THE QUEEN'S MEDICAL CENTER

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April 8, 2010

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

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

Dear Dr. Roldan,

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

NRC Request #1:

The requirement in 10 CFR 30.35(b)(1) requires you to provide financial assurance and a decommissioning funding plan (DFP) for the quantities of unsealed byproduct materials with half-lives greater than 120 days that you are authorized to possess.

You may wish to avoid providing a DFP by reducing your possession limits for unsealed byproduct material of half-life greater than 120 days in the following or similar manner: If only one such isotope is possessed, the quantity possessed will be maintained at a quantity less than or equal to 10^5 times the applicable quantity in Appendix B of Part 30. For a combination of such isotopes, where R is defined as the sum of ratios of the quantity of each isotope to 10^5 times the applicable quantities in Appendix B, R shall not exceed 1 (unity rule). This would limit your requirement for financial assurance to $1,125,000 in accordance with 10 CFR 30.35(d). However, because the possession limits of your license are over this limit, you must justify why the reduced amounts are sufficient for your activities.

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 with atomic numbers 1 through 83, except as noted	Activated components associated with the cyclotron target assembly	50 microcuries per nuclide, 1 millicurie total possession, except as noted
3.	Vandium-48, Chromium-51, Manganese-52, Manganese-54, Cobalt-56, Cobalt-57, Cobalt-58, Rhenium-183, Rhenium-184	Activated components associated with the cyclotron target assembly	10 millicuries per nuclide, 30 millicuries total possession
4.	Any byproduct material authorized under 10 CFR 35.65(a), (b)	Sealed sources	10 millicuries total possession

Please refer to Attachment A for justification of this response.

NRC Request #2:

Submit a description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training.

Applicant Response:

We will implement and maintain the Radiation Safety Training Program for Cyclotron Workers and Ancillary Workers in accordance with guidance published in NUREG – 1556, Volume 21, "Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator" as follows:

NRC Request #2: (continued)

1. Applicable regulations, criteria, and scope for the training program are based on guidance in Vol.21 Section 8.8, “Training for Individuals Working In or Frequenting Restricted Areas.”

2. Content of training program is based on guidance in:
    a. Vol.21 Appendix F, “Radiation Safety Training” and
    b. Vol.21 Appendix K, “General Topics for Safe Possession and Use of Radioactive Materials and Model Emergency Procedures”

3. An outline of the The Queen’s Medical Center Radiation Safety Program is attached.

NRC Request #3:

In your application you commit to meet the radiation monitoring instrument specifications published in Appendix H to NUREG 1556. Please note that Appendix H provides guidance on the audit program. Please confirm you will use instruments that meet the radiation monitoring instrument specifications published in Appendix I to NUREG-1556, Vol. 21, Programs-Specific Guidance About Possession License for Production of Radioactive Material Using an Accelerator.

Applicant Response:

The incorrect reference to Appendix H in Vol. 21 was due to the use of the old draft report for Vol. 21 published May 2007.

In reference to the current version of Vol. 21, the section under “Radiation Monitoring Equipment” of our application should state the following:

“Survey Meters - We use instruments that meet the radiation monitoring instrument specifications published in Appendix I to NUREG-1556, Vol. 21, “Programs-Specific Guidance About Possession License for Production of Radioactive Material Using an Accelerator,” dated October 2007.

NRC Request #4:

Please confirm you will develop and maintain written emergency procedures to use for accelerator-specific scenarios, such as target failures, spills or releases outside a containment enclosure, delivery line failures, malfunction of air supply or exhaust systems, and high radiation levels in exhaust monitors or systems. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of users

NRC Request #4: (continued)

and the radiation safety staff. Please note Appendix K does not address the accelerator-specific scenarios mentioned above.

Applicant Response:

We will develop and maintain written emergency procedures to use for accelerator-specific scenarios, such as target failures, spills or releases outside a containment enclosure, delivery line failures, malfunction of air supply or exhaust systems, and high radiation levels in exhaust monitors or systems.

NRC Request #5:

Please confirm procedures will be revised only if: (1) the changes are reviewed and approved by the licensee management and the RSO in writing, (2) the licensee staff is provided training in the revised procedures prior to implementation, (3) the changes are in compliance with NRC regulations and the license, and (4) the changes do not degrade the effectiveness of the program.

Applicant Response:

We will revise procedures for safe handling of radionuclides and accelerator-specific emergency scenarios only if all following conditions are met:

1. The changes are reviewed and approved by the licensee management and the RSO in writing.
2. The licensee staff is provided training in the revised procedures prior to implementation.
3. The changes are in compliance with NRC regulations and the license.
4. The changes do not degrade the effectiveness of the Radiation Safety program.

NRC Request #6:

Please confirm you will survey your facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix M to NUREG-1556, Vol 21.

Applicant Response:

We revise Item 10.8 - SURVEYS of our license application to read as follows:

“We will survey our facility and maintain contamination levels in

accordance with the survey frequencies and contamination levels published in Appendix M to NUREG-1556, Vol. 21, Programs-Specific Guidance About Possession License for Production of Radioactive Material Using an Accelerator, dated October 2007."

NRC Request #7:

In your application you stated there are 8 zone detectors and the trigger levels for an audible alarm warning is set for 100mr/hr. Can you 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) (i.e. stack monitoring data from RADACS).

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.

