

UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION III 2056 WESTINGS AVENUE, SUITE 400 NAPERVILLE, IL 60563-2657

June 13, 2025

John P, Lowden, MS, DABR, Senior Medical Physicist Radiation Safety Officer Goshen Health Dept. of Nuclear Medicine 200 High Park Ave. Goshen, IN 46526

SUBJECT: AMENDMENT NO. 71 TO RADIOACTIVE MATERIALS LICENSE FOR GOSHEN

HEALTH, NRC LICENSE NO. 13-18845-01

Dear John Lowden:

Enclosed is Amendment No. 71 to Goshen Health's (your) U.S. Nuclear Regulatory Commission (NRC) Materials License No. 13-18845-01, in accordance with your December 18, 2024, and April 22, 2025, requests. Your letters are available electronically from the NRC's Agencywide Documents Access and Management System (ADAMS) at Accession Nos. ML25077A056 and ML25113A174, respectively. The NRC's ADAMS is accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

Please note that, in addition to the requested revisions, the final condition, now No. 15, has been revised to remove references to the licensee's ability to update its radiation protection programs for 10 CFR 35.1000 uses. For updates to the yttrium-90 microspheres radiation protection program, a new Condition No. 14 has been added, clarifying the licensee's ability to update it's 10 CFR 35.1000 yttrium-90 microspheres program, based on information previously submitted to the NRC. Our office was unable to identify a similar licensee request for such flexibility to update the iodine-125 seeds for non-palpable lesion localization use radiation protection program.

To add a condition explicitly highlighting the scope of the licensee's authority to update its iodine-125 seeds for non-palpable lesion localization use radiation protection program, please provide additional information – if not previously submitted to NRC – as outlined in NRC's guidance document, "Low Activity Radioactive Seeds Used for Localization of Non-Palpable Lesions and Lymph Nodes Licensing Guidance," Revision 1, dated October 7, 2016 (ML16197A568), or alternative equivalent information. A copy of the applicable items from the guidance is attached to this letter in Enclosure 2.

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.

An environmental assessment for this action is not required because this action is categorically excluded under Title 10 of the *Code of Federal Regulations* (10 CFR) Section 51.22(c).

J. Lowden 2

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/fag.html.

J. Lowden 3

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS.

Sincerely,

SARA FORSTER/ Digitally signed by SARA FORSTER Date: 2025.06.13 11:09:44 -05'00'

Sara A. Forster, MS Senior Health Physicist Materials Licensing Branch Division of Radiological Safety and Security

Docket No. 030-14254 License No.: 13-18845-01

Control No.: 645739

Enclosures: 1. Amendment No. 71 to NRC

License No. 13-18845-01

 Emerging Medical Technologies 10 CFR 35.1000 Guidance Excerpt from "Low Activity Radioactive Seeds Used for Localization of Non-Palpable Lesions and Lymph Nodes Licensing Guidance," Revision 1, October 7, 2016 (ML16197A568)

cc: C. Kelly Stoneberg, Consultant Physicist,

kstoneberg@ohiomedphys.com