



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

May 27, 2022

Zachary C. Smith, M.D.
Radiation Safety Officer
Helen Newberry Joy Hospital
502 W. Harrie St.
Newberry, MI 49868

SUBJECT: RENEWAL OF RADIOACTIVE MATERIALS LICENSE FOR HELEN NEWBERRY
JOY HOSPITAL, U.S. NRC MATERIAL LICENSE NO. 21-32004-01

Dear Dr. Smith:

Enclosed is Amendment No. 10 renewing your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 21-32004-01, in accordance with the letters dated April 29, 2022 and May 17, 2022, both signed by Hunter Nostrant, CEO.

Congratulations on your appointment as Radiation Safety Officer. Additional information, guidance and resources are available from the agency to assist you. This includes NUREG-1556, Volume 9, Rev. 3, September 2019, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," particularly including Appendix I, "Radiation Safety Officer Duties, Responsibilities and Delegation," and Appendix L, "Model Medical License Audit." This guidance document is available on the U.S. NRC website at: <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html>

In addition to identifying your appointment as Radiation Safety Officer, your license has also been amended to reflect the following changes:

- Addition of Niksa Vlastic, M.D. and Zachary C. Smith, M.D., as Authorized Users of licensed material described in Title 10 of the *Code of Federal Regulations* (10 CFR) §35.100 and 10 CFR §35.200;
- Removal of Paul A. Lyle, M.D., Ethelbert M. Lara, M.D., and Nathan McParlan, M.D., as Authorized Users.

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

An environmental assessment for this action is not required because this action is categorically excluded under [10 CFR Section 51.22\(c\)](#).

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

1. Operate in accordance with NRC regulations [10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspections and Investigations,"](#) [10 CFR Part 20, "Standards for Protection Against Radiation,"](#) [10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material,"](#) [10 CFR Part 35, "Medical Use of Byproduct](#)

Material.” and other appropriate regulations.

2. Notify NRC in writing 30 days in advanced of any change in mailing address.
3. In accordance with [10 CFR §30.36\(d\)](#), notify NRC promptly, in writing, within 60 days and request termination of the license:
 - a. When you decide to terminate all activities involving materials authorized under the license whether at the entire site or any separate building or outdoor area;
 - b. If you decide not to acquire or possess and use authorized material; or
 - c. When no principal activities under the license have been conducted for a period of 24 months.
4. In accordance with [10 CFR §35.14](#), notify the NRC no later than 30 days after:
 - a. The date that the licensee permits an individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist under [10 CFR §35.13\(b\)\(1\) through 35.13\(b\)\(4\)](#);
 - b. An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues duties under the license or has a name change;
 - c. The licensee’s name changes but the name change does not constitute a transfer of control of the license as described in [10 CFR §30.34\(b\)](#); or
 - d. The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either [10 CFR §35.100](#) or [§35.200](#).
5. Request and obtain a license amendment before you:
 - a. Change Radiation Safety Officers;
 - b. Order 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 or address or addresses of use identified in the license application or on the license (except for areas of use where byproduct material is used only in accordance with either [10 CFR §35.100](#) or [§35.200](#)) or
 - d. Change the name or ownership of your organization.
6. 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 60 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations.

An electronic version of the U.S. NRC’s regulations is available on the NRC Web Site at: <https://www.nrc.gov/reading-rm/doc-collections/cfr/index.html>. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/med-use-toolkit.html>. This site also provides the updated Training and Experience [NRC Form 313A](#) series of forms and guidance, as well as information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

You will be periodically inspected by U.S. 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 NRC Enforcement Policy. Since serious consequences to employees and the public can result from failure to comply with U.S. 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 that NRC expects of its licensees.

The U.S. 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 <https://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.

Please be aware that, as a holder of a U.S. NRC license, you may be subject to the U.S. NRC's licensing and inspection fees in accordance with [10 CFR Part 170](#), and annual fees in accordance with [10 CFR Part 171](#). If you have any questions concerning the fee requirements, please contact the License Fee and Accounts Receivable Branch at (301) 415-7544.

In accordance with [10 CFR §2.390](#) of the U.S. NRC's "Rules of Practice and Procedure," a copy of this letter and its enclosure will be available electronically for public inspection in the U.S. NRC Public Document Room or from the U.S. NRC's ADAMS, accessible from the U.S. NRC website at <https://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

Jason M. Kelly, MPH
Health Physicist
Materials Licensing Branch

Docket No.: 030-34481
License No.: 21-32004-01

Enclosure: Amendment No. 10 to NRC License No. 21-32004-01