



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

December 19, 2013

Docket No. 03033058
Control No. 581304

License No. 52-21051-02

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

SUBJECT: Hector R. Leon, M.D., LICENSE RENEWAL, CONTROL NO. 581304

Dear Dr. León:

This refers to your request dated June 25, 2013 for renewal of your NRC license. Enclosed with this letter is the renewed license. Thank you for providing the following additional information by phone on December 17, 2013: (1) that you have purchased a Bicon 2000 survey meter, which has been calibrated for the performance of surveys, (2) that you will perform and record surveys of patients at the completion of each treatment in accordance with 10 CFR 35.404, and (3) 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 Licenses." Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

The NRC expects licensees to conduct their programs with meticulous attention to detail and high standards of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your program according to NRC regulations, the conditions of your NRC license, and the representations made in your application. Please note that the last condition on your license indicates that "This license condition applies only to those procedures that are required to be submitted in accordance with the regulations." Therefore, any procedures submitted that were not required by regulation to be submitted, e.g., calibration of dose calibrators, will not be considered a part of your license and were not reviewed during the licensing process. These procedures will be reviewed during inspections, as necessary.

Please note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify the NRC in writing when:
 - a) an authorized user, authorized medical physicist or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name

- change;
- b) the mailing address changes;
 - c) the name on the license changes; or
 - d) permitting an individual to function as a temporary Radiation Safety Officer in accordance with 10 CFR 35.24(c).
3. In accordance with 10 CFR 30.36(d), notify the NRC, promptly, in writing, and request termination of the license:
- a) when you decide to terminate all activities involving materials authorized under the license; or
 - b) if you decide not to acquire or possess and use authorized material.
4. Request and obtain a license amendment before you:
- a) permanently change Radiation Safety Officers;
 - b) receive byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - c) add or change the areas of use, except as allowed by 10 CFR 35.13(e) and with the appropriate notification described in 10 CFR 35.14(b)(4);
 - d) change the name or ownership of your organization;
 - e) change the address(es) of use identified on the license;
 - f) receive, prepare, or use byproduct material for a type of use that is not authorized on the license; or
 - g) permit anyone to work as an authorized user, or authorized medical physicist, except as allowed by 10 CFR 35.13(b) and with the appropriate notification described in 10 CFR 35.14(a).
5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations.

You will be periodically inspected by the NRC. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and the representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, imposition of a civil penalty, or an order suspending, modifying or revoking your license.

An environmental assessment for this action is not required, since this action is categorically

excluded under 10 CFR 51.22(c)(14).

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).

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

Enclosure:
Amendment No. 5

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