St Luke's HOSPITAL & Health Network

801 Ostrum Street
Bethlehem, PA 18015
610-954-4000

MS16
Q-9

June 28, 2007

37-07939-01
03003100

Pamela J. Henderson
Chief, Medical Branch
Division of Nuclear Materials Safety
U.S.N.R.C. Region I
475 Allendale Rd.
King of Prussia, PA 19406-1415

Dear Ms. Henderson,

I'm writing in reference to your letter dated June 4, 2007 requesting additional information concerning a recent license amendment, (Control No. 140530).

Regarding training for manual brachytherapy use authorized in Item 6.D.;

Please find two letters of attestation regarding Mr. Liddington's training and experience with manual brachytherapy.

Regarding training for instrument calibration use authorized in Item 6.E.;

Please note that in-house calibrations are no longer performed at St. Luke's Hospital and Health Network. The Tech/Ops, Model 773 146 mCi Cesium 137 source is currently in storage. Please find confirmation of this action in the attached letter dated June 21, 2007 and signed by our authorized medical physicist Tianyou Xue.

As we no longer perform in-house instrument calibrations, we request that you amend our NRC license for storage of our Tech/Ops, Model 773 Calibration device with a possession limit of 150 mCi. Kim Kearney, M.S. will continue to supervise this source.

Regarding training for intravascular brachytherapy use authorized in Item 6.F.;

We have discontinued our intravascular brachytherapy program authorized in item 6.F. All sources have been returned to the manufacturer/vendor. We intend to amend our license to remove intravascular brachytherapy from our license. Please find confirmation of this action in the attached letter dated June 21, 2007 and signed by our authorized medical physicist Tianyou Xue.

140530

NMSS/RGN1 MATERIALS-002

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We request that you amend our license to remove intravascular brachytherapy use as authorized in item 6.F. We have contacted Novoste (now Best Vascular) for confirmation of receipt of our most recent source shipments. We will fax this information to your office as soon as it is received.

Regarding training for brachytherapy using the seedSelectron device authorized in Item 6.J.;
Please find the letter of attestation dated June 21, 2007 and signed by our authorized medical physicist Tianyou Xue, regarding Mr. Liddington's training on the seedSelectron brachytherapy device.

Regarding training for microspheres use in the SIR-Spheres delivery system authorized in Item 6.K.;

Please find the letter of attestation dated June 17, 2007 and signed by our Radiation Safety Officer Walter L. Robinson, regarding Mr. Liddington's training in the use of microspheres in the SIR-Spheres delivery system.

Additionally, we confirm that the RSO's responsibilities will involve oversight of all authorizations on our license and will include the following:

- Stopping unsafe activities involving licensed material;
- Maintaining radiation exposures to ALARA;
- Up-to-date radiation protection procedures in the daily operation of the licensee's byproduct material program are developed, distributed and implemented;
- Possession, use, and storage of licensed material is consistent with the limitations on the license, the regulations, the SSDR Certificate(s), and the manufacturer's recommendations and instructions;
- Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license;
- Personnel training is conducted and is commensurate with the individual's duties regarding licensed material;
- 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;
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- Licensed material is properly secured;
- 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 general public;

- Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, and fire;
- 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;
- Audits of the radiation protection program are performed at least annually and documented;
- If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
- Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- Licensed material is disposed of properly;
- Appropriate records are maintained; and
- An up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner.

If you have any questions please contact Mr. Liddington at 1-800-446-7622 ext. 2.

Sincerely,

Lisa Dutterer
Associate Vice President, Administration
St. Luke's Hospital and Health Network

St Luke's HOSPITAL & Health Network

801 Ostrum Street
Bethlehem, PA 18015
610-954-4000

June 21, 2007

Pamela J. Henderson
Chief, Medical Branch
Division of Nuclear Materials Safety
U.S.N.R.C. Region I
475 Allendale Rd.
King of Prussia, PA 19406-1415

Dear Ms. Henderson:

On June 21, 2007, I met with Mr. Mark Liddington of Walter L. Robinson and Associates for an education and training session on our Nucletron, seedSelection brachytherapy device. Specific topics included;

- The treatment planning process,
- Source receipt, inventory and storage,
- Treatment procedures, and
- Precautions, safeguards and emergency procedures.

