

VIOLATION 3

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

Violation 3, Part 1

Contrary to the above, training had been provided on new and revised procedures to correct findings from the 2006 inspection, but the NPI did not possess records to show that the Clerk/Document Control Clerk/Document Control Coordinator completed required training on procedures. "Control of Nonconforming Packaging, Radioactive Material Transportation," R5507, Revision 0, "Purchasing - Radioactive Transportation Packages," Revision 0, R-5508 and C-9001. Consequently at the time of the 2007 inspection, some NPI personnel had still not been adequately trained prior to performing activities affecting qualities which were intended to correct violations identified during the 2006 inspection. In this case, responsibilities for performing activities affecting quality are assigned to the position identified herein.

RESPONSE, VIOLATION 3, PART 1

Subsequent to the inspection, the Records Clerk/Document Control Coordinator has completed required training on all procedures involved in radioactive material transportation for which she captures and maintains documents or records, including the "Control of Nonconforming Packaging, Radioactive Material Transportation," R-5507, Revision 0; "Purchasing - Radioactive Transportation Packages," R-5508, Revision 0 and "Document and Data Control," C-9001, Revision 3.

The tables, Personnel by Job Titles, Responsibility in Quality Procedures by Job Position, and Training Requirements by Job Position; and procedure R-5509, Revision 1, "Training and Proficiency Assessments for Radioactive Material Shipments," which are referenced in our response to Violation 1, provide a mechanism for assuring that the training of all personnel is current in the future.

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The titles of Records Clerk and the Document Control Coordinator are being standardized as the applicable procedure is revised.

The training of the Records Clerk and Document Control Coordinator on procedures R-5507, R-5508 and C-9001 is current. Training on the revised procedures is scheduled to be completed by February 29, 2008.

Violation 3, Part 2.

Contrary to the above, the team identified that the Radiation Safety Officer (RSO)-03 did not receive required training on procedure, "Document and Data Control" C-9001, Revision 3. Consequently at the time of the 2007 inspection, some NPI personnel had still not been adequately trained prior to performing activities affecting quality which were intended to correct violations identified during the 2006 inspection. In this case, responsibilities for performing activities affecting quality are assigned to the position identified herein.

RESPONSE, VIOLATION 3, PART 2

Subsequent to the inspection, the RSO-03 has completed required training on procedure C-9001, Document and Data Control.

As stated in our response to Violation 1, the:

- Tables of Personnel by Job Titles; Responsibility in Quality Procedures by Job Position; and Training Requirements by Job Position; and,
- Procedure R-5509, Revision 1, "Training and Proficiency Assessments for Radioactive Material Shipments"

provide a mechanism for assuring that the training of all personnel is current in the future.

Implementation of the revised procedure, R-5509 Revision 1, "Training and Proficiency Assessments for Radioactive Materials Shipments" is scheduled to be complete by February 29, 2008.

Violation 3, Part 3

Contrary to the above, training had been provided on a new procedure, but only the MRSP and the QAMRT attended the training on procedure "Corrective and Preventative Action for Radioactive Material Transportation" Revision 0, when

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other NPI staff were required to attend according to their assigned responsibilities. Consequently at the time of the 2007 inspection, some NPI personnel had still not been adequately trained prior to performing activities affecting quality which were intended to correct Violations identified the 2006 inspections.

RESPONSE 3, PART 3

Reiterating our response to Violation 2, Part 1:

Procedure R-5506, Revision 0, "Corrective and Preventive Action for Radioactive Material Transportation," had been made obsolete; and had been replaced by our Corporate procedure C-9003 "Corrective and Preventive Action" prior to the August 2007 Inspection.

Our Corporate procedure C-9003 "Corrective and Preventive Action" is being revised as part of the improvement of our QA Programs referred to in our response to your general concern and to harmonize with our procedures for the transportation of radioactive materials.

Implementation of the revised Procedure C-9003 is scheduled to be completed by February 29, 2008.

VIOLATION 4.

10 CFR 71.135 requires in part that the CoC holder shall maintain sufficient written records to describe the activities affecting quality. These records must include qualification of personnel

Contrary to the above, NPI could not produce sufficient written records during the 2007 inspection to support the training performed for corrective actions associated with the 2006 inspection. NPI did perform training however; some personnel requiring training were not trained.

RESPONSE: VIOLATION 4

Training of all personnel associated with the 2006 inspection has been completed.

Again, as stated in our response to Violation 1, the:

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- Tables of Personnel by Job Titles; Responsibility in Quality Procedures by Job Position; and Training Requirements by Job Position; and,
- Procedure R-5509, Revision 1, "Training and Proficiency Assessments for Radioactive Material Shipments"

provide a mechanism for assuring that the training of all personnel is current in the future.

Violation 5.

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. The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel,

Violation 5, Part 1

Contrary to the above, the team noted that NPI could not produce any documentation supporting the adequate training of the lead auditor of the most current NPI internal audit. In addition, no documentation to support the certification of the lead audit was provided.

RESPONSE: VIOLATION 5, PART 1

Documentation for the lead auditor's training and experience, previously on file, has not been found. Therefore, the new QAMRT has evaluated, documented and qualified the lead auditor based on his education, training and experience.

Reiterating our response to Violation 1, the:

- Tables of Personnel by Job Titles; Responsibility in Quality Procedures by Job Position; and Training Requirements by Job Position; and,
- Procedure R-5509, Revision 1, "Training and Proficiency Assessments for Radioactive Material Shipments"

provide a mechanism for assuring that the training of all personnel is current in the future.

The QAMRT will ensure that any additional auditors of radioactive materials shipping activities are evaluated, qualified and documented before they are added.

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Violation 5, Part 2

In addition, contrary to the above, the NPI procedures do not include a method for developing a periodic audit schedule.

RESPONSE: VIOLATION 5, PART 2

The existing "Quality Audit Procedure, QC-1007" covers four areas of activity for Neutron's Division III, including the shipment of radioactive materials. A new procedure is being written covering only the shipment of radioactive materials in accordance with our Quality Assurance Program for the Transportation of Radioactive Materials. This procedure will include audit frequencies and the individual responsible for scheduling audits.

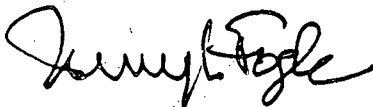
Implementation of the new audit procedure is scheduled for completion by March 31, 2008 to allow it to be meshed with the revised Corporate audit procedure.

We believe this letter and our on-going actions to be responsive to your concerns and the specific violations. We look forward to your response.

I can always be reached through our Dickerson, MD office per our letterhead, but since my base of operations is our Ranson, West Virginia office, I have included my West Virginia contacts as follows:

Telephone 304 725-7041
fax 304 725-1804
email neutrontele@frontiernet.net

Regards,
Neutron Products Inc.



Jerry L. Fogle
Quality Assurance Manager Radioactive Transportation

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CC: Mr. David W. Pstrak, Chief
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