

From: Thomas Thompson
To: Internet:Gp219@columbia.edu
Date: Wed, Mar 31, 2004 3:58 PM
Subject: Additional information needed to complete the HDR amendment

I have completed a preliminary review of your application and need some additional information and clarifications as follows:

1. Please provide an indication that senior management concurs with this request.
2. Please confirm that the manufacturers HDR training you have described will be received by all operators before use of the HDR unit.
3. Please clarify that you intend to have both the Authorized Medical Physicist and the Authorized User physically present as required in 10 CFR 35.615.
4. Describe your spot check procedure for checking timer accuracy and clock date and time.
5. Please note that recently we have determined that some HDR units have not been approved by FDA for greater than 10 curies of Ir-192 . We therefore are only authorizing Ir-192 sealed sources of 10 curies for installation into HDR units unless indication of FDA approval for greater than 10 curies is provided. If this is your intent you should provide this information.

You may reply by fax to 610 337 5269 and refer to Mail Control 134579.

Thank you.