From: Sandra Gabriel
To: rick.hughes@amersham.com
Date: Thu, Apr 15, 2004 5:58 PM
Subject: Renewal of NRC license for Medi-Physics pharmacy in Bensalem, PA, mail control 134214

Rick:

As we discussed earlier, would you please provide the following information for renewal of the Bensalem pharmacy's NRC license:

1) The current license lists the Bensalem address as the mailing address. In the renewal application, two different mailing addresses are listed: form 313 shows the Princeton address and page 1 of the typed application shows the Bensalem address. Please specify which address should be listed as the official mailing address for this license.

2) In Item 5, H-J of your application, you requested authorization for 5 Ci each for byproduct material authorized under 10 CFR 35.100, 35.200, and 35.300. Authorization for this material is covered under your requests for A-G, so there is no need for H-J. Please let me know if there is a need to increase your possession limits in A-G to include H-J.

3) In Item 5K of your application, you requested authorization for brachytherapy sources under 35.400. 10 CFR 30.32(g) requires that a licensee provide the manufacturer's name and model number for each requested sealed source and device. Please provide the manufacturer's name and model number for each requested brachytherapy source.

4) Also regarding brachytherapy sources under 35.400, please indicate if you will redistribute brachytherapy sources in the manufacturer's original packaging, labeling, and shielding or if you will manipulate these sources in any way. If you will dispense loose I-125 seeds into vials and cartridges, please describe the packaging, labeling, and shielding that you will use to redistribute these sources.

5) On page C-3 of the NRC form you submitted, you checked off some items under the heading "for redistribution of used generators", however you did not check off the box for "description attached." It appears that you do not intend to redistribute used generators. Please confirm this.

6) Under Item 6B, Sealed Calibration or Reference Sources, the first sentence states "these sources will be distributed by the nuclear pharmacy to authorized licensees." The following paragraph appears to refer to redistribution, rather than to distribution. Please confirm that in the first sentence of Item 6B, the word "distributed" should be replaced by "redistributed."

7) Your current license authorizes possession of 999 kilograms of depleted uranium for shielding for Mo-99/Tc-99m generators. This was not addressed in the renewal application. Do you wish to retain this authorization?

8) Item 7 of your application requests authorization for any visiting pharmacist working as an authorized nuclear pharmacist listed on a specific license of the US Nuclear Regulatory Commission for a maximum period of sixty days. To the best of my knowledge, current NRC regulations do not define "visiting authorized nuclear pharmacist". Under certain circumstances 10 CFR 32.72(b) does authorize you to allow a nuclear pharmacist to begin work, as long as you provide the required documentation to the NRC within 30 days.

9) Please supply a copy of the Pennsylvania pharmacist license for the following individuals: Clyde Cole, R.Ph., Janet Reuther, R.Ph., Cathy Bach, R.Ph., John Marzocca, R.Ph., and James Mantel, R.Ph. Your application included a Pennsylvania pharmacist license for Daniel Shearer, R.Ph., however you did not request to list him as an authorized nuclear pharmacist. Do you wish to name Mr. Shearer as an authorized nuclear pharmacist on this license?

10) Item 9 of your application states that effluent monitoring will be performed to demonstrate compliance with 10 CFR 20.1301 and 20.1302. Please be aware that 10 CFR 20.1101(d) specifies a constraint on air emissions of radioactive material to the environment such that no individual member of the public will receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions.

11) Item 10, page C-16 of the NRC form, requests information about dosage measurement systems. Your application described your method to setup dose calibrator dial settings for assay of Y-90. In addition, please provide a description of dosage measurement systems for photon-emitting (and alpha-emitting, if applicable) radioactive drugs.

12) Your application included procedures for dispensing I-131 solution and compounding I-131 capsules. Please indicate the maximum activity and type/thickness of transport radiation shield for each type of container used for these materials. Also provide maximum radiation level at the surface of the transport radiation shield when the container is filled with the maximum activity.

Thank you for your attention to these questions. Please provide a response within 30 days, referencing mail control 134214. You may fax your response to 610-337-5269.

Sandy Gabriel
Senior Health Physicist
NRC Region I
Nuclear Materials Safety Branch 1
(610) 337-5182