

From: Penny Lanzisera
To: Jrizzi@wpahs.org
Date: Mon, Sep 26, 2005 2:48 PM
Subject: Amendment Request dated July 28, 2005

L.N. 37-01317-01
D.N. 030-02981
Mail Control No. 137476

1. Items 3 and 4 of your letter dated July 28, 2005, addresses training of your staff members involved in HDR procedures. Please confirm that Authorized Users, in addition to Authorized Medical Physicists, will receive HDR vendor training, including a drill of emergency response procedures, prior to first clinical use. In addition please confirm that a drill of emergency response procedures will be included in the annual refresher training provided.

2. For AGH personnel providing annual refresher training and subsequent training for new employees using the HDR device, please confirm that these training personnel will have received the training outlined in Appendix **1 provided by the vendor**.

3. In addition to the information provided in Appendix 3 of your letter, please provide your procedures for restricting access to and posting the HDR treatment area in an emergency to minimize the risk of inadvertent exposure. Also, confirm that you will update your emergency procedures to include both this information and the names and telephone numbers of the authorized user(s) and authorized medical physicist(s) to be contacted if the unit or console functions abnormally.

I understand that you would like this amendment completed by September 30th. Please note that you may not reply to this letter by return e-mail. Your reply must be in writing by letter or facsimile. Please fax your response as soon as possible to 610-337-5269 and reference mail control number 137476.

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Mail Envelope Properties

(4338428C.9D8 : 17 : 55940)

Subject: Amendment Request dated July 28, 2005
Creation Date: Mon, Sep 26, 2005 2:48 PM
From: Penny Lanzisera

Created By: PAN@nrc.gov

Recipients

wpahs.org
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Size

2526

Date & Time

Monday, September 26, 2005 2:48 PM

Options

Expiration Date: None
Priority: Standard
Reply Requested: No
Return Notification: None

Concealed Subject: No
Security: Standard