From: <u>Gabriel, Sandra</u>
To: <u>"Crmidmr@aol.com"</u>

Subject: Additional information for NRC license renewal, mail control 576202

Date: Wednesday, February 15, 2012 7:55:00 PM
Attachments: NUREG 1556 Vol 15 Appendix F.pdf

Licensee: Hospital Metropolitano License Number: 52-16033-01 Docket Number: 03011155 Mail Control: 576202

To: David Rhoe, Physics Consultant

This is in reference to the renewal application for this license. In order to continue our review, we need the additional information listed below.

Please send a return e-mail to confirm that you received this message.

- 1) The name in item 1 of the current license is Hospital Metropolitano. The renewal application included the following statement: This license will be under an ownership of a corporation or legal entity. Corporation or legal entity name: MetroPavia Health System Inc." Has a transfer of control occurred? If so, please provide the information listed in Appendix F of NUREG-1556, Vol. 15 (copy attached).
- 2) The renewal application requested a maximum quantity of 1.5 Ci for byproduct material permitted by 10 CFR 35.400, together with a statement "...Iodine 125 seeds shall not exceed 55 GBq (1.5 Ci), Cesium 137 shall not exceed 17.6 GBq (0.5 Ci)." Does Hospital Metropolitano wish to retain the total possession limit of 2 Ci listed on the current license?
- 3) The renewal application requested two models of 35.400 sources, in comparison with the five models listed on the current license. Does Hospital Metropolitano wish to remove or retain Bard Brachytherapy, Inc. Model STM 1251, BEBIG Model I25.SO6, and Isotope Products Laboratories Laboratories Model 67-6500 series?
- 4) The renewal application requested authorization to use byproduct material permitted by 10 CFR 35.600, however no supporting documentation was provided. The license has authorized use of Iridium 192 in a high dose rate remote afterloader device (HDR) since 2000. Our understanding is that the HDR program was never initiated and there is no indication that the HDR authorized users (AUs) and authorized medical physicist (AMP) have had continuing training and experience within the past 10 years. Does Hospital Metropolitano wish to remove the HDR authorization? If they wish to initiate an HDR program, please submit a request in accordance with current regulations and the licensing guidance in NUREG-1556, Vol. 9, Rev. 2, including documentation that the AUs and AMP meet the current training and experience requirements.
- 5) The renewal application stated "Patients can be released under the provisions of 10 CFR 35.75." This license authorizes Cesium 137 brachytherapy sources, and an inpatient Cesium 137 treatment was in progress during the last NRC inspection in June 2010. Has the Cesium 137 brachytherapy program been discontinued? If not, and Hospital Metropolitano wishes to continue to be able to perform inpatient Cesium 137 brachytherapy treatments, please describe the rooms used to house these patients. Confirm that the patients will be housed in private rooms with private bathrooms. Provide room diagrams including adjacent areas on the same floor, above, and below. Provide a description of any shielding and show that adequate steps have been taken to ensure that radiation levels in surrounding unrestricted areas will not result in doses to individuals in excess of those specified in 10 CFR 20.1301.
- 6) The facility diagram for Nuclear Medicine included in the renewal application did not include all of the information indicated by the boxes checked in Item 9-Facility Diagram. Please identify activities conducted in all contiguous areas surrounding the areas of licensed material use, including above and

below. Identify the location of the treadmill room and storage of radioactive waste. In addition, please describe and identify the location of shielding used for storage and preparation of radiopharmaceuticals. Also identify the floor on which Nuclear Medicine is located.

- 7) The renewal application included diagrams of the Radiation Oncology Department, but did not indicate where brachytherapy sources are stored and prepared, or provide a description of shielding in these areas. Please provide this information.
- 8) This license authorizes use of Iodine 125 brachytherapy sources. Please provide a description of the survey instrument(s) used to detect stray or dislodged sources. Use of a thin sodium iodide crystal detector probe is advisable for detection of this low energy radionuclide.
- 9) NUREG-1556, Vol. 9, Rev. 2 asks for a description of emergency response equipment for manual brachytherapy facilities. Please describe the emergency response equipment for Iodine 125 and Cesium 137 brachytherapy treatments, for example, long handled forceps and shielded containers.
- 10) The report from Hospital Metropolitano's most recent NRC inspection showed that a violation was issued for failure to survey the stress lab. Please confirm that this violation was corrected.
- 11) A request to relocate the Nuclear Medicine Department was submitted in a letter dated October 31, 2003. It does not appear that the license files include closeout surveys of the old Nuclear Medicine Department. Please provide this information.

Please provide a written response to these items within 30 days under signature of Hospital Metropolitano's senior management. This may be provided to my attention by letter or fax (610-337-5269), referencing mail control 576202.

Please contact me by telephone or e-mail with any questions. I am frequently away from the office, but generally check e-mail and voicemail messages daily. Thank you.

Sandy Gabriel, Ph.D. Senior Health Physicist Medical Branch NRC Region I 610-337-5182 (voice) 610-337-5269 (fax)