

From: Donna Janda
To: Marios29us@yahoo.com
Date: Fri, Jun 2, 2006 3:41 PM
Subject: Additional information needed for amendment request

Licensee: Centro de Radioterapia
License No. 52-30937-01
Docket No. 03036635
Mail Control No. 138694

Subject: Additional information needed for amendment request

Mr. Rios,

In order to continue our review of your amendment request dated April 3, 2006, we need the following additional information:

1. Item 9 of your amendment request states that an additional C-arm unit will be housed and used in the HDR room and will be the only other radiation producing device. Please describe the method used to ensure that the HDR unit and C-arm unit cannot be operated simultaneously.
2. In Item 9 of your request, the section titled "HDR Unit Source Strength Calibration," states that the HDR unit shall be calibrated before first use and after each source exchange. Please confirm that, in addition to the calibration measurements stated above, full calibration measurements shall be performed before medical use under the following conditions: (1) following reinstallation of the unit in a new location outside the facility and, (2) following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly.
3. In Item 9 of your request, the section titled "Discussion of Layout 2" states that long-handle forceps will be located at the treatment console station when treating patients. Please confirm that all emergency response equipment, including forceps and a shielded container, will be readily available to the Authorized User.
4. Please confirm that your emergency procedures will include a survey of the patient after the physician removes the implant from the patient and places the implant in a shielded container.
5. Please confirm that your emergency procedures will contain the names and telephone numbers of the authorized user, authorized medical physicist, and Radiation Safety Officer.
6. Item 10, Safety and Emergency Procedures, of your request states that, before starting an exposure, the therapist shall make sure that the physician and medical physicist are within audible range. Please confirm that the physician and medical physicist within audible range are the authorized user and authorized medical physicist, respectively.
7. Please confirm that, in addition to a "Caution Radioactive Materials" sign, a "Caution (or Danger), High Radiation Area" sign will be posted on the HDR treatment room door.
8. Please describe the method used to secure the HDR console keys and locker keys from unauthorized access (e.g., stored in a locked cabinet) when the keys are stored in the physics office.
9. The section titled "Prior to Treatment Checks" in Item 10 of your request provides a list of items to be checked for correct function and/or accuracy. Please submit detailed step-by-step periodic spot-check procedures, including acceptance criteria if applicable, for the following items:

- a. electrical interlock at the HDR treatment room entrance;
- b. source exposure indicator lights on the HDR unit, on the control console, and in the facility;
- c. timer accuracy;
- d. clock (date and time) in the unit's computer; and
- e. decayed source activity in the unit's computer

10. Please confirm that if the results of the periodic spot checks indicate the malfunction of any system, the control console shall be locked in the "off" position and shall not be used except as may be necessary to repair, replace, or check the malfunctioning unit.

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. 138694 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 a reply from you within 30 calendar days from the date of this email, we will assume that you do not wish to pursue your 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

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