UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

June 4, 2007

Docket No. 03003100 License No. 37-07939-01
Control No. 140530

Richard A. Anderson
President and Chief Executive Officer
St. Luke's Hospital
801 Ostrum Street
Bethlehem, PA 18015

SUBJECT: ST. LUKE'S HOSPITAL, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NO. 140530

Dear Mr. Anderson:

This is in reference to the letter from Lisa Dutterer of your staff dated May 17, 2007 requesting to amend Nuclear Regulatory Commission License No. 37-07939-01. Ms. Dutterer informed us that your current Radiation Safety Officer (RSO), Walter L. Robinson, is no longer able to fulfill his duties due to a medical condition and you wish to name Mark Liddington, a consultant, as RSO. Ms. Dutterer referenced two licenses on which Mr. Liddington is currently named as RSO.

Please consider that it has been our experience that hospitals such as St. Luke's Hospital, with large, complex licensed programs operating at multiple separate locations, usually have a full-time, on-site RSO with dedicated support staff. Consultants often oversee multiple programs simultaneously and may not be able to commit adequate time on-site to a complex licensed program. Strong consideration should be given to naming a full-time, on-site RSO with significant medical experience including high risk therapeutic uses. Options might be to (1) name as RSO one of your Radiation Oncology Authorized Medical Physicists who can devote a significant portion of their time to RSO duties, or (2) hire an experienced, full-time health physicist as RSO. Should a consultant be named as your RSO, please ensure that this individual can devote sufficient time to your program.

We reviewed your current license in comparison with the two licenses on which Mr. Liddington is currently named as RSO. We noted that your license authorizes a large number of complex, high risk therapeutic uses licensed under 10 CFR 35.400, 35.600, and 35.1000; however we only have documentation of Mr. Liddington's experience as RSO involving Nuclear Medicine uses under 10 CFR 35.100, 35.200, and 35.300.

If you wish to name Mr. Liddington as consultant RSO, it is necessary to document that he meets the requirements of 10 CFR 35.50(d) and (e) for all of the medical uses authorized on your license. Please provide the following additional information:

1. It is necessary to document that Mr. Liddington has training in the radiation safety, regulatory issues, and emergency procedures for the types of use currently authorized

on your license for which he has not previously been named as RSO. Ms. Dutterer has already provided documentation of this training for high dose rate remote afterloader use authorized in Items 6.H. and 6.I. of your license. Please provide documentation of this training, including the training provider, for the following additional uses:

a. Manual brachytherapy use authorized in Item 6.D.
b. Instrument calibration use authorized in Item 6.E.
c. Intravascular brachytherapy use authorized in Item 6.F.
d. Brachytherapy using the seedSelectron device authorized in Item 6.J.
e. Microspheres use in the SIR-Spheres delivery system authorized in Item 6.K.

2. Please submit the required preceptor attestation signed by a preceptor RSO, stating that Mr. Liddington has satisfactorily completed the requirements in 10 CFR 35.50(e) for each of the items listed above, as well as for high dose rate remote afterloader use, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO for this medical use license. It is necessary for the preceptor RSO to be authorized for each use listed in the attestation statement. Use of multiple preceptors is permitted.

3. During our most recent inspection, we noted that your RSO generally focused on your Nuclear Medicine program uses under 10 CFR 35.100, 35.200, and 35.300. Please confirm that your RSO's responsibilities will involve oversight of all authorizations on your license and will include the following:

a. Stopping unsafe activities involving licensed material;

b. Radiation exposures are ALARA;

c. Up-to-date radiation protection procedures in the daily operation of the licensee's byproduct material program are developed, distributed, and implemented;

d. Possession, use, and storage of licensed material is consistent with the limitations in the license, the regulations, the SSDR Certificate(s), and the manufacturer's recommendations and instructions;

e. Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license;

f. Personnel training is conducted and is commensurate with the individual's duties regarding licensed material;

g. Documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided;

h. When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;

i. Licensed material is properly secured;

j. Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;

k. Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, and fire;

l. Medical events and precursor events are investigated and reported to NRC, and cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;

m. Audits of the radiation protection program are performed at least annually and documented;

n. If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;

o. Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;

p. Licensed material is disposed of properly;

q. Appropriate records are maintained; and

r. An up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material;** then **Regulations, Guidance, and Communications.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 140530. If you have any questions regarding this letter, please call me at (610) 337-6952 or Sandy Gabriel at (610) 337-5182.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Pamela J. Henderson

Pamela J. Henderson, Chief
Medical Branch
Division of Nuclear Materials Safety

cc:
Jack Bruno, D.O. Vice President, Medical Affairs
Lisa Dutterer, Associate Vice President, Administration

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