U.S. NUCLEAR REGULATORY COMMISSION,
Division of nuclear materials safety
REGION I
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REGION 1
2006 JUL -5 AM 7:48

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

Subject: Additional information requested for amendment request

Ms. Janda,

Additional information requested:

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.

The HDR unit cannot be operated while the door is open. When the C-Arm unit is in use the door remains open and thus prevents the HDR unit from operating. The C-Arm is operated from inside the room and before any HDR exposure the room is verified to be either empty or occupied by the patient.

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.

We confirm that a full calibration will be performed as stated in the above paragraph.

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.

We confirm that all emergency response equipment, including forceps and a shielded container, will be readily available to the Authorized User

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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.

We confirm that our 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.

We confirm that our 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.

We 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.

We confirm that, in addition to a "Caution Radioactive Materials" sign, a "Caution (or Danger), High Radiation Area" sign is 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;

This interlock is verify by opening the door while the source is out and must retract the source.

b. Source exposure indicator lights on the HDR unit, on the control console, and in the facility;

This is visually inspected when interlock and emergency switches are tested using a predefined exposure sequence.

c. timer accuracy;

Tested by running the source a predetermine amount of time, and verifying with a stopwatch the time. Tolerance of +/- 1 sec.

d. clock (date and time) in the unit's computer;

Visually verified and compare with current time on secondary watch.

e. decayed source activity in the unit's computer

By calculating current source activity using a calculator or spreadsheet.

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.

We 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.

Jose E. Matta

Administrator
Hospital Auxilio Mutuo