



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

September 24, 2021

Nanci A. Burchell, MBA, CNMT  
Radiation Safety Officer  
Children's Mercy Hospital  
2401 Gilham Rd.  
Kansas City, MO 64108

SUBJECT: ADDITIONAL INFORMATION NEEDED REGARDING RENEWAL OF  
CHILDREN'S MERCY HOSPITAL, NRC LICENSE NO. 24-15513-01

Dear Ms. Burchell:

Our office has reviewed the June 29, 2021 request for NRC to renew Children's Mercy Hospital's (your) U.S. Nuclear Regulatory Commission (NRC) Materials License for medical, research & development, 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 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 ML21008A334. 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 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, Section 8.9, "Facilities and Equipment," pp. 8-14 to 8-16, and Section 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 confirmed that no explosive or flammable materials would be irradiated. However, the application was silent as to whether corrosive 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."**

**FACILITIES AND EQUIPMENT:**

3. 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:**

4. 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.”**
5. 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.**

6. 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 28 days (on or prior to October 22, 2021). 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.: 030-09259  
License No.: 24-15513-01  
Control No.: 627183