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ATTN: Document Control Desk
Director, Spent Fuel Project Office
Office of Nuclear Material Safeguards and Security
U. S. Nuclear Regulatory Commission
Washington, D. C.

To Whom It May Concern:

As required by 10CFR71, (71.95), Neutron Products, Inc. is submitting this report to describe the condition of nonconforming package components that were identified during an NRC inspection that was completed at our facility in Ranson, WV on November 29, 2012. The requirements in ***71.95, Reports***, and responses are referenced by letter and number as follows:

(c) (1) A brief abstract describing the major occurrences during the event, including all component or system failures that contributed to the event and significant corrective action taken or planned to prevent recurrence.

There were no component failures that contributed to this event.

Over the years, the international shipment of radioactive material has become considerably more difficult, so that the shipment of packages is often delayed by several months due to permitting, scheduling, and shipping problems that cannot be controlled by Neutron Products, Inc. Neutron's procedure R-2019, Shipping Packaging Maintenance and Storage Procedure prescribes an inspection schedule for various components of Neutron's USA/9215/B(U) package. In order to address the possibility of a loaded package being delayed overseas to the point where it is beyond its prescribed inspection frequency, Neutron modified Procedure R-2019 on May 3, 2011 to make provisions for such a return shipment. Once the package had been safely returned, it would be taken out of service until it could be satisfactorily inspected. In addition, wording was added to R-2019 to make replacement of certain packaging parts optional if the inspection determined that those parts were in good condition. As a result of these modifications the resulting revision of R-2019 was less restrictive than procedure R-2019G, Rev. 1, Teletherapy Shipping Packaging Maintenance Procedure, which is referenced in the Certificate of Compliance.

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(c) (2) (i) Status of components or systems that were inoperable at the start of the event and that contributed to the event.

There were no components or systems of the packaging that were inoperable at the start of the event.

(c) (2) (ii) Date and approximate times of occurrences.

Since the procedure was modified, there have been three times when international return shipments were made at a time when the packages were beyond their normally scheduled inspection frequency. In these cases, the packages were inspected by Neutron personnel in accordance with Neutron's procedures at the time the packages were prepared for the return shipment. After each package was inspected in the field, they were loaded with the sources and were prepared for return shipment to the U.S. It should be noted that the field inspection is intended to ensure that the package is shipped in a safe and conforming condition, but it is not as detailed as the scheduled inspection. The maintenance inspections which were performed after the packages were returned found no unusual package conditions.

(c) (2) (iii) The cause of each component or system failure, or personal error, if known.

A review of the operating procedure used to maintain the packages during the revision process did not adequately compare procedure elements to the maintenance procedure approved in the C of C, resulting in a procedure being used which was less restrictive than the approved procedure.

(c) (2) (iv) The failure mode, mechanism, and effect of each failed component, if known.

There were no failures of the function of the package and no practical effect on the safety of the package resulting from this deficiency.

(c) (2) (v) A list of systems or secondary functions that were also affected for failures of components with multiple functions.

There were no failures of components that occurred as result of this event.

(c) (2) (vi) The method of discovery of each component or system failure or procedural error.

The differences between the procedure used to maintain the packages and the approved procedure were not recognized as nonconforming until the NRC inspection which ended on November 29, 2012.

(c) (2) (vii) For each human performance related root cause, a discussion of the cause(s) and circumstances.

The intent of R-2019G is to have a basic procedure which meets regulatory requirements but which does not provide much operational detail. The intent of R-2019 is to provide significantly more operational detail, but to also provide necessary flexibility so that we can modify the procedure to meet changing conditions related to our operations, without having to amend the C of C to do so. In this case, our review process failed to identify that the proposed revisions were less restrictive than the approved basic procedure.

(c) (2) (viii) The manufacturer and model number (or other identification) of each component that failed during the event.

As noted in (c) (2) (iv), there was no failure of the function of any package components.

(c) (2) (ix) For events occurring during use of a packaging, the quantities and chemical and physical form(s) of the package contents.

The three packages used for shipments after the maintenance procedure was revised contained:

- 12.9 curies of cobalt-60;
- 1,456 curies of cobalt-60; and
- 398 curies of cesium-137.

(3) An assessment of the safety consequences and implications of the event. This assessment must include the availability of other systems or components that could have performed the same function as the components and systems that failed during the event.

There were no failures of packaging components during the shipments/event. The shipments were conducted safely and there were no safety consequences as a result of the shipments. Based upon the fact that the packages were stored in an appropriate facility awaiting shipment, and that they had been inspected and found to be safe and conforming at the time they were loaded and prepared for shipment, we submit that – related to the specific shipments that were made, there were no significant safety implications due to the shipments. However, because the operational procedure which was used was less restrictive than the approved procedure, there was a possibility of conducting a shipment with adverse safety implications.

(4) A description of any corrective actions planned as a result of the event, including the means employed to repair any defects, and actions taken to reduce the probability of similar events occurring in the future.

A request to modify R-2019G will be submitted to the NRC. Until that request has been approved, the more restrictive conditions will be in effect.

In the bigger picture, this nonconformance is not unlike other deficiencies identified during the inspection involving parts of components which were not consistent with the package drawings. As a result, an effort is underway to realign the corporate culture in a way which will broaden the focus of the entire QA program.

(5) Reference to any previous similar events involving the same packaging that are known to the licensee or certificate holder.

Taking a narrow view, we are not aware of similar events related to the modification of procedures involved in the use of these packages. However, as noted above, in the broader sense, this event is similar to the violations concerning the physical package itself in that – although it did not create a safety hazard in and of itself – it is part of a collection of similar program failures which – when considered together – reveals weaknesses which need to be addressed in the overall effectiveness of the quality system.

(6) The name and telephone number of a person within the licensee's organization who is knowledgeable about the event and can provide additional information.

Jerry L. Fogle, QA Manager for Radioactive Transportation – 304 725-7041

(7) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

There was no exposure to radiation or radioactive materials to any individuals beyond normal handling as a result of this nonconformance.

We believe that this letter fulfills the requirements of 71.95 Reports. If you require any additional information, please contact me at 304 725-7041 or at neutrontele@frontiernet.net. If I am unavailable at this phone number, I can be reached through our main office at 301 349-5001.

Respectfully submitted,

Neutron Products, Inc.

Jerry L. Fogle, Q. A. Manager
For Radioactive Transportation

Copy via electronic mail to: michele.sampson@nrc.gov