



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

MAY 27 2016

Maximo V. Bleza, D.O.
Radiation Safety Officer
Pinnacle Hospital
9301 Connecticut Drive
Crown Point, IN 46307

Dear Dr. Bleza:

Enclosed is your NRC Material License No. 13-35297-01 in accordance with your request.

Please note that we were not able to add Dr. Sarma at this time because you only requested he be added for 10 CFR 35.400 authorizations and the use of those materials was not requested in your license application. In addition, for Drs. Alkadri, Forde, Lee, Mishra, Quackenbush and Barakat, we are only able to add them to your license for 10 CFR 35.300, limited to the oral administration of sodium iodide I-131 in quantities less than 33 millicuries. If you wish to include the additional authorizations you requested for these doctors, please submit an amendment request to add the additional uses to your license. Please refer to NUREG 1556, Vol. 9, Rev. 2, "Consolidated Guidance About Materials Licenses Program-Specific Guidance About Medical Use Licenses," for guidance on the information that would need to be provided to the NRC.

As discussed during our visit to your facility, please provide an updated facility drawing detailing where all equipment will be placed once they become available.

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 III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 Code of Federal Regulations (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 NRC, in writing, within 30 days:
 - a. When an authorized user or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
 - b. When the mailing address listed on the license changes.
3. In accordance with 10 CFR 30.36(d) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

4. Request and obtain a license amendment before you:
 - a. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;
 - b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;
 - c. Change Radiation Safety Officers except as provided by 10 CFR 35.24;
 - d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - e. Add or change the areas of use or address or addresses of use identified in the license application or on the license except as provided by 10 CFR 35.14; or
 - f. Change ownership of your organization.
5. Submit a complete renewal application with proper fee 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. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and 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, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

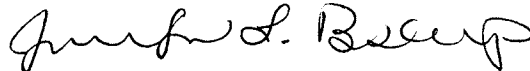
The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material 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.

M. V. Bleza

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In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,



Jennifer L. Bishop
Health Physicist
Materials Licensing Branch

License No. 13-35297-01

Docket No. 030-38910

- Enclosures:
1. License No. 13-35297-01
 2. 10 CFR Part 19
 3. 10 CFR Part 20
 4. 10 CFR Part 30
 5. 10 CFR Part 35
 6. Form NRC-3