NEUTRON PRODUCTS inc

22301 Mt. Ephraim Road P.O. Box 68 Dickerson, Maryland 20842 USA 301/349-5001 TWX: 719-828-0542 FAX: 301-349-5007

February 9, 1994

Mr. Walter J. Pasciak, Chief Industrial Applications Section Division of Radiation Safety and Safeguards U.S. Nuclear Regulatory Commission Region 1 475 Allendale Road King of Prussia, Pennsylvania 19406-1415

Re: Notice of Violation NRC Inspection Report No. 99990001/93-018 Your letter of January 25, 1994

Dear Mr Pasciak:

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Confirming my letter of November 23, 1993 to Mr. David Collins of NRC Region II, a copy of which is attached, Neutron Products failure to request and obtain approval for performing the source installation at Mayaguez Medical Center, Mayaguez, Puerto Rico was inadvertent and was caused by the documentation for the shipment to Mayaguez being prepared by individuals who prepare international shipments, since the shipment to Puerto Rico was by ocean. Because the documentation for domestic and foreign shipment are very different, the responsibility at Neutron has been assigned to different individuals. Since reciprocity is not required for foreign shipments, the preparers did not consider reciprocity for the Mayaguez shipment.

This installation was unique and no other similar failures have occurred.

The corrective steps which were taken are:

- everyone involved has been reminded that Puerto Rico, as well as Hawaii, Alaska, American Samoa and the Virgin Islands are part of the United States; and,
- Neutron Products' primary authorization and control document for teletherapy activities at Dickerson and in the field, the Teletherapy Notice, has been modified to document that reciprocity is required and received for each individual field operation.

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Full compliance was achieved on November 23, 1993.

The reference to Mr. Edward Putman as the Field Technician to whom Mr. Henson discussed the findings of his inspection at the conclusion of his November 16, 1993 inspection is incorrect. Neutron Products does not have an employee or licensed source handler with that name. I understand that Mr. Henson discussed his findings with Neutron Products source handler, Mr. Dale Repp.

I tried to call you on February 8 to obtain clarification on Mr. Putman, but was told that you would be out of the office until February 14, and we did not want to delay our response until after you returned.

We believe that the Violation is of minor significance and should be a Severity Level V (Supplement VII), not Severity Level IV (Supplement VI), because the Violation:

- involved failure to provide information to the NRC, which if provided should have resulted in approval of the source installation;
- did not involve a safety or environmental concern;
- did not involve treatment of patients;
- should not recur because of the prompt corrective action which was completed on the same day Neutron was advised of the potential violation by telephone; and,
- was an isolated failure that is inconsistent with Neutron's outstanding prior performance of requesting reciprocity.

However, if a civil penalty is proposed, we believe that it should be adjusted downward to reflect the above factors.

If there are any further questions or if you have any recommendations for additional action, please call me.

Sincerely,

NEUTRON PRODUCTS, INC.

Marvin M. Turkanis Vice President

MMT/afc

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