UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

October 8, 2013

Docket No. 03033058 License No. 52-21051-02
Control No. 581304

Héctor R. León, M.D.
Calle Fernández Juncos B-3
Urb, Rosa María
Carolina, PR 00985

SUBJECT: HECTOR R. LEON, M.D.; REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO LICENSE; CONTROL NO. 581304

Dear Dr. Leon:

This is in reference to your application dated June 25, 2013 requesting to amend Nuclear Regulatory Commission License No. 52-21051-02. In order to continue our review, we need the following additional information:

1. In order to facilitate future communications please provide a business facsimile number.

2. Please confirm that your mailing address zip code has been changed to 00985.

3. Please provide the sealed source manufacturer and model number for the source listed in item 5 of your application. In addition, please provide the current activity.

4. Please confirm that you have developed and will 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. For instance, surveys following use of the applicator, 6 month leak tests, and radiation level surveys of the storage area should be performed and your procedures should address these surveys.

5. Please provide a description of the radiation monitoring instrumentation (e.g. portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, etc.) that will be used to perform required surveys. Please indicate if this instrument will be kept on site, or if provided on short notice in the event of an accident or malfunction involving the applicator. If provided on short notice, please indicate who will be providing the instrumentation.

6. Please confirm the following statement: “We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.”

7. Your application did not address procedures for survey meter calibration. Please confirm that radiation monitoring instruments will be calibrated by a person qualified to

perform survey meter calibrations.

8. It appears that your Authorized Medical Physicist (AMP) is a consultant. If so, please indicate the Authorized Medical Physicist's availability for audits and surveys.

9. Please confirm that you will either perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or that you will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Vol. 9, Rev. 2., "Consolidated Guidance About Materials Licenses: Program Specific Guidance About Medical Use Licensees," dated January 2008 (http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/).

10. Please confirm that you will dispose of the source to an authorized recipient when you decide to terminate licensed activities or purchase a new source.

11. On your facility diagram, please confirm what areas are above and below the therapy treatment/storage room, indicating whether the adjacent areas are restricted or unrestricted as defined in 10 CFR 20.1003.

12. Please provide a description of the safety equipment/shielding used in the storage and use area to minimize exposures to employees and members of the public.

13. Please address security of the source. Specifically, please indicate whether the door to the therapy treatment room that leads to the emergency exit is locked from the outside to prevent unauthorized entry.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Licensee Toolkits, see our toolkit index page.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 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. 581304. If you have any technical questions regarding this deficiency letter, please call Robin Elliott at (610) 337-5076.

In order to continue our 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.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Thank you for your cooperation.

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\L52-21051-02.581304.doc

**SUNSI Review Complete:** RElliott

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 | RElliott ***/RE/*** | | PLanzisera ***/pl/*** | | | | | |
| DATE | 10/8/13 | | 10/8/13 | | | | | |

OFFICIAL RECORD COPY