

**From:** Ullrich, Elizabeth  
**Sent:** Thursday, January 26, 2012 4:24 PM  
**To:** Edmond DeRosa; Bill Ransohoff  
**Subject:** amendment request Control No. 576705

Neutron Products, Inc.  
LN 19-25203-01  
DN 030-38295  
Control No. 576705

Ed and Bill,

This refers to the letter dated January 10, 2012 requesting that you be authorized to provide source installation and removal services for the ViewRay, Inc prototype radiotherapy system. We understand the device is under review by the State of Ohio, but that the device registration is not yet issued. Based on your amendment request and telephone discussions we have had, I understand that some modification of your source transfer equipment will be required, and that you plan to perform 'cold' practice runs of the source transfers at your facility in Ranson, West Virginia. In the near future. Please provide the following additional information in support of your amendment request:

1. Provide more detail on the modifications that you will need to do in order to transfer the sources from the ViewRay prototype device to your shipping cask. Based on our discussions, you believe the source drawer is the same as for teletherapy heads for which you are authorized to perform source transfers, and I confirmed that information with the State of Ohio staff performing the device review. Briefly describe the differences from your current authorized devices, and how you will adapt or modify your equipment to accommodate those differences.
2. Provide us with emergency procedures and equipment you will have available during source transfer of the prototype ViewRay device. You may reference any procedures already submitted as commitments to your license, if applicable.
3. Confirm that you will notify us when you believe you are ready to perform the practice transfers; we would like to observe such practice sessions prior to authorizing service on the prototype device. Based on telephone discussions, I understand that you could be ready to perform such practices as early as next week. Other NRC staff may accompany me (or be present if I am not available) to observe your practice runs.

Please respond to this request for information in hard-copy letter with signature, or pdf or facsimile of a hard-copy letter. If we do not get a response in 30 days, we will assume that you do not wish to proceed with the amendment. You can contact me if you have any questions about this request as shown below.

Thanks,  
Betsy

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