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

Sincerely,

Brian Oyadomari
Radiation Safety Officer

THE QUEEN'S MEDICAL CENTER
RADIATION SAFETY PROGRAM

Radiation Safety Training Program

All Employees
General Annual Training – Self directed Supplement On Safety (SOS)

Central Transport Services
49 CFR and 10 CFR 71 – Initial and 3 year training for DOT/NRC RAM Shipments

Cyclotron Staff
10 CFR 19.12 and 10 CFR 35.27 – Initial and Annual training for licensed activities
49 CFR and 10 CFR 71 – Initial and 3 year training for DOT/NRC RAM Shipments

Diagnostic Laboratory Services
10 CFR 19.12 and 10 CFR 35.27 – Initial and Annual training for licensed activities (Blood Irradiation)

Housekeeping Staff
10 CFR 19.12 and 10 CFR 35.27 – Initial and Annual training for licensed activities (Hot Trash)
10 CFR 35.310 – Initial and Annual training for I-131 therapy patients

Cystoscopy (Kam 4) Staff
10 CFR 35.410 – Initial and Annual training for Manual Brachytherapy (PSI)

Medical Physics
10 CFR 19.12 and 10 CFR 35.27 – Initial and Annual training for licensed activities (HDR, PSI)
10 CFR 35.310 – Initial and Annual training for I-131 therapy patients (Technicians)
10 CFR 35.410 – Initial and Annual training for Manual Brachytherapy (PSI)
10 CFR 35.610 – Initial and Annual training for HDR Brachytherapy
49 CFR and 10 CFR 71 – Initial and 3 year training for DOT/NRC RAM Shipments (Technicians)

Radiation Therapy (Nae'a) Nurses
10 CFR 19.12 and 10 CFR 35.27 – Initial and Annual training for licensed activities (Sr-90, HDR, GliaSite)
10 CFR 35.610 – Initial and Annual training for HDR Brachytherapy

Nuclear Medicine
10 CFR 19.12 and 10 CFR 35.27 – Initial and Annual training for licensed activities
10 CFR 35.310 – Initial and Annual training for I-131 therapy patients

PET Imaging
10 CFR 19.12 and 10 CFR 35.27 – Initial and Annual training for licensed activities

Radiation Oncologists
10 CFR 19.12 and 10 CFR 35.27 – Initial and Annual training for licensed activities (Sr-90, HDR, PSI)
10 CFR 35.410 – Initial and Annual training for Manual Brachytherapy (PSI)
10 CFR 35.610 – Initial and Annual training for HDR Brachytherapy

T-7E Nurses
10 CFR 35.310 – Initial and Annual training for I-131 therapy patients

Note: "Refresher training should include topics with which the individual is not involve frequently and requires reaffirmation. Topics for refresher training need not include review of procedures or basic knowledge that the trainee routinely uses." NUREG-1556, Vol. 9, Appendix J.

ATTACHMENT A

Reference: CTI RDS-111 Operating Instructions published 1997.

Chapter 1, page 18 describes the low-level nature of residual radiation due to component activation:

> "Residual radiation due to direct charged-particle bombardment of cyclotron components, such as collimators, is rendered negligible due to the choice of appropriate materials lying in the beam path.
>
> Residual neutron-induced radiation in the accelerator and the shield itself is manifest as a diffuse, low-level background, which is held to a minimum by absorbing most thermal neutrons in the heavy borated inner layer of shielding."

Chapter 1, page 20 describes how the cyclotron shielding is designed to contain secondary neutron activation:

> "The effect of neutron activation is a diffuse, low-level, background radiation reading of below a few mR/hr, primarily around the targets. The levels are generally small in comparison with the primary proton-induced activation within the targets themselves.
>
> An important innovation in the design of the RDS 111 shield is the use of polyethylene and boron-carbide loaded concrete. The hydrogen content of this material is quite high (approximately 90% that of water by volume), resulting in a high dose attenuation for neutrons."

Chapter 1, page 20 describes how the cyclotron target material is the highest source of residual activity:

> "In contrast with low activation levels inside the cyclotron, the residual activity in the targets due to irradiated target material as well as proton activation of foils and target bodies, can be quite high."

Reference: O'Donnell, R.G., et al., "Measurement of the residual radioactivity induced in the front foil of a target assembly in a modern medical cyclotron," Applied Radiation and Isotopes 60, 539-542

The article provides explanation of how the cyclotron foil of the target is the highest source of residual activity:

> "Firstly, the location of the foil at the entrance of the target means that it will be exposed to both an intense primary beam of protons and to a large

> flux of secondary neutrons produced by the $^{18}O(p,n)^{18}F$ reaction in the target.
>
> Secondly, because the foil needs periodic replacement, it constitutes a source of radioactive waste whose handling, storage and disposal must be taken into consideration.
>
> Finally, Havar is an alloy containing cobalt (~40%), chromium (~20%), iron (~19%), nickel (~13%), manganese (~2%), tungsten (~3%) and molybdenum (~2%); since many of these elements are likely to be present in other metallic components of the cyclotron, analysis of the activation products present in the foil can provide information on the radionuclides likely to be induced in these other materials."

Therefore, the published results from the article by O'Donnell, et al., is used as the key basis for establishing the possession limits for our cyclotron operation as the foil is considered the highest source of residual activity.

Furthermore, using the results from the O'Donnell paper would be a conservative overestimate for our cyclotron operation, which utilizes a 11 MeV proton beam in comparison to the higher 16 MeV proton beam utilized for O'Donnell's paper.