

From: Nguyen, Janice
Sent: Tuesday, April 12, 2011 3:20 PM
To: dberkley@ccmh.org
Subject: NRC Amendment Request Mail Control Number 574457

Licensee: Camden-Clark Memorial Hospital Corporation
License No.: 47-09772-02
Docket No: 030-03390
Control No: 574457

Mr. Berkley;

This is regarding your amendment request received February 17, 2011. The following additional information is needed to allow us to continue our review of your request:

1. With regards to your request to add a high dose rate remote afterloader (HDR) facility:
 - a. Please confirm the type of alarming radiation monitor that will be installed in the treatment room and note its location on the facility diagram (e.g., will it be visible to someone who enters the room during source exposure).
 - b. Please confirm if the HDR will be stored in a lockable storage closet when not in use as indicated on your facility diagram.
2. 10 CFR 35.12(b)(2) requires that licensees submit procedures for periodic spot-checks for HDR units. Please provide step-by-step spot-check procedures and acceptance criteria for the items listed in 10 CFR 35.643 (e.g., electrical interlocks).
3. 10 CFR 35.610 requires, in part, that all device operators, authorized medical physicists, authorized users, and the Radiation Safety Officer participate in drills of the emergency procedures, initially and at least annually. Please confirm that emergency drills will be done as part of the initial and annual training and specify who will participate in them.
4. Please confirm that extremity monitors will be provided to individuals who may be called upon to respond to an emergency involving an unretracted or stuck HDR source.
5. Your Radiation Safety Officer Daniel Berkley appears to be an outside consultant/contractor. If this is so, please address the following:
 - a. Describe the control over the radiation safety program that will be delegated so that the consultant-RSO will be able to exercise authority over authorized users when confronted with radiation safety problems that require implementation of corrective actions.
 - b. Describe the relationship that will exist between the consultant-RSO and your institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related regulatory requirements.
 - c. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate

- time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of on-site time (hours per week).
- d. Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.
 - e. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his presence.
6. In support of your request to authorize Dr. Gabor Altdorfer and Dr. Michael E. Galloway as your Authorized Users (AU), please submit evidence of the training and experience required by 10 CFR 35.57 or 10 CFR 35.690(a) by providing one of the following:
- a. Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the individual was specifically named as an Authorized User for the units requested; or
 - b. A copy of the certification(s) for the board(s) recognized by NRC in 10 CFR 35.690(a); and
 - c. A description of the training and experience demonstrating that the proposed Authorized User is qualified by training and experience identified in 10 CFR 35.690 for the units requested and written certification, signed by a preceptor Authorized User, that this training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an Authorized User has been achieved. NRC form 313A may be used to document this information.

Please note that if any of the documents in a, b, or c above reference training and experience which was received more than 7 years ago, evidence of recentness of training in accordance with 10 CFR 35.59 must also be submitted.

If you are submitting a copy of a NRC or Agreement State license, please submit the full license showing that the physician was specifically listed as an AU for a HDR unit. If the authorized user was not specifically licensed for the use of a Nucletron device, please confirm that the authorized user will receive vendor training from Nucletron prior to medical use of the HDR unit at your facility.

7. In support of your request to authorize Joshua L. Hayes as your Authorized Medical Physicist (AMP), please submit all four pages of the NRC Form 313A (AMP). Please be sure to indicate where Mr. Hayes completed his training and experience. Please also include a copy of the radioactive material license that preceptor Dr. Murali Nair is listed on. If Mr. Hayes was not specifically trained on a Nucletron device, please confirm that he will receive vendor training from Nucletron prior to medical use of the HDR unit at your facility.

8. Please confirm that you will post a "Caution Radiation Area" sign in addition to the "Caution Radioactive Material" sign.
9. Please confirm that the emergency contact information for Camden-Clark Memorial Hospital personnel will be recorded on the posted emergency procedures.
10. Please confirm that the proposed shielding was actually what was installed.

Please note that you may not reply to this letter by return e-mail. You may reply to my attention by mail to the Region I office or by fax to 610-337-5269, referencing mail control 574457. If we do not receive a reply from you within 30 days, we will assume that you do not wish to pursue your application.

Thank you for your cooperation. Please feel free to contact me by telephone or e-mail if you have any questions.

Sincerely,

Jan Nguyen

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