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

June 15, 2010

Docket No. 03035314 License No. 52-25507-01
Control No. 144584

Araceli Rivera Serrano, M.D.
Owner and Radiation Safety Officer
Mayagüez Nuclear Medicine
P.O. Box 6468
Mayagüez, PR 00682-6468

SUBJECT: MAYAGÜEZ NUCLEAR MEDICINE, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO. 144584

Dear Dr. Rivera Serrano:

This is in reference to your application dated March 30, 2010 requesting to renew Nuclear Regulatory Commission License No. 52-25507-01. In order to continue our review, we need the following additional information:

1. Please provide the applicant's name and mailing address, as required in NRC form 313, Item 2.

2. The address where licensed material will be used or possessed that you provided in the NRC form 313 is not the same as currently listed on your NRC license. Please clarify. For instance, is 351 Hostos Avenue located in the Medical Emporium Building at State Road #2, Km. 156.3?

3. Your license will be written in a format which requires modification of some possession limits. In your response to this letter, please provide a total possession limit for licensed material permitted by 10 CFR 35.300.

4. Concurrent with the issuance of the new medical regulations in 10 CFR Part 35, NRC published NUREG-1556, Volume 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses." You will note that new Part 35 and this guidance generally do not require the submission of detailed procedures during the licensing process. As detailed in NUREG-1556, Vol. 9, Appendix C, in many cases a licensee is required only to supply a statement regarding the development, implementation, and maintenance of written operating and emergency procedures; and therefore retain greater flexibility when revising these procedures. Therefore, please confirm the following:

    a. Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations. Please note that Lantheus Medical Imaging

does not possess an NRC license to calibrate survey instruments for other licensees.

b. The equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.

c. Either you will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or you will provide dosimetry that meets the requirements listed under 'Criteria' in NUREG-1556, Vol. 9, Rev. 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.

d. You will develop, implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.

e. You will develop, implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20 and 10 CFR 35.92.

f. You will develop, implement and maintain written procedures for the safe use of unsealed byproduct materials that meet the requirements of 10 CFR 20.1101 and 20.1301.

g. You will develop, implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 Part 20.1101.

5. Please provide a description of the instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required radiation level and contamination surveys. In addition, please confirm whether you reserve the right to upgrade your survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.

6. With regard to your facility description, please provide a detailed description of:

a. Facilities used to house therapy patients (e.g., inpatient facilities) or confirm that therapy treatments are performed on outpatients only;

b. PET shielding or confirm that the shielding description provided in your letter dated August 10, 2009 is still applicable; and

c. Areas above and below your areas of use.

7. Please note that several procedures were not required to be submitted, were not

reviewed in detail, and will not be included as a commitment in your license. These procedures include Items 8.1, 8.2, 10.1, 10.2, 10.3, 10.6, 10.7, 10.8, and 10.14. These items will be reviewed during a future inspection of your licensed activities. A cursory review of these items, however, identified the following concerns:

a. The duties of the RSO reference the Texas regulations instead of the NRC regulations;

b. Various sections (e.g., leak tests, package surveys, etc.) reference exceeding limits. Please note that if this occurs, a notification of the NRC may be required.

c. 10 CFR 20.1906 requires contamination surveys of incoming packages regardless of whether the shipper performed the survey.

d. Package survey triggers appear excessive since most packages received by nuclear medicine departments are shipped with a Transport Index of much lower than 10.

e. 10 CFR 35.70 requires daily surveys when handling licensed material requiring a written directive; and

f. The area survey trigger levels for unrestricted areas are in excess of those described in Table R.1 of NUREG-1556, Volume 9.

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. 144584. If you have any technical questions regarding this deficiency letter, please call Leira Cuadrado at (610) 337-5370.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Sincerely,

Original signed by Penny Lanzisera

Penny Lanzisera
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

DOCUMENT NAME: G:\WordDocs\Current\Lic Def Letter\L52-25507-01.144584.doc

SUNSI Review Complete: PLanzisera

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	N	DNMS/RI			
NAME	LCuadrado ***/LC/***		PLanzisera ***/PL/***					
DATE	6-15/10		6-15-10					

OFFICIAL RECORD COPY