

From: [Lanzisera, Penny](#)
To: [Norweck, Jim](#)
Cc: luc.desgagne@nordion.com
Subject: Request for Additional Information for Cabell Huntington Hospital amendment
Date: Monday, August 22, 2016 12:55:00 PM

Licensee: Cabell Huntington Hospital
License No. 47-00404-02
Docket No. 03003370
Mail Control No. 591053

Mr. Norweck, thank you for the additional information to support the addition of TheraSphere to your license. In order to complete my review, please provide additional information for the following 2 items:

1. The documentation that you provided for all 3 physicians to confirm their receipt of vendor training on the delivery system and in-vitro casework was signed by a representative from BTG International, Inc. instead of the manufacturer listed on the Sealed Source and Device Registry (Nordion [Canada] Inc.). Please provide documentation signed by the manufacturer's representative of Nordion (Canada) Inc. (the manufacturer) to support completion of 3 in-vitro cases for each requested authorized user. Alternatively, if Nordion (Canada) Inc. is in the process of updating the SDDR for TheraSphere to acknowledge BTG International, Inc. or has contracted with BTG International, Inc. to provide representations from Nordion (Canada) for TheraSphere in-vitro casework and vendor training; please provide this information. I have copied Mr. Desgagne on this email as he may assist you in this query.
2. Thank you for providing commitment regarding your procedures. Please confirm that all "should"s will be changed to "shall"s in your final procedures.

Thank you for your assistance,

Penny Lanzisera
US NRC Region I