

NEUTRON PRODUCTS inc

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November 2, 2009

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 a Notice of Violation
Mr. David W. Pstrack letter and Notice of Violation, dated October 2, 2009
NRC Inspection Report No. 71-0121/2009-201

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

Dear Sir or Madam:

This letter is in timely response to the referenced Notice of Violation dated October 2, 2009 and received here on October 5, 2009.

VIOLATION A

10 CFR 71.105(b), "Quality Assurance Program", states in part, that the Certificate of Compliance holder through its quality assurance program shall provide for control over activities affecting quality of identified materials and components to an extent consistent with their importance to safety and as necessary to assure conformance to the approved design of each individual package used for shipment of radioactive material. The Certificate holder shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality and the need for verification of quality by inspection and test.

Contrary to the above, NPI failed to develop or procure the necessary staff to serve in evaluating the certain needs in association with the repair of the OP-10 overpack. The needs included, but were not limited to; applicable codes and standards, weld procedure specification process, welder qualification to a specific process, weld filler metal identification and control, material compatibility, associated certified material test

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reports, and contractor procurement. In addition, the team noted that consideration was also needed for associated inspections of the processes and repair of the OP-10 overpack, to ensure the transportation package design was maintained. Consequently the OP-10 overpack was used for transport of radioactive material while not in compliance with Part 71 requirements.

RESPONSE TO VIOLATION A

We now recognize that weld repairs made to OP-10 overpack were not in accordance with the drawings approved as part of the Certificate of Compliance for the package. The following corrective actions have been completed:

- Corrective action CA-2009-RT-002 was initiated during the inspection in July;
- OP-10 overpack was in Brazil at the time, was placed in nonconforming status pending regulatory approval for completion of the shipment within Brazil;
- Submitted report to the USNRC on the use of the nonconforming packaging per 10 CFR 71.95;
- Issued a directive limiting package repairs to those that maintain the original design approved in the Certificate of Compliance;
- Received necessary approvals for one time return shipment of OP-10 to Southwest Research Institute (SwRI), San Antonio, Texas;
- Instructed SwRI to hold OP-10 overpack and not use for shipment after receipt in San Antonio, Texas; and,
- Supplied SwRI with identification tags noting the nonconforming status to be attached upon receipt of the package in San Antonio, Texas.

In addition, we will revise procedure R-2031, Repair of Teletherapy Shipping Package Components to include, as necessary, use of a qualified engineer to:

- Ensure that proposed repairs do not change package design specifications;
- Specify applicable codes and standards;
- Develop and/or evaluate procedures and specifications for repair processes; and,
- Specify materials to be used, in conformance with package design and existing packaging material.

In addition, provisions will be added to address contractor qualifications to perform the required activities, requirements for certified material test reports, and inspections of completed repairs for conformance with package design.

All engineering and repair services will be evaluated and procured in accordance with R-1516, Vendor Qualifications.

Implementation of revisions to these procedures is scheduled to be completed by January 31, 2010. No repairs to packages involving special processes will be made until the revisions have been completed and training of personnel has taken place.

VIOLATION B

10 CFR 71.111, "Instructions, Procedures, and Drawings," states, in part that the certificate holder shall prescribe activities affecting quality by documented procedures and shall require that these procedures be followed.

- 1. Contrary to the above requirement, the following instance was identified where activities were not prescribed in documented procedures, or where procedures were not followed when NPI performed welding to repair a transport package. NPI's implementing Procedure R2019-G, "Teletherapy Shipping Maintenance Procedure, Revision 5," paragraph 7.4.1 requires a written procedure for repair. This R2019-G procedure lacks details to ensure that: a) an acceptable welding code or standard is used for the development of a Welding Procedure Qualification Record and a Welding Procedure Specification; b) the welder is acceptably qualified and the qualification is properly documented; c) the identification for base and filler metals is provided and; d) that each of the previous three items are acceptably reviewed and approved prior to implementation. In the case of this weld repair, no other lower tier documents were provided for specific guidance.*

RESPONSE TO VIOLATION B 1

Corrective actions shall include at minimum revisions to R-2019, Teletherapy Shipping Maintenance Procedure and/or R-2031, Repair of Teletherapy Shipping Package Components:

- requiring use of an acceptable code or standard to be used for the development of a Welding Procedure Qualification Record and a Welding Procedure Specification;
- verifying that those performing repairs are acceptably qualified and the qualification is properly documented;
- requiring identification of base and filler metals for proposed weld repairs; and,

- Requiring independent review and approval of proposed work guidance and weld specifications.
2. *Contrary to the above requirement, NPI failed to document the need for a weld repair on the OP-10 overpack on a nonconformance which is also a violation of the "Quality Assurance Program for the Transportation of Radioactive Materials," Revision 10.*

RESPONSE TO VIOLATION B 2

While we now recognize the shortcomings associated with our repair of OP-10, as described in Violations A and B 1, we take issue with alleged Violation B 2, in that the nonconforming status of OP-10 overpack was documented in the maintenance log for this package component when it was received from Southwest Research Institute in 2004. OP-10 was removed from service until repairs could be made. Until it was removed for repair, OP-10 had been in the designated nonconforming area of our current facility ever since we moved in along with other nonconforming components. Within that isolated area, OP-10 had a red identification tag indicating its nonconforming status and that it was not to be used for shipping.

Since the inspection, we have provided refresher training on R-5507, Control of Nonconforming Packaging, Radioactive Material Transportation, to include details of triggering events and required actions. Based on the foregoing, it is our understanding that our actions were in compliance with our program and the regulations. No additional corrective action is contemplated at this time. If our understanding is incorrect, please advise.

3. *Contrary to the above, NPI procedures fail to: a) support the control of an appropriate design process, the necessary design methods to determine what parts and materials are essential to maintaining design configuration as well as the required review of the function of the items selected and determination for suitability of application of the materials and processes; b) check, review, and approve design drawings in accordance with quantitative or qualitative acceptance criteria for determining that prescribed results have been attained was undefined, and c) approve design drawings by NPI Engineering prior to use.*

RESPONSE TO VIOLATION B 3

During the inspection, corrective action CA-2009-RT-001 was initiated.

As described above, we have imposed a moratorium on special processes until program deficiencies, including those enumerated in Violation B 3 have been satisfactorily addressed. We are in the initial stages of interviewing providers of engineering services. Any engagement of an outside engineering firm will be in accordance with procedures for vendor qualification.

It is our goal to resolve this issue by the end of the first quarter of 2010. Until resolution, the moratorium will remain in place.

4. *Contrary to the above, audits of NPI's Quality Assurance Program were performed by personnel having direct responsibility in the areas being audited. The team noted that: a) procedures were both reviewed and approved by the author; b) procedures to support quality activities were written by the lead auditor; and c) proficiency documents of the QAMRT were approved by the lead auditor.*

RESPONSE TO VIOLATION B 4

To the extent that procedures implementing the QA Program were reviewed and approved only by the author, all such procedures will be reviewed by the QAMRT or other appropriate reviewer in accordance with C9000 (or its successor) and revised and/or reissued as applicable.

Those QA procedures which were authored by the lead auditor include C9000, C9001, and C9003. These are corporate procedures initially developed for use by other divisions and adopted for use by the transportation program by expanding their scope. The lead auditor played no direct role in the decision to do so. It is our intention to replace all "C" series procedures now implementing the QA program with stand alone division procedures in order to avoid the appearance of conflict.

In addition, Mr. Williams was signatory to, but not author of, R-1503, R-1511, R-1516, and R-2014, in connection with his assignment as QA Manager for Teletherapy Manufacturing or as RSO for the 01 facility license. We will address the 1500 series procedures as with the C-9000 procedure. As for R-2014, court order precludes us from loading and unloading radioactive material at our Dickerson, Maryland facility under the 01 license, therefore any involvement for radiation safety connected with this procedure has been suspended.

The approval of proficiency documents by the lead auditor was made in order to have confirmation of proficiency by a knowledgeable party. The QAMRT does not report to the lead auditor and there was no intention of establishing such a relationship. The proficiency review will be reconducted by the president to whom the QAMRT reports.

