



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

June 5, 2007

Docket No. 03003056
Control No. 140492

License No. 37-05811-02

Anthony H. Bliss
Vice President, Professional Services
Pocono Medical Center
206 East Brown Street
East Stroudsburg, PA 18301-3094

SUBJECT: POCONO MEDICAL CENTER, REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL
NO. 140492

Dear Mr. Bliss:

This is in reference to the letter dated April 27, 2007 requesting to amend Nuclear Regulatory Commission License No. 37-05811-02. In order to continue our review, we need the following additional information.

Your application should have been signed by a management representative rather than Ms. Jacqui Cotterall. Please submit a letter signed by a management representative indicating that management has reviewed the application and concurs in the statements and representations contained therein. Note also that a management representative should sign all future correspondence that requests a change in your license.

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

If you wish to name Mr. Ramsey 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. Ramsey 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. Please provide documentation of this training, including the training provider, for the following additional uses:
 - a. Therapeutic use authorized in Item 6. C.
 - b. Manual brachytherapy use authorized in Item 6.D.
 - c. Instrument calibration use authorized in Item 6.E.
 - d. High dose rate remote afterloader use authorized in Items 6.F.

2. Please submit the required preceptor attestation signed by a preceptor RSO, stating that Mr. Ramsey has satisfactorily completed the requirements in 10 CFR 35.50(e) for each of the items listed above, 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. 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. 140492. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5006.

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 Shirley Xu

Shirley Xu
Health Physicist
Medical Branch
Division of Nuclear Materials Safety

cc:
William F Tatu, M.D., Radiation Safety Officer

DOCUMENT NAME: C:\FileNet\ML071570404.wpd

SUNSI Review Complete: SXu

After declaring this document "An Official Agency Record" it will be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI			
NAME	SXu /SSX/							
DATE	6/5/07							

OFFICIAL RECORD COPY