

→ R10B

## NEUTRON PRODUCTS inc

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30 November 2009

Via FAX: (301) 492-3348 (Original by UPS NDA)

Mr. William Brach  
Division of Spent Fuel Storage and Transportation  
Office of Nuclear Material Safety and Safeguards  
Mail Stop EBB-3D02M  
US Nuclear Regulatory Commission  
One White Flint North  
11555 Rockville Pike  
Rockville, Maryland 20852-2738

Re: Management meeting of 11/10/2009 and NRC Inspection Report No. 71-0121/2009-201

Dear Mr. Brach,

As we discussed during our management meeting on 10 November, I am writing to supplement our response of 2 November and to describe additional actions we are taking in order to restore our Quality Assurance Program for the Transportation of Radioactive Materials to full compliance with the regulations in a manner which provides a level of confidence to NRC of our continuing ability to maintain that Program.

During our meeting, reference was made to the three legged stool upon which our various quality programs are based, with the three legs comprised of management oversight, procedures and training. As we discussed, the first two legs will be addressed contemporaneously by virtue of the Review Committee, created with the express purpose of performing a top down review of our entire Program.

### **Program Review Scope and Description**

I am chairing the Review Committee, whose members also include:

NM5501

Jerry Fogle, QA Manager for Radioactive Transportation;  
Les Forrest, Manager of Radioactive Shipping Packages; and,  
Edmond DeRosa, Radiation Safety Officer for Neutron's License MD-031-26-03

In addition, at times, the Review Committee may also use the services of:

Marvin M. Turkanis, who is now semi-retired, but who has been with the company since 1967 and has extensive experience with radioactive shipments and with the QA Program;

Jackson A. Ransohoff, founder and President of the company;

James Jordan, treasurer of the company (Procurement procedures); and,

Carol M. Campbell, Quality Control Manager III, in the company's Radiation Processing Services Division.

Finally, in order to gain the benefit of objectivity and a fresh perspective on the company's Program, the Review Committee will also use the services of qualified parties from outside the company.

The program review will include a review of the QA Program itself against the requirements of 10 CFR Part 71 Subpart H, as well as the guidance provided by Regulatory Guide 7.10, Revision 2.

The Quality System procedures to undergo review shall include the current revisions of the following procedures:

R-1503	Control of Inspection, Measuring and Test Equipment
R-1511	Receiving Inspection for Parts and Materials (Teletherapy Activities)
R-1516	Vendor Qualification
R-2014	Teletherapy Shipping/Transportation Cask Unloading & Loading Procedure
R-2019	Teletherapy Shipping Package Maintenance Procedure
R-2031	Repair of Teletherapy Shipping Package Components
R-5507	Control of Non-Conforming Packaging, Rad. Mat. Transportation
R-5508	Purchasing - Radioactive Transportation Packages
R-5509	Training for Radioactive Materials Shipments
R-5510	Audits - Radioactive Materials Transportation
C-9001	Document and Data Control

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C-9003      Corrective and Preventive Action  
C-9008      Compliance with 10 CFR Part 21

Design control, fabrication and maintenance control, test control, internal inspection, and Drawings 240122 and 240116 will also be addressed.

### **Training**

The third leg of the stool concerns training. In the past, NRC inspectors have identified deficiencies in the training of some personnel, as well as deficiencies regarding the clarity of job titles, job descriptions, roles and responsibilities, etc. To address both of these issues, in the process of reviewing the aforementioned procedures, the Review Committee will develop documented job descriptions for those positions affecting the quality program. The job descriptions will summarize the authorities and responsibilities of each position, as currently described in the individual procedures. Training requirements will be more readily identifiable, thereby improving the administration of the training program and management's ability to monitor its implementation.

In addition, we also believe that the Program could benefit from relevant training provided by others in the nuclear industry. As such, both Jerry Fogle and Jeffrey Williams, lead auditor, will undergo NQA-1 training. We expect that this training will also provide some fresh perspective for the entire Program.

### **Schedule**

The work of the Review Committee is underway, and we anticipate the review to be completed by April 30, 2010.

### **Conclusion**

Throughout the review, emphasis will not only be on adding depth and detail, as necessary, to the individual procedures themselves, but will also be placed upon strengthening (and better defining) managerial controls in an effort to make our corrective actions more comprehensive and to eliminate the perception of programmatic weakness.

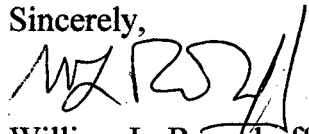
We recognize the undesirable situation under which our Program is currently operating,

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and appreciate the input we received from you and your staff at the meeting on 10 November. I look forward to sharing the results of our Review with your staff during the next inspection and believe this letter to be totally responsive to our discussions during the meeting. If you feel otherwise, or have additional questions or concerns, please let me know.

Sincerely,



William L. Ransohoff  
Director of Operations  
Neutron Products inc

cc: Mr. James Pearson  
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