Walt, Geralyn

From: Nguyen, Janice
Sent: Friday, August 28, 2015 3:29 PM
To: 'spersad@wvuheathcare.com'
Subject: NRC License Renewal for Berkeley Medical Center - Request for Additional Information

Licensee: Berkeley Medical Center (University Healthcare)
License No.: 47-15501-01
Docket No.: 030-09218
Mail Control No.: 587052

Dear Mr. Persad:

Please reply to this email to confirm receipt.

This is in reference to your applications dated May 14 and July 20, 2015, requesting to renew Nuclear Regulatory Commission License No. 47-15501-01. In order to continue our review, we need the following additional information:

1. Please provide the manufacturer and model number for all sealed sources requested for 10 CFR 35.400.

2. Please provide the manufacturer and model number for all sealed sources requested for 10 CFR 35.500.

3. On page 3 of the initial application, the Delegation of Authority for Radiation Safety Officer does not include the estimated time commitment that the delegated individual will spend per week conducting radiation protection activities. Although this was not required to be submitted with the application, please consider revising the Delegation of Authority to include the time commitment as shown in NUREG 1556, Volume 9, Rev. 2, Appendix I.

4. Please confirm that you will develop, implement and maintain ***written*** procedures for the safe use of unsealed byproduct materials that meet the requirements of 10 CFR 20.1101 and 20.1301.

5. On the facility diagram for your Nuclear Medicine Department, please indicate what is adjacent to your areas of use, including areas above and below. Please also indicate what areas are restricted or unrestricted as defined in 10 CFR 20.1003.

6. Please describe the emergency response equipment available for manual brachytherapy. This equipment should include gloves, reverse action tweezers, shielded containers, a low energy gamma scintillation survey instrument, and caution radioactive materials labels.

7. You requested to be authorized for any manual brachytherapy procedure permitted by 10 CFR 35.400 for which the patient can be released under the provisions of 10 CFR 35.75. However, you submitted brachytherapy training information for staff caring for patients who cannot be released under 10 CFR 35.75 under Item 8, Page 2, and your procedures indicate the patients are admitted. Please confirm if you wish to be authorized for inpatient or outpatient studies. If you will be housing brachytherapy patients, please provide diagrams of the rooms in which these patients will be housed, showing any installed shielding and/or portable shields, and indicating all adjacent areas, including above and below. Please also confirm that these patients will be quartered in private rooms with private bathroom facilities, and that surveys will be performed to ensure compliance with 10 CFR 20.1301(a). Alternatively, you may commit that Iodine 125 permitted by 10 CFR 35.400 will only be

administered to those patients who are releasable pursuant to 10 CFR 35.75. This would be reflected on your license so that only outpatient studies could be performed.

8. Please submit the probe manufacturer and model number for your portable survey meter instrumentation (Ludlum Model 14C survey meters). Information currently available to the NRC indicates that iodine-125 seeds may become dislodged during implantation or after surgery. Please specify the survey instrument used to locate seeds. This instrument should be equipped with a thin sodium iodide crystal detector probe in order to detect iodine-125.

9. You are requesting to possess and use radioactive materials permitted by 10 CFR 35.200 which now includes positron emitting tomography (PET) radiopharmaceuticals. Your application does not request the use of PET. Please confirm you do not wish to be authorized for the use of PET materials. Alternatively, you may request this authorization and include a list of installed shielding and any specialized equipment specific to 511 keV.

10. Please indicate if there are any required sealed sources that do not fall under 10 CFR 35.65.

11. Please include contact information (i.e. phone number and email address) for your certifying official.

12. Please indicate if there are any areas used for the storage, preparation, and receipt of manual brachytherapy sources other than the Nuclear Medicine Department. Under Item 10, a brachytherapy storage room was mentioned. If so, please provide facility diagrams for these areas, indicating what areas are adjacent, above, and below.

13. Please indicate if there are any additional areas used for Nuclear Medicine (i.e. stress labs, waste storage area, etc.). If so, please provide facility diagrams for these areas, indicating what areas are adjacent, above, and below.

14. Please confirm if the licensee name should be Berkeley Medical Center (University Healthcare) or Berkeley Medical Center.

15. Please describe how the area used to prepare and store radioactive material is secured from unauthorized access. 10 CFR 20.1801 requires that licensed material be secured against unauthorized removal from the place of storage. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance over materials in unrestricted areas that are not in storage. In your application you did not indicate how you will secure licensed material.

16. After a cursory review of your brachytherapy procedures, which were not required to be submitted, it appears that your procedures may not be in full compliance with NRC regulations. For example,

    a. In your application under Section 10.1, it stated that radiation levels in unrestricted areas will be maintained less than the limits specified in 10 CFR 35.400. No limits are specified in 10 CFR 35.400. Please confirm that radiation levels in unrestricted areas will be maintained less than the limits specified in 10 CFR 20.1301(a).

    b. In your brachytherapy procedures, it indicates that the written directive will include the information in 10 CFR 35.500. 35.500 is the use of sealed sources for diagnosis. 35.400 is the use of sealed sources for manual brachytherapy. 35.40 is the regulation for written directives. Please confirm that the written directive will contain all information required in 10 CFR 35.40.

    c. The term “misadministration” should be changed to “medical event.”

    d. “Recordable event” is no longer defined in NRC regulation.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Licensee Toolkits, see our toolkit index page.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 587052. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5006.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's expectations for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Thank you for your cooperation.

Jan Nguyen

Janice Nguyen
Senior Health Physicist
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5006
FAX (610) 337-5269