From: Donna Janda
To: radrem@aol.com
Date: Tue, Jul 11, 2006 9:15 AM
Subject: Additional information for amendment request

Licensee: Charlotte Hungerford Hospital
License No. 06-08349-04
Docket No. 03009293
Mail Control No. 138815
ATTN: Gerald Randall, Radiation Safety Officer

Subject: Additional information needed for amendment request

Mr. Randall:

In order to continue our review of your amendment request dated April 26, 2006, we need the following additional information:

1. Item 7 of your application lists Dr. Elizabeth Whalen as the proposed authorized user of the HDR device. In order to continue our review of your request, please provide a written attestation, signed by a preceptor authorized user, that Dr. Whalen has satisfactorily completed the requirements in 10 CFR 35.690(b)(1), (b)(2), and (c) and has achieved a level of competency sufficient to function independently as an authorized user of a high dose rate remote afterloader. Please note that the written attestation must be signed by a preceptor authorized user who meets the requirements in 10 CFR 35.690, or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which Dr. Whalen is requesting authorized user status. Provide the NRC license number or a copy of the Agreement State license which lists the preceptor and his/her authorization.

In addition, please confirm that your Radiation Safety Officer, Gerald Randall, your proposed authorized medical physicist, Lee Ann Zarger, and Dr. Whalen, will have device-specific training on the Varian HDR device prior to the first patient treatment with the device.

2. Section 9 of your application, Facilities and Equipment, lists rooms and areas adjacent to the HDR treatment room. Please describe the area below the HDR treatment room. If this area is an occupied area, provide the room number and principal use of the area (e.g., office, closet, corridor). Indicate whether this area is restricted or unrestricted as defined in 10 CFR 20.1003.

3. Section 9, Item c. of your application states that the HDR afterloader will be physically attended at all times by an authorized user when the device is in use. Please review the physical presence requirements of 10 CFR 35.615(f)(2) and confirm that an authorized medical physicist will also be physically present during the initiation and continuation of all HDR patient treatments.

4. Describe the method used to ensure that the keys to the HDR unit are secured from unauthorized persons (e.g., keys will be kept in a locked cabinet in Physics office).

5. Please note that the shielding calculations provided assume a tenth value layer in concrete of 4.3 centimeters (cm) for iridium-192 (Ir-192). NCRP Report No. 49, Appendix C, Table 28, lists the tenth value layer for Ir-192 in concrete as 14.7 cm.

6. Provide the manufacturer and model number for the area radiation monitor to be used during HDR treatments. In addition, provide the frequency (e.g., monthly, quarterly) for testing the backup battery for the area radiation monitor.

7. The section of your application titled "Other Equipment and Facilities" sates that the device installation will include "interlock wiring" that precludes the operation of two radiation-producing devices at the same time. Describe in more detail the method used to ensure that no two radiation-producing units can be

operated simultaneously (e.g., dual-position switch located at the control console).

8. Section 10 of your application describing personnel monitoring states that personnel working in restricted areas near the HDR remote afterloader will wear whole body dosimetry. Please indicate whether extremity monitoring will be provide to individuals who may be called upon to respond to an emergency involving an unretracted or stuck source.

9. We did not review in detail the section of your application titled "Quality Management Program For HDR Brachytherapy" because it is not necessary to submit any of this information except for Item 3. However, we did note the following:

a. Item 1 lists the information you will include in HDR written directives, including treatment site, radioisotope, and dose. Please review the requirements in 10 CFR 35.40(b)(5) and confirm that your HDR written directives will include the radionuclide, treatment site, dose per fraction, number of fractions, and total dose.

b. Item 3 provides a list of items to be checked before each treatment. In accordance with 10 CFR 35.643, please submit detailed, step-by-step periodic spot-check procedures, including acceptance criteria if applicable, to assure proper operation of the following:

1)Electrical interlocks at each remote afterloader unit room entrance;
2)Source exposure indicator lights on the HDR unit, on the control console, and in the facility;
3) Viewing and intercom systems in each HDR facility;
4) Emergency response equipment;
5) Radiation monitors used to indicate the source position;
6) Timer accuracy;
7) Clock (date and time) in the HDR unit's computer; and
8) Decayed source(s) activity in the HDR unit's computer.

c. Item 11.k. states that any changes or modifications to the QMP will be submitted to the NRC within 30 days of the implementation. Please note that, as of October 25, 2002, there is no longer a provision to submit QMPs to the NRC.

d. Items 11.l. and 11.m. address recordable events and misadministrations. Please note that, as of October 25, 2002, 10 CFR Part 35 no longer uses the terminology "recordable event" and "misadministration". Please confirm that you will update your procedure to eliminate these references, and to be consistent with the current requirements of 10 CFR 35.3045 for reporting and notification of "medical events."

10. In the Operating Procedures for Varian HDR Remote Afterloaders section of your application, Item 3 of the "Use of the HDR Afterloader" portion states that, during all patient treatments, both the Authorized User and either the Medical Physicist or Radiation Safety Officer must be physically present. As noted in our Item #3 above, the physical presence requirements for HDR treatments are stated in 10 CFR 35.615(f)(2). Your procedure is not consistent with these requirements. Please confirm that you will update your procedure to assure that an AU and AMP are physically present during the initiation of all HDR patient treatments; and that an AMP and an AU (or a physician, under the supervision of an AU, who has been trained in HDR operation and emergency response) will be physically present during continuation of all HDR treatments.

11. Your emergency procedures provided with your amendment request describe the steps to be implemented if the source fails to return to the safe. 10 CFR 35.610(a)(4)(i) and (ii) require that these procedures include the names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally. Please confirm that you will update your emergency procedures to include this information. In addition, please confirm that a copy of these procedures will be physically located at the HDR unit console.

12. Confirm that for each treatment with an HDR unit, before releasing a patient from licensee control, the patient and the HDR unit will be surveyed with a portable radiation detection survey instrument to confirm that the source has been removed from the patient and returned to the safe shielded position.

Because your response will contain license commitments, please have your response signed and dated by an individual authorized to make binding commitments and sign official documents on behalf of the licensee. Please be sure to include Mail Control No. 138815 in your response. Please note that you may not reply to this email by return email. Your reply must be in writing by letter or facsimile (610-337-5269). If we do not receive your response to this request for additional information within 20 days from the date of this email, we will assume that you do not wish to pursue this application.

If you have any questions regarding these items, please call me at 610-337-5371.

Thank you for your attention to this matter.

Sincerely,

Donna Janda
Health Physicist, Medical Branch
Division of Nuclear Materials Safety
U.S. NRC Region I
dmj@nrc.gov

Mail Envelope Properties (44B3A469.DF6 : 8 : 55404)

Subject:	Additional information for amendment request
Creation Date	Tue, Jul 11, 2006 9:15 AM
From:	Donna Janda
Created By:	DMJ@nrc.gov

Recipients
aol.com
radrem (radrem@aol.com)

Post Office	**Route**
	aol.com

Files	**Size**	**Date & Time**
MESSAGE	12500	Tuesday, July 11, 2006 9:15 AM

Options

Expiration Date:	None
Priority:	Standard
ReplyRequested:	No
Return Notification:	None
Concealed Subject:	No
Security:	Standard