Regarding instrument calibration use authorized in item 6E of our license, we are no longer performing in-house instrument calibrations. Our Tech/Ops Model 773, 146 mCi Cesium source is currently in storage.

Finally, we have discontinued our intravascular brachytherapy program authorized in item 6.F. All sources have been sent back to the manufacturer/vendor. We intend to amend our license to remove intravascular brachytherapy as an authorized use.

I am an authorized medical physicist on NRC license # 37-08939-01 (St. Luke's Hospital).

Sincerely,

Tianyou Xue, Ph.D.
Medical Physicist
St. Luke's Hospital & Health Network

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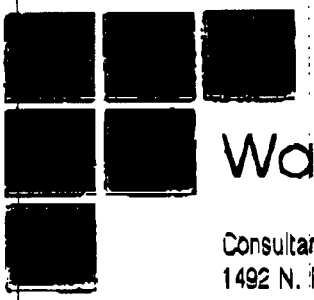

Walter L. Robinson & Associates

Consultant Medical Radiation Health Physicists
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www.walterrobinson.com Fax 610-873-2619

US Nuclear Regulatory Commission, Region I
Medical Licensing Division
475 Allendale Road
King of Prussia, PA 19406-1415

June 17, 2007

Subject: Confirmation of Training
Control # 140530

To whom it may concern:

I'm writing in reference to your letter to St. Lukes Health Network, June 4, 2007, requesting additional information and confirmation of Mark Liddington's training, within the last seven years, as related to his being named as RSO on license #37-07939-01.

Manual brachytherapy use authorized in Item 6.D.
Mr. Liddington has received training in manual brachytherapy and he was responsible for the health physics program at Good Samaritan Regional Medical Center (37-15480-01). I supervised his training in brachytherapy and educated him regarding the administrative controls to avoid oversights during administration and treatment, radiation safety surveys of patient and storage rooms, prevention of radioactive exposure from high energy photon sources, proper source handling procedures, as well as sealed source leak tests and inventories.

Microspheres use in the SIR-Spheres delivery system in Item 6.K.
Mr. Liddington has received training in and has observed the use of the SIR-spheres delivery system at St. Lukes Health Network, Bethlehem Campus. This training included the administrative controls to avoid mistakes during administration, proper radio-assay and dose assessment, radiation safety surveys, prevention of radioactive contamination, and proper decontamination procedures.

I am the current RSO on NRC license # 37-08939-01 (St. Luke's Hospital).

Sincerely,

Walter L. Robinson

Walter L. Robinson, M.S., A.B.S.N.M., A.B.M.P.
Consultant Certified Medical Radiation Health & Diagnostic Imaging Physicist
R.S.O, St. Luke's Hospital & Health Network

June 18, 2007

US Nuclear Regulatory Commission, Region I
Medical Licensing Division
475 Allendale Road
King of Prussia, PA 19406-1415

Subject: Confirmation of Training
Control # 140530

To whom it may concern:

I'm writing in reference to Mark Liddington's request for confirmation of his ability to oversee a manual brachytherapy program.

As Radiation Safety Officer at Good Samaritan Regional Medical Center (37-15480-01), I relied on Mr. Liddington to oversee our manual brachytherapy program when it was functional. His duties included:

- supervising the program to ensure that the proper administrative controls were in place and followed to avoid mistakes during administration,
- performing source inventories, leak tests and related safety surveys,
- preparing and shipping all unused and/or spent Ir-192 sources in accordance with applicable regulations,
- reviewing all brachytherapy cases for compliance with our quality management program, and
- providing staff training when necessary.

Sincerely,

Stephen R. Whitmoyer, M.D.
Radiation Safety Officer