10 CFR 71.95 REPORT EVALUATION FORM

Docket No.:	71-9215
Package Model No.:	NPI-20WC-6 MkII
Report Submitted By:	J. L. Fogle, Neutron Products, Inc.
Report Date:	January 25, 2013
Report ADAMS Accession No.:	ML13030A043

Review the incoming report to determine if additional Commission or staff action is warranted. The review should consider whether the report identifies a generic defect or problem with the package design and the safety significance of the issue. Note that a high safety significance represents a potential for significant radiation exposure, medium safety significance represents a potential for some moderate radiation exposure, and low safety significance represents little or no potential for radiation exposure.

1. The report identifies:

__ Significant reduction in the effectiveness of a package during use;
__ Defect with a safety significance;
✓ Shipment in which conditions of the approval were not observed.

2. What is the safety significance? ___ High ✓ Medium __ Low

3. Summary of the report:

During an inspection of the Neutron Products Ranson, WV, facility by the Nuclear Regulatory Commission from November 26-29, 2012, inspectors determined that maintenance procedures were being employed which did not adequately implement the requirements of the certificate of compliance (CoC) for Neutron Products' package USA/9215/B(U). The basic maintenance requirements for Neutron Products' package USA/9215/B(U) are identified in R-2019G, Rev. 1, "Teletherapy Shipping Package Maintenance Procedure," which is referenced in the CoC. Although R-2019G, Rev. 1, satisfies the regulatory requirements, it does not provide much operational detail. Therefore, Neutron Products developed procedure R-2019, "Shipping Package Maintenance and Storage Procedure." The intent of R-2019 is not only to provide greater operational detail, but also allow maintenance operations to be modified to meet changing operational needs without modifying the CoC.

The USA/9215/B(U) package has been used to ship radioactive material internationally, and delays of several months have occurred for reasons beyond the control of Neutron Products, Inc. Such delays could cause the maintenance schedule for various package components to be exceeded. Therefore, on May 3, 2011, Neutron Products modified R-2019 to make provisions for such a possibility. (In those instances where the annual inspection of a package used for an international shipment was delayed, Neutron Products, Inc., would remove the package from service upon its return until the package could be satisfactorily inspected.) In addition, wording was added to R-2019 to make replacement of certain packaging parts optional if they were determined to be in good condition. These modifications resulted in R-2019 becoming less restrictive than the requirements contained in R-2019G, Rev. 1.

Since R-2019 was modified on May 3, 2011, three international return shipments were made when packages were beyond their normally scheduled inspection frequency. No packaging components failed during these shipments and the shipments were conducted safely. Nevertheless, because R-2019 was less restrictive than the approved procedure, the possibility of conducting a shipment with adverse safety implications did exist.

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4. Corrective actions taken by the licensee:

A request to modify R-2019G will be submitted to the Nuclear Regulatory Commission. Until that request is approved, the more restrictive conditions will be in effect. Also, Neutron Products, Inc., is seeking to realign the corporate culture to broaden the focus of the entire Quality Assurance program.

5. Staff comments:

The dimensions, mounting pattern and shielding ability of the non-conforming components are identical to those of approved components. Survey results during the shipment utilizing the non-conforming component not only showed dose rates were within regulatory limits, but also showed they were equivalent to those associated with the use of approved components. Thus, neither radiation workers nor members of the public were exposed to abnormal dose rates. Consequently, staff has determined this incident is not safety significant.

6. Staff conclusion:

_✓_ The report does NOT identify generic design or license/certificate issues that warrant additional Commission or staff action. This report is considered closed.

__ There is a need to take additional action. Provide a summary of the bases and recommended actions:

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