

APR 22 1985

Research Medical Center
ATTN: Morton H. Levitt, M.D.
Vice President
Clinical Services
2316 East Meyer Boulevard
Kansas City, MO 64132

License No. 24-18625-01

Gentlemen:

We have reviewed your application dated August 1, 1984, for renewal of NRC License No. 24-18625-01 and your application for a license amendment dated January 24, 1985. Additional information is needed in support of your requests. Please respond to the following:

1. Physician User

You requested in your renewal application that Drs. Dukstein and White be authorized to use byproduct materials specified in Groups I-VI of Schedule A, 10 CFR 35.100. Please be advised that we can authorize physicians to use Group VI materials only if they meet the criterion described in Item 5 Appendix A of Regulatory Guide 10.8 (enclosed) or if they have been certified by the American Osteopathic Board of Radiology in Radiation Oncology.

Likewise, we can not authorize Dr. Paradelo to use materials specified in Groups IV and V until we have evidence that he has fulfilled the requirements outlined in Item 4, Appendix A of Regulatory Guide 10.8.

2. Materials

Your current license authorizes you to possess depleted uranium as shielding in a linear accelerator. This material, however, was not mentioned in your renewal application. Please inform us if you wish continued authorization to possess depleted uranium. If not, inform us of the disposition of the shielding material.

It is our understanding that your Gamma Survey Instrument Calibrator containing 120 millicuries of cesium-137 is in storage and that you have no intentions of using it in the near future. Please confirm if our understanding is correct and specify the area in which the calibrator is stored and the measures you have taken to insure that there will be no unauthorized use or removal of the device.

3. Facilities

It is not clear how access to your long term storage area on Level B is controlled. Please clarify.

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4. Therapeutic Use of Iodine-131

Your safety precautions for therapeutic use of iodine-131 include a statement that liquid iodine-131 in an open system will be used in a well ventilated area. In a letter to our office, dated November 2, 1984, you stated specifically that this procedure will be done in one of two rooms located in the Department of Nuclear Medicine in which the air flow exhaust rate is at least 1,040 cfm. Please confirm if the statement made in your November 2 letter accurately reflects your intentions. Otherwise, clarify the term "well ventilated area" by providing a minimum air flow rate.

Regulatory Guide 8.20 (enclosed) suggests action levels for iodine-131 intake (as determined by thyroid measurements) and a proposed follow-up plan to assist in exposure control. You may wish to incorporate some if not all of these recommendations in your safety precautions.

5. Sealed Sources

It is not clear how access to your brachytherapy sources is controlled when they are stored in their shipping containers in the Radiation Oncology Department. Please clarify.

Please describe in greater detail, the safety precautions you use when handling brachytherapy sources, e.g., use of tongs/forceps, working behind lead glass window, etc.

6. Xenon-133

Please describe your procedures for handling saturated filters in the trapping device contained in your Pulmonex unit. Your discussion should include a description of the area where saturated filters are stored, available shielding, ventilation or the method used to restrict the release of xenon from the filter, etc. Inform us also how you determine that the filter is saturated.

Please confirm that air flow measurements in areas where xenon-133 is used and stored are conducted on a semiannual basis to insure that air flow rates meet the specification described in your application.

7. Gadolinium-153

Please submit responses to the following:

- a. Specify the names of the physicians who will use or supervise the use of the bone mineral analyzer. If the proposed physician-users are not listed on your license as being authorized to use materials specified in one or more groups in 10 CFR 35.100, Schedule A, then document their training and experience with radioactive materials on NRC Form 313M - Supplement A. As a minimum, they should have received the training outlined in Enclosure 1 of the attached directive.

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- b. Specify the name or title of the individual who will be responsible for source exchange.

Discuss the method to be used for determining whole body and extremity exposures during source exchange.

Submit step-by-step procedures for installing and removing the gadolinium-153 source from the scanner. (You may submit a copy of the supplier's recommended procedures.)

- c. Discuss the method to be used for securing from unauthorized use or removal:
- i. the device containing the source and
 - ii. the source when not installed in the device.
- d. Specify who will service the bone mineral analyzer if repair or maintenance is required. We are particularly concerned about maintenance or repair of the device shutter and other components that may compromise the safety of the unit.
- e. Discuss the method to be used for disposing of gadolinium-153 sources that have decayed beyond their useful life or that are otherwise no longer needed.

We will continue the review of your applications upon receipt of this information. Please reply in duplicate within 30 days and reference Control Number 77241.

Sincerely,

Original Signed By
B. J. Holt
Materials Licensing Section

Enclosure: Regulatory Guide 10.8

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