THE QUEEN'S MEDICAL CENTER

1301 Punchbowl Street • Honolulu, Hawaii 96813 • Phone (808) 538-9011 • FAX: (808) 547-4646 • www.queens.org

April 9, 2010

Lizette Roldan, Ph.D.
Health Physicist
Nuclear Regulatory Commission
612 E. Lamar Blvd., Suite 400
Arlington, TX 76011

Docket No. 030-38265
Control No. 472613

RE: Additional Information for Queen's Medical Center Cyclotron Radiopharmacy License Application

Dear Dr. Roldan,

To facilitate the processing of our license application for the Cyclotron Radiopharmacy, I am submitting the following responses to your requests for additional information.

NRC Request #1:

In your application you requested "Any byproduct material with atomic numbers 1 through 83" with a chemical form and purpose of use that is inconsistent with the type of license you are requesting. Please confirm if you wish to add this byproduct material on the license, provide a chemical form (e.g., Any or Sealed Source), and state the purpose of use according to the license you are requesting. Section 8.6 in NUREG 1556, Vol. 13, Rev.1 Programs-Specific Guidance About Commercial Radiopharmacy Licenses gives examples on the different purpose of uses.

NRC Request #1: (continued)

Applicant (Queen's Medical Ctr) Response:

We will revise Item 5 of our license application to read as follows:

	(a) Radionuclide (Element, Mass Number)	**(b) Chemical, Physical Form**	**(c) Maximum Possession Limit**
1.	Fluorine-18	Any	20 curies
2.	Any byproduct material authorized under 10 CFR 35.65(a), (b)	Sealed sources	10 millicuries total possession

Accordingly, we revise Item 6 of our license application to read as follows:

	Radionuclide	**Purpose of Use**
1.	Fluorine-18	10 CFR 32.72 – Prepare and distribute radiopharmaceuticals to medical use licensees pursuant to the terms and conditions of a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State. Positron Emission Tomography (PET) radiopharmaceuticals will be prepared under the supervision of an Authorized Nuclear Pharmacist (ANP) pursuant to 10 CFR 32.72.
2.	Any byproduct material authorized under 10 CFR 35.65(a), (b)	For calibration and checking of the licensee's instruments.

NRC Request #2:

You have proposed Dr. John Lim as the Authorized Nuclear Pharmacist (ANP); please provide a copy of Dr. Lim's pharmacist license number and issuing entity. Also, choose one of the pathways outlined below and provide the following additional documents:

a) For an individual previously identified as an ANP on an NRC or Agreement State license or permit or by a commercial nuclear pharmacy that has been authorized to identify ANPs (10 CFR 32.72(b)(2)(i))
b) For an individual qualifying under 10 CFR 32.72(b)(4)
c) For an individual qualifying under 10 CFR 35.55(a)
d) For an individual qualifying under 10 CFR 32.72(b)(2)(ii)

Applicant Response:

As specified in Item 7.3 of our Cyclotron Radiopharmacy license application, Dr. John Lim is specified as the Authorized Nuclear Pharmacist.

Dr. Lim is a radiochemist by doctorate degree and does not have a pharmacist license number. However, Dr. Lim has practiced as the nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material at our Cyclotron Radiopharmacy.

Dr. Lim meets the criteria under 10 CFR 32.72(b)(4) and documentation is provided to demonstate:
(i) Dr. Lim was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material
(ii) Documentation that the individual practiced at a pharmacy, a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC

Specifically, our Cyclotron Radiopharmacy is licensed by the Hawaii State Board of Pharmacy for Positron Emission Tomography (PET) drug production (No. 85 issued October 11, 2002). Dr. Lim is recognized by the Hawaii Radiological Health Branch licensing authority as specified in the Cyclotron Radiation Facility License (No. H0014). Please refer to Appendix 3 of our Cyclotron Radiopharmacy License application for copies of these documents.

NRC Request #3:

In your application you commit to follow the personnel training program published in Appendix N in NUREG 1556, Vol. 13, Rev. 1. In addition, please confirm the person conducting the training will be a qualified individual (e.g., RSO, ANP, AU, or radiation safety professional familiar with the licensee's program) and the method for assessing the success of the training will be documented.

Applicant Response:

We commit to follow the personnel training program published in Appendix N in NUREG 1556, Vol. 13, Rev. 1. In addition, we confirm the person

Applicant Response #3: (continued)

conducting the training will be a qualified individual (e.g., RSO, ANP, AU, or radiation safety professional familiar with the licensee's program) and the method for assessing the success of the training will be documented.

NRC Request #4:

Please describe how you verify the ventilation system ensures the effluents are ALARA, within the dose limits of 10 CFR20.1301, and are within the ALARA constraints for air emissions established under 10 CFR 20.1101(d) (e.g., stack monitoring data from RADACS, COMPLY code). NUREG 1556, Vol. 13, Rev 1, Appendix R may be helpful to you in providing your response.

