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As per your request.

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September 20, 2012

Mr. Jose Garcia Ramirez, MS, DABR
Medical Physicist
Washington University School of Medicine
4921 Parkview Pl.
St. Louis, MO 63110

Nordion file number: OT12079
Product: TheraSphere® Y-90 glass microspheres
Lot number: 2990077

Re: Investigation Report – May 17, 2012 TheraSphere treatment where the dose remained residual in the administration system in entirety

Dear Mr. Garcia Ramirez,

This letter is in response to your request September 11, 2012 to provide a report of the investigational findings of the May 17, 2012 event at WUSM wherein the TheraSphere dose remained residual in the administration system.

Details reported by WUSM regarding the event:

- Dr. Darryl Zuckerman, MD, FSIR observed a higher-than-normal pressure required on the syringe, and significant flow diverted to the pressure relief vial.
- After 3 flushes, the Rados dosimeter read approximately zero mR/h, however a high radiation field was observed in the room, suggesting radioactive material in the outlet tubing and catheter.
- The procedure used a Navilyst Medical, Embarc microcatheter with GLYCE Hydrophilic Coating, 2.8F x 135 cm High Flow.
- Post treatment measurements of the waste indicated that the entire dose had remained residual in the administration system and catheter(s). None of the dose had been administered to the patient. This was further visualized by a radiographic exposure of the administration shortly post treatment.

Following the event, WUSM posed questions to Nordion regarding possibility that the catheter type or model could be related to the event, and inquired whether the procedure around opening the Administration Set pinch clamp and massaging out the indent could be related to the event.

- Nordion's review of the catheter used in the administration finds no design attributes of that model catheter which would make it unsuitable for use with TheraSphere. The inner diameter meets the required 0.020" specified in the TheraSphere package insert, and the materials are consistent with other microcatheters on the market which are also used for TheraSphere. The package insert's Instructions for TheraSphere Infusion

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recommends that the IR flush the infusion catheter to ensure flow prior to connecting the microcatheter to the Administration Set.

- The package insert's Instructions for TheraSphere Infusion recommends that the user rolls the outlet tubing with fingers after removing the pinch clamp to help remove an indent. When the user is following the recommended flow rate per the package insert, dents in the tubing are not of significant consequence to passage of microspheres.

The administration system from the treatment (contaminated waste) was retained by WUSM and after a decay period the materials were returned to Nordion for inspection. A thorough inspection was performed and we found the following:

- The returned materials were visually inspected and the device appears to have been assembled properly per the package insert's instructions for use.
- Review of the production batch records for the dose vial lot showed no anomalies.
- The WUSM radiation measurements were confirmed, indicating that the entire 3 GBq dose was residual in the system, with the residual located in the outlet tubing from labels 'D' to 'E' and in the catheters.
- Functional testing of the Administration Set components did not identify any defects.
- Functional testing of the catheters (micro and guide catheters) showed that initially the flow was blocked. After soaking and repeated flushing attempts, flow was established through the catheters. There were microspheres observed in the effluent, and also two pieces of matter which were brown in color, suspected to be blood clots.

From our investigation it appears that an obstruction to flow occurred in the microcatheter during the administration, stopping the flow to the patient, and the microspheres remained residual in the outlet tubing and the microcatheter. The source of the obstruction cannot be positively confirmed.

There are no corrective actions recommended for WUSM identified from the investigation completed. It is recommended that your team continue following the Instructions for TheraSphere Infusion provided in the package insert, which contains administration steps designed to achieve effective delivery of the product.

Thank you very much for reporting this important product feedback, and for supporting the investigation. Your input is valued in Nordion's efforts to provide the highest quality products.

Should you have any further questions or comments about this information, please contact myself, or your regional representative.

2012/09/24
Scott McGhee
TheraSphere Technical Design Authority

120924
Susan Eller
Quality Assurance