



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

November 23, 2021

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

SUBJECT: ADDITIONAL INFORMATION NEEDED REGARDING RENEWAL OF VHS
HARPER - HUTZEL HOSPITAL, INC., NRC LICENSE NO. 21-04127-02

Dear Dr. Joyrich:

Our office has reviewed the May 25, 2021 request for NRC to renew VHS Harper - Hutzel Hospital, Inc.'s (your) U.S. Nuclear Regulatory Commission (NRC) Materials License for medical and self-shielded irradiator use. Upon review, our office has determined that additional information is needed to renew the license, regarding the purpose of use for the self-shielded irradiator to be authorized under the license, your training program, your facilities & equipment, and your radiation safety program. 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>.

For additional guidance, please refer to NUREG 1556, Volume 9, revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," Sections 8.8, "Training for Individuals Working in or Frequenting Restricted Areas," pp. 8-42 to 8-43, 8.9.1, "Facility Diagram," pp. 8-45 to 8-50, and 8.10, "Radiation Safety Program," pp. 8-61 to 8-82; and NUREG 1556 Volume 5, revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses," Sections 8.6, "Purpose(s) for Which Licensed Material Will Be Used," pp. 8-8 to 8-9, 8.9, "Facilities and Equipment," pp. 8-14 to 8-16, and 8.10, "Radiation Safety Program," pp. 8-16 to 8-40.

PURPOSE OF USE TO BE AUTHORIZED ON THE LICENSE:

1. The requested authorization for cesium-137 was silent as to whether flammable, corrosive, or explosive materials would be used with the irradiator. **Please confirm the statement, "We will not irradiate flammable, corrosive, or explosive materials."**
2. The requested authorization for cesium-137 indicated the sealed sources and devices to be used. However, conformity to the sealed source & device registry was unclear. **Please confirm the statement: "This self-shielded irradiator will be used for the purposes described in its SSD registration certificate."**

TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS:

3. The renewal application referenced a training provided by Landauer Academy but omitted training criteria such as topics covered, instructor qualifications, and evaluation criteria. **Please confirm the statement: “We have developed and will implement and maintain written procedures for a program for training required under 10 CFR 19.12 for each group of workers, including (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training.” In the alternative, you may provide specific training program details associated with your license.**

FACILITIES AND EQUIPMENT:

4. The diagrams submitted in the renewal application were unclear regarding addresses, facility dimensions, or the activities (10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.1000, or self-shielded irradiator) authorized in each diagram. **Please indicate the scale or dimensions and the specific street address associated with each of the diagrams provided.**
5. The request confirmed that radiation monitoring instruments would be used by qualified – but not explicitly licensed - individuals. **Please confirm the statement regarding calibrations of radiation monitoring instrument statement, “Radiation monitoring instruments will be calibrated by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations.”**
6. The renewal application omitted a discussion of routine checks of the irradiator interlocks. **Please confirm the statement: “We will conduct electrical and mechanical safety interlock checks of each irradiator at least quarterly, in accordance with the irradiator’s user’s manual.” AND EITHER**

Please confirm the statement: “We will ensure that each area where a self-shielded irradiator is located corresponds to the ‘Conditions of Normal Use’ and ‘Limitations and/or Other Considerations of Use’ on the applicable irradiator’s Sealed Source and Device registration certificate; the floor beneath the self-shielded irradiator is adequate to support the weight of the irradiator; each self-shielded irradiator is secured to prevent unauthorized access or removal; and each area where a self-shielded irradiator is located is equipped with an automatically operated fire-detection and -control system (sprinkler, chemical, or gas) or the location of the area and other controls ensure a low level of radiation risk attributable to fires.” OR

Please provide alternative information; be sure to include justification for placing an irradiator in an area that does not correspond to the “Conditions of Normal Use” and the “Limitations and/or Other Considerations of Use.”

RADIATION SAFETY PROGRAM:

7. The application provided a leak test commitment for non-Part 35 sealed sources but was unclear as to leak test procedures for Part 35 sealed sources. **Please confirm the statement regarding leak testing of Part 35 sealed sources: “We have developed and will implement and maintain written procedures for sealed-source leak testing that meet the requirements of 10 CFR 35.67.”**
8. The application was unclear as to procedures and inventory schedules surrounding irradiator sealed source inventory. **Please confirm the statements: “We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times.” AND “Physical inventories will be conducted and documented at intervals not to exceed 6 months to account for all sealed sources and devices received and possessed under the license.”**
9. The application was unclear as to irradiator operating and emergency procedures. **Please confirm the statement: “If we change our operating, emergency, or security procedures without amending our license, we will ensure that (i) the changes are reviewed and approved by licensee management and the RSO; (ii) affected licensee staff are trained in the procedures before they are implemented; (iii) the changes are consistent with applicable license conditions and the procedures or commitments submitted in the license application; and (iv) the changes do not degrade the safety of the program.” AND EITHER**

Please confirm the statement: “Operating, emergency, and security procedures will be developed, implemented, maintained, and distributed and will meet the Criteria in the section entitled ‘Radiation Safety Program - Operating and Emergency Procedures’ in NUREG-1556, Volume 5, Revision 1, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses.” OR

Please provide operating and emergency procedures for the irradiator.

10. The application omitted information regarding maintenance of the irradiator. **Please confirm the statements, respectively, for maintenance, routine maintenance, and non-routine maintenance of the irradiator: “We will maintain documentation of the use of all non-OEM replacement parts and components. If OEM replacement parts cannot be used for the shielding of any sealed sources, the driving unit of any sources, safety interlocks, or other electrical or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the device or any sources, we will obtain and document NRC approval before beginning the nonroutine maintenance activity. In addition, if a service provider plans to remove any aspect of the Global Threat Reduction Initiative (GTRI) irradiator-hardening hardware, we will discuss this matter with the NRC before allowing this service to be initiated.” AND “We will implement and maintain procedures for routine maintenance of our self-shielded irradiators according to each manufacturer’s or distributor’s written recommendations and instructions.” AND “We will have the self-shielded irradiator manufacturer, distributor, service provider, or another person authorized by the NRC or an Agreement State perform nonroutine maintenance.”**

In the alternative to confirming statements, as noted, the licensee may provide alternative procedures for routine and non-routine maintenance of the irradiator.

Please provide a response via a signed and dated letter within 7 days (on or prior to November 30, 2021). If you are unable to provide a response before November 30, 2021, please provide a signed and dated letter by that date indicating the date by which you will be able to provide a written response to the items outlined in this request. For quickest processing, please submit your response as a pdf file attached to an email message. You may also submit a response via fax or via regular mail. If you have any questions regarding this message, please do not hesitate to reach out to me at 630-829-9892.

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Section 2.390 of the NRC's "Rules of Practice and Procedure," 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, M.S.
Health Physicist
Materials Licensing Branch
Division of Nuclear Materials Safety

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