Applicant Response:

Our cyclotron facility monitors effluent through the ventilation stack from the cyclotron radiopharmacy. Based on data from the RADACS monitoring system and design specification of the cyclotron ventilation stack, the following describes our compliance with regulatory ALARA limits:

The cyclotron ventilation system is designed to exhaust 3600 CFM through the vent stack on the roof of the Manamana building. The total exhaust volume in one minute is 3,600 cu.ft. or 1.0E8 ml.

10 CFR 20.1302 (b)(2) requires compliance with limits specified in Table 2 of Appendix B to part 20. The specified effluent concentration limit for F-18 in Table 2 is 1E-7 uCi/ml.

The RADACS data for the stack effluent shows high values of approximately 300,000 CPM for a period of about 30 minutes during a cyclotron production run. Using a conservative estimation of detector efficiency as 5%, the estimated effluent F-18 activity is calculated to be 6,000,000 DPM. To be conservative, no correction for 2 photons/decay is applied. The corresponding activity is 3.6E8 Bq or 9,800 uCi.

The calculated F-18 effluent concentration during a cyclotron production run is 9,800 uCi / 1.0E8 ml = 9.8E-5 uCi/ml per minute. Normally, there are 2 production runs each day, so the daily F-18 effluent concentration is calculated to be 9.8E-5 uCi/ml x (60 minutes/1,440 minutes) = 4.1E-6 uCi/ml.

Further correction to account for the fact that production runs are done only 250 days of the year is applied to give the final estimated annual F-18 effluent concentration to be 4.1E-6 x (250 days/365 days) = 6.8E-7 uCi/ml.

The 15-foot tall stack is mounted on the roof of a 3-story building effectively putting the point of gaseous effluent discharge at least 50 feet above the nearest boundaries of unrestricted areas. Factoring wind dispersion and

diffusion, a conservative estimation of 10% is used as the maximum amount of effluent concentration at the nearest unrestricted area boundary. Therefore, the effective effluent F-18 concentration at an unrestricted boundary is 6.8E-7 uCi/ml x 10% = 6.8E-8 uCi/ml.

The calculated F-18 effluent concentration from our cyclotron operation is 30% less than the regulation limits established in table 2 of Appendix B to Part 20.

Finally, we will instruct cyclotron personnel to notify the RSO in the event of a high alarm for the ventilation stack that exceeds 300,000 cpm. Repeated high alarms in excess of 300,000 cpm will be investigated by the RSO to determine the cause and corrective action necessary to ensure regulatory ALARA limits are not exceeded.

NRC Request #5:

Please confirm you will include written procedures identifying and responding to radiation spills and contamination in your emergency procedures.

Applicant Response:

We confirm we will include written procedures identifying and responding to radiation spills and contamination in your emergency procedures.

NRC Request #6:

Please confirm your survey program will include contamination level surveys in restricted and unrestricted areas.

Applicant Response:

We confirm our survey program will include contamination level surveys in restricted and unrestricted areas.

NRC Request #7:

In your application you commit to implementing the model leak test program published in Appendix L in NUREG 1556, Vol. 13, Rev. In addition, please confirm you will develop and will implement and maintain written procedures for leak testing that meet the requirements in 10 CFR 30.53, 10 CFR 20.1501, and 10 CFR 20.2103.

Applicant Response:

We commit to implementing the model leak test program published in Appendix L in NUREG 1556, Vol. 13, Rev. In addition, we confirm to develop, implement and maintain written procedures for leak testing that meet the requirements in 10 CFR 30.53, 10 CFR 20.1501, and 10 CFR 20.2103.

NRC Request #8:

In your application you commit to implementing the model procedure for return of radioactive wastes from customers published in Appendix S to NUREG 1556, Vol. 13, Rev. 1. In addition, please confirm you will provide:

a) instructions to radiopharmacy customers for the proper preparation and packaging of the radioactive waste for return to the radiopharmacy; and
b) instructions to pharmacy staff for the pick-up, receipt, and disposal of the returned radioactive waste

that meet the requirements in 10 CFR 20.2001(a), 10 CFR 30.33, and 10 CFR 71.5, as applicable.

Applicant Response:

We commit to implementing the model procedure for return of radioactive wastes from customers published in Appendix S to NUREG 1556, Vol. 13, Rev. 1. In addition, we confirm that we will provide:

a) instructions to radiopharmacy customers for the proper preparation and packaging of the radioactive waste for return to the radiopharmacy; and
b) instructions to pharmacy staff for the pick-up, receipt, and disposal of the returned radioactive waste

that meet the requirements in 10 CFR 20.2001(a), 10 CFR 30.33, and 10 CFR 71.5, as applicable.

Please contact me at (808) 547-4884 or email at boyado@queens.org for further information. Thank you.

Sincerely,

Brian Oyadomari
Radiation Safety Officer