

UNITED STATES NUCLEAR REGULATORY COMMISSION

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

September 27, 2022

Sharon Updike, MHP, DABR Radiation Safety Officer The South Bend Clinic, LLC 211 N. Eddy St. South Bend, IN 46634

SUBJECT: RENEWAL OF RADIOACTIVE MATERIALS LICENSE FOR THE SOUTH BEND CLINIC, LLC, U.S. NRC MATERIALS LICENSE NO. 13-32393-01

Dear Ms. Updike:

Enclosed is Amendment No. 08 renewing your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 13-32393-01, in accordance with the letters dated July 5, 2022 and September 22, 2022, both signed by Anna Swanson, RT(R)(M), Manager of Imaging Services.

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 <u>10 CFR Section 51.22(c)</u>.

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:

- Operate in accordance with NRC regulations <u>10 CFR Part 19</u>, "Notices, Instructions and <u>Reports to Workers: Inspections and Investigations,"</u> <u>10 CFR Part 20</u>, "Standards for <u>Protection Against Radiation,"</u> <u>10 CFR Part 30</u>, "Rules of General Applicability to <u>Domestic Licensing of Byproduct Material,"</u> <u>10 CFR Part 35</u>, "Medical Use of Byproduct <u>Material,"</u> and other appropriate regulations.
- 2. Notify the U.S. NRC in writing 30 days in advance of any change in mailing address.
- In accordance with <u>10 CFR §30.36(d)</u>, notify the U.S. 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 <u>10 CFR §35.14</u>, notify the U.S. 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 <u>10 CFR</u> <u>§35.13(b)(1) through 35.13(b)(4)</u>;

- 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 <u>10 CFR §30.34(b)</u>; 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 <u>10 CFR</u> <u>§35.100</u> or <u>§35.200</u>.
- 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 <u>10 CFR §35.100</u> or §35.200) or
 - d. Change the name or ownership of your organization.
- 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 the U.S. NRC regulations.

An electronic version of the U.S. NRC's regulations is available on the U.S. NRC website at: <u>https://www.nrc.gov/reading-rm/doc-collections/cfr/index.html</u>. Additional information regarding medical uses of radioactive materials may be obtained on the U.S. NRC website at: <u>http://www.nrc.gov/materials/miau/med-use-toolkit.html</u>. This site also provides the updated Training and Experience <u>NRC Form 313A</u> 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 the U.S. NRC. Failure to conduct your program in accordance with U.S. NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with U.S. 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 U.S. 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 U.S. 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 U.S. NRC's safety culture website at <u>https://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html</u>.

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 <u>10 CFR Part 170</u>, and annual fees in accordance with <u>10 CFR Part 171</u>. 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 <u>10 CFR §2.390</u> 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 <u>https://www.nrc.gov/reading-rm/adams.html</u>.

Sincerely,

Jason M. Kelly, MPH Health Physicist Materials Licensing Branch

License No.: 13-32393-01 Docket No.: 030-36006

Enclosure: Amendment No. 08 to U.S. NRC Materials License No. 13-32393-01