



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

December 1, 2021

Dr. Richard N. Joyrich, M.D.
Radiation Safety Officer
VHS Harper - Hutzel Hospital, Inc.
2990 John R. St.
Detroit, MI 48201

SUBJECT: RENEWAL OF RADIOACTIVE MATERIALS LICENSE FOR VHS HARPER -
HUTZEL HOSPITAL, INC., NRC LICENSE NO. 21-04127-02

Dear Dr. Joyrich:

Enclosed is Amendment No. 107 renewing your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 21-04127-02 in accordance with VHS Harper - Hutzel Hospital, Inc.'s (your) May 25, 2021 renewal application. Your renewal application is available electronically from NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML21153A120. The NRC's ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Please note that we have made some minor corrections to existing license conditions, and removed Condition No. 15 from your license, in accordance with Amendment No. 106, which removed your phosphorus-32 research and development authorization.

Please also note that the renewed license includes your letter dated November 30, 2021 (ADAMS Accession No. ML21334A438) in Condition No. 20.B., which was received via your November 30, 2021 email message. In accordance with that letter and email message, please submit updated and annotated facility diagrams within 30 days of this letter (on or before December 31, 2021). If additional time is needed to prepare the diagrams, please let us know.

Finally, please note that the renewed license also includes your previous letters dated October 30, 2007, May 9, 2017, and October 2, 2017 (ADAMS Accession Nos. ML073050468, ML17198A547, and ML17279A898, respectively) in Condition Nos. 20.C through 20.E of your license. To update your license with the most recent version of NRC's Title 10 of the *Code of Federal Regulations* (10 CFR) Section 35.1000 guidance for yttrium-90 microspheres, please submit a signed and dated letter containing updated license requirements. The current guidance requirements – including criteria for authorizing physicians for 10 CFR 35.1000 use – are contained in the document, "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance," rev. 10.2, dated April 20, 2021 (ADAMS Accession No. ML21089A364), pp. 2 through 15.

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 630-829-9892 so that we may provide appropriate corrections and answers.

The enclosure to this letter contains sensitive security-related information.
When separated from this cover letter this letter is uncontrolled.

R. Joyrich

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An environmental assessment for this action is not required since this action is categorically excluded under 10 CFR 51.22(c).

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 NRC Enforcement Policy. 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 that 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 <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.

NRC's Regulatory Issue Summary (RIS) RIS 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through NRC's ADAMS, the NRC's electronic document system. Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability. The RIS may be located on the NRC's Generic Communications Web page under "Regulatory Issue Summaries" at <https://www.nrc.gov/reading-rm/doc-collections/gen-comm/>, and the link for frequently asked questions regarding protection of security-related sensitive information may be located at <https://www.nrc.gov/reading-rm/sensitive-info/faq.html>.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

Sara A. Forster

Digitally signed by Sara A.
Forster
Date: 2021.12.01 14:10:47 -06'00'

Sara A. Forster
Health Physicist, Materials Licensing Branch
Division of Nuclear Materials Safety

Docket No.: 030-02045
License No.: 21-04127-02
Control No.: 626909

Enclosure: Amendment No. 107 to NRC License No. 21-04127-02