From: Lanzisera, Penny
To: "Mohapatra, Shashadhar M"
Subject: Request for Additional Information
Date: Tuesday, May 22, 2012 3:48:00 PM

Licensee: Washington Hospital Center
License Nos. 08-03604-03 & 08-03604-05
Docket Nos. 030-01325 & 030-35985
Mail Control Nos. 577204 & 577231

Dear Shashi,

To continue our review of your licensing actions to combine the above two licenses, we need the following additional information:

1. Descriptions of areas above and below the gamma knife suite.
2. Shielding calculations for the suite, including the type, density, and thickness of the shielding installed. In addition, describe any shielding installed around any wall penetrations (e.g., east/west walls).
3. Provide the manufacturer name and model number for the portable survey instrument and the area radiation monitor used. In addition, confirm that the area radiation monitor includes a backup battery that is tested periodically.
4. Confirm that the door to the gamma knife is posted as required by 10 CFR 20.1902.
5. Emergency procedures for the gamma knife.
6. With regards to your spot-check procedures, please provide the acceptance criteria for the timer accuracy and linearity tests performed monthly and the timer termination test performed daily. In addition, please confirm that the timer accuracy and timer termination tests will be documented on the monthly calibration log sheet and daily QA check list, respectively.
7. It appears from review of your possession limits, that financial assurance pursuant to 10 CFR 30.35 may be required. For instance, the possession limit for sealed sources, with the addition of the gamma knife sources, appears to require financial assurance. However, if you wish to reduce your gamma knife possession limit by 10%, you may alleviate the requirement for financial assurance for sealed sources. Please confirm this lower possession limit. In addition, for unsealed licensed material, the total possession limits appear to require financial assurance if the sources that do not meet the requirements in 10 CFR 30.32(g) are considered unsealed. Therefore, please submit the manufacturer and model number for the Cs-137, Ba-133, and Gd-153 sources listed in Items 6.P, Q, and S or documentation to support that they are sealed. Alternatively, you may submit financial assurance as described in 10 CFR 30.35.
8. Confirm that the procedures used by the Radiation Safety Committee to approve new authorized users includes confirmation that the user meets the requirements in 10 CFR 35.690.
9. Confirm that the procedures used by the Radiation Safety Committee to approve new authorized medical physicists includes confirmation that the physicist meets the requirements in 10 CFR 35.51 and 35.59.
10. Confirm that all individuals who operate the gamma knife are provided instruction initially and annually in accordance with 10 CFR 35.610 and that operators, authorized medical physicists, and authorized users participate in drills of the

emergency procedures, initially and at least annually.

11. Please note that the regulatory references in Item 9.B. of your letter dated March 16, 2012, should be corrected to 10 CFR 35.645 and 35.635. Additionally, the regulatory reference in Item 10.5 (iv) should be corrected to 10 CFR 35.3067 and should include all instructions in this regulation including storing (not decontaminating) a leaking source. Finally, the regulatory reference in the Daily and Monthly Gamma Knife Procedure for SRS Treatment should be corrected to 10 CFR 35.635.
12. Please confirm that surveys conducted under the gamma knife program include those required by 10 CFR 35.652.
13. In several places in your letter dated March 16, 2012 (e.g., Item 4 of letter and Item 10.12G) you request a waiver to the regulation in 10 CFR 35.655 for the five year inspection. However, it appears from your description of the routine service conducted (generally semiannually), the maintenance includes assuring proper functioning of the source exposure mechanism described in 10 CFR 35.655 (e.g., operation of the vault doors and proper docking of the helmet). Therefore, a waiver (or exemption) appears unnecessary. Please confirm.
14. Please note that your procedures for annual calibration and operation were not required to be submitted and were not fully reviewed. However a cursory review identified the following items that should be corrected: (i) helmet factors should also be verified after any helmet damage; and (ii) timer linearity and accuracy tests should include their respective acceptance criteria.
15. In your Daily and Monthly Gamma Knife Procedure for SRS Treatment, you indicated that a treatment may proceed if either the camera or microphone is operational. Please note that 10 CFR 35.645(f) requires both to be operational. Please confirm that you will follow the requirement in 10 CFR 35.645 to assure that the viewing and intercom systems are operational prior to any treatments.
16. Please note that “cyclotron produced radionuclides” are now under NRC’s purview. Please correct the bottom of Item IV in your ALARA program to reflect this revision in the regulatory oversight.

We will continue review of your amendment upon receipt of the above listed information. You may fax your response to my attention to 610-337-5269. Please refer to Mail Control Nos. 577204 and 577231 in your reply and mark all Security-Related information accordingly.

Sincerely,

Penny Lanzisera
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