Mr. Williams has more experience with quality system audits than any other member of Neutron's staff and, while very familiar with radioactive transportation regulations and

Neutron's operations, has never held direct responsibility for any aspect of the transportation program. We believe that a robust internal audit program is best served by having auditors with more than passing familiarity with the company's operations as well as applicable standards and feel that Mr. Williams is the best person on our staff to fulfill this function.

Corrective actions and revisions to procedures are scheduled to be completed by January 31, 2009.

VIOLATION C

10 CFR 71.133, "Corrective Action," states in part that the certificate holder shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformance, are promptly identified and corrected.

- 1. Contrary to the above requirement, and continuing from earlier inspections, NPI was not able to produce documentation supporting the adequate training of NPI personnel. During the 2009 inspection supporting documents were not provided to support the NPI's lead auditor training and also the NPI Quality Assurance Manager for Radioactive Transportation.*

RESPONSE TO VIOLATION C 1

The lead auditor and QAMRT will receive NQA-1 training during an upcoming local training session and will obtain documentation to complete their training files.

- 2. Contrary to the requirement, NPI's program guidance is unclear as to what each employee's job responsibilities are, consequently the training requirements for each employee is similarly unclear. One specific example was a distinction between RSO-3 training and lead auditor training, within the NPI system since the RSO-3 fills both of the positions.*

RESPONSE TO VIOLATION C 2

Subsequent to the 2007 inspection, we revised a number of procedures and created documents that were intended to clearly define the responsibilities of all positions. The specific example cited above is incorrect, in that the RSO-03 and lead auditor positions are not filled by the same person. That said, during the inspection, we acknowledged deficiencies in various procedures including the responsibilities of personnel in the system. Accordingly, we have initiated corrective action CA-2009-RT-004. Corrections shall include at minimum:

- Review and revise any procedure in the system where personnel responsibilities are not clearly defined; and,
- Revise procedure R-5509, Training for Radioactive Materials Shipments to clarify training requirements, and independence in review and approval of proficiency assessments.

Corrective actions and revisions to procedures are scheduled to be completed by December 31, 2009.

VIOLATION D

10 CFR 71.137, "Audits," states in part that the certificate holder shall carry out a comprehensive system of planned audits to verify compliance with all aspects of the quality assurance program... In addition, the audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited.

Contrary to the above, NPI's audit procedure did not include a method for: (1) the development of an audit schedule or checklist, (2) certifying and qualifying auditors and/or lead auditors, (3) defining auditor roles and responsibilities, and (4) provisions to maintain lead auditor independence in the area being audited.

RESPONSE TO VIOLATION D

Procedure R-5510 was written in response to prior NRC inspections and provides for internal audits to be conducted on an annual basis and vendor audits to be conducted before initial use and at intervals not to exceed 3 years thereafter. Although the procedure does not specify the use of a checklist, the last internal audit and recent vendor audits were conducted using an audit checklist generated by the lead auditor or the QAMRT, and were consistent with the objectives of the audit. We will modify R-5510 to specify the use of an audit checklist or other schedule of items to be reviewed.

Provisions will also be added to R-5510 to require documentation regarding the qualification of auditors and/or lead auditors.

Section 5.2 of R-5510 addresses auditor responsibilities in a way which we believe to be consistent with the regulations. We would appreciate additional clarification if our understanding is incorrect on this matter, as modifications to this section are not contemplated at this time.

Section 6.1.1 of R-5510 requires the lead auditor for internal audits to have no direct responsibilities in radioactive materials transportation. As described in our response to

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Violation B 4, we will expand this limitation to include direct responsibilities over any program element to be audited.

Corrective actions and revisions to procedures are scheduled to be completed by December 31, 2009.

CONCLUSION

We acknowledge the deficiencies, except those noted, found during the inspection and the need for continued improvement in our Q A program. It is our goal to extend Neutron's decades long record of safely packaging and transporting radioactive materials. To that end, we submit this response and believe that our on-going actions are responsive to your concerns and specific violations. We look forward to your response.

I can always be reached through our Dickerson, Maryland office per our letterhead, as can Jerry Fogle. Since Mr. Fogle's base of operations is our Ranson, West Virginia office, I have also included his local office contacts as follows:

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Regards,

Neutron Products, Inc.



William L. Ransohoff
Director

Cc: Mr. David W. Pstrak, Chief
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