

From: Willie Lee
To: wlr@comcast.net
Date: Fri, Dec 23, 2005 11:40 AM
Subject: Information Request for Reading Renewal

REQUEST FOR ADDITIONAL INFORMATION
LICENSE RENEWAL

READING HOSPITAL AND MEDICAL CENTER

License Number: 37-00485-04

Docket Number: 030-02960

Control Number: 137404

Date: December 23, 2005

ATTN: Walter L. Robinson, M.S., RSO

Additional information is needed for completion of license renewal, as follows:

1. Please provide the manufacturer and model numbers for all Iodine-125 sealed sources (seeds), containing byproduct material as permitted by 35.400, as listed in the renewal application. Also, your application included both 800 millicuries and 1 curie as a possession limit for these sources. Please clarify your statements regarding the possession limit for 35.400 sources.
2. Your renewal application states that you never had sources authorized by 10 CFR 35.500 and no longer wish to be licensed for them. It also states that you wish to be licensed for Gadolinium-153 line sources for quality control of gamma cameras permitted by 35.500. Please clarify your statements regarding possession of 35.500 sources.
3. Your renewal application states that you no longer possess Cs-137 low dose rate brachytherapy or intravascular brachytherapy sources. Please provide documentation that the Cs-137 sources permitted by 35.400 and Sr-90/Y-90 sources used in the Novoste IVB devices were transferred to an authorized recipient. Include transfer records and confirmation of receipt from the authorized recipient.
4. For types of use permitted by 10 CFR 35.300 and 35.400, please provide a description of areas above and below those in which byproduct materials are stored, used or prepared for use. Also describe the rooms where patients will be housed if they cannot be released under 10 CFR 35.75. Include a description of shielding, if applicable. In addition, describe emergency equipment available for brachytherapy events.
5. For use of the remote afterloader permitted by 10 CFR 35.600, please provide a description of additional facilities, equipment and procedures to include (1) warning systems and restricted area controls (e.g. locks, signs, warning lights and alarms, interlock systems); (2) area radiation monitoring equipment; (3) viewing and intercom systems; (4) methods to ensure that whenever the device is not in use or unattended, the console keys will be inaccessible to unauthorized persons, and (5) confirmation that no other radiation-producing equipment will be operated within the HDR treatment room.
6. It appears that calculated radiation exposure in the area designated as "Control" in the considerations for HDR Ir-192 shielding could exceed 100 millirem annually for unrestricted use. Please describe how occupancy will be restricted or controlled for members of the general public to meet applicable dose limits. Also, please confirm that the HDR treatment room is on the ground floor, with foundation and earth beneath it.
7. Some items in HDR Attachments VI through IX are contrary to NRC regulations. Therefore, please re-submit emergency procedures that include shielding the source in all instances and identifies current Authorized Medical Physicists, Authorized Users, and Radiation Safety Officer responsible for responding to emergencies. In addition, describe emergency response equipment (e.g. long-handled forceps, heavy

duty cable cutters, emergency personnel dosimeters, portable survey meter, stop watch/timer) possessed for HDR emergency events.

8. You indicated in Item 10 of the application checklist that employees may perform installation, maintenance, adjustment, repair, and inspection of therapy devices containing sealed sources. If so, please provide the tasks and include the training and experience of employees providing such service.

9. Please verify that the HDR vendor will provide the annual refresher training outlined in 10 CFR 35.610.

10. For use of Iodine-125 Gliasite Radiotherapy permitted by 35.1000, please provide information in support of your program. Guidance on NRC's website at <http://www.nrc.gov/materials/miau/med-use-toolkit.html#other> may be used in preparation of your response.

11. Regarding the 100 millicuries Cs-137 instrument calibration device, should the manufacturer be listed as TMA/Eberline and not Victoreen? Also, should the source model number be New England Nuclear (NEN) NER-570?

12. Please confirm whether the Cs-137 instrument calibrator is in use or in storage. If in use, please provide a description of facilities, training and experience for persons performing instrument calibrations, and procedures used. If in storage, describe the storage location, including shielding, and plans for disposal.

13. Please describe instrumentation used for low-energy gamma surveys following I-125 seed implants (e.g. sodium iodide).

14. Please confirm that previous commitments submitted in the letter dated June 2, 2005 regarding Radiation Safety Officer delegation, duties, and responsibilities are still in effect.

15. Please confirm whether Abdulmehdy M. Jabir, M.Phil. should continue to be listed as an Authorized Medical Physicist on your NRC license.

16. Please note that the Dupont Model NES-8412 sealed source is now manufactured by Bristol Myers-Squibb and will be listed on your NRC license in that manner.

17. Please note that procedures submitted for the HDR Unit Calibration were not required for license renewal and were not reviewed. These items will be addressed during inspection, as necessary.

Please note that you may not reply to this request by return e-mail. Your reply must be in writing by letter or facsimile (610-337-5269), signed by a member of Senior Management.

Willie J. Lee, Health Physicist
US Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406
(610) 337-5090 (Phone)
(610) 337-5269 (FAX)

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From: Willie Lee

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