Saint Luke's
HEALTH SYSTEM

4401 Wornall Road
Kansas City, MO 64111
816-932-2000

October 13, 2023

Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region III
2443 Warrensville Road, Ste 210
Lisle, IL 60532-4352

Re: Response to Additional Information Requested dated August 10, 2023;
License number: 24-00889-01; Docket number: 030-02286; Mail Control Number: CN 63517

Attn: Laura Cender

1. 10 CFR 35.1000 Yttrium-90 Authorized Users
Please provide a statement confirming that AU's permitted for 10 CFR 35.1000 medical uses of Yttrium-90 microspheres will meet the requirements described in the NRC guidance document: "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance."

Response: We will continue to ensure that the AU's permitted for 10 CFR 35.1000 medical uses of Yttrium-90 microspheres will meet the requirements described in the NRC guidance document: "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance."

2. Team approach:
Commit to providing training in the licensee's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. This training must be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

Response: We will continue to provide training in the licensee's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. This training will be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

3. Procedures for Administration
• Commit to having procedures for administration requiring a written directive in place as specified in 10 CFR 35.41, specifically to ensure high confidence that the patient's or human

Saint Luke's
HEALTH SYSTEM

4401 Wornall Road
Kansas City, MO 64111
816-932-2000

research subject's identity is verified before each administration and each administration is in accordance with the written directive.

Response: We will continue to have procedures for administration requiring a written directive in place as specified in 10 CFR 35.41, specifically to ensure high confidence that the patient's or human research subject's identity is verified before each administration and each administration is in accordance with the written directive.

• As Y-90 microspheres are too small to be calibrated in accordance with 10 CFR 35.432, confirm the licensee shall determine and record the activity of each dosage before medical use in accordance with 10 CFR 35.63 and 10 CFR 35.60 even though Y-90 microspheres are listed as sealed sources in their Sealed Source and Device Registries.

Response: We will continue to determine and record the activity of each dosage before medical use in accordance with 10 CFR 35.63 and 10 CFR 35.60 even though Y-90 microspheres are listed as sealed sources in their Sealed Source and Device Registries

• Commit to following the manufacturer's procedures or submit alternative methods for calculating and documenting the dose or activity to the treatment site; preparing the dose for administration; determining shunting to nontreatment sites; and determining if a medical event has occurred (e.g., performing pre- and post-vial dose measurements with appropriate instrumentation, evaluating post-treatment imaging).

Response: We will continue to follow the manufacturer's procedures for calculating and documenting the dose or activity to the treatment site; preparing the dose for administration; determining shunting to nontreatment sites; and determining if a medical event has occurred (e.g., performing pre- and post-vial dose measurements with appropriate instrumentation, evaluating post-treatment imaging). If we decide to make significant changes to alternative methods in the future, we will follow the review process described in the "program changes and changes to procedures" process described for **Question 9** response below.

• Confirm that administration of Y-90 microspheres will be performed in accordance with the written directive, and that dose or activity to the treatment site will be recorded within 24 hours of completion or termination of the administration and will include the name of the individual who determined the dose or administered activity and the date that the record is completed.

Response: We will continue to perform the administration of Y-90 microspheres in accordance with the written directive, and that dose or activity to the treatment site will be recorded within 24 hours of completion or termination of the administration and will include

Saint Luke's
HEALTH SYSTEM

4401 Wornall Road
Kansas City, MO 64111
816-932-2000

the name of the individual who determined the dose or administered activity and the date that the record is completed.

4. Written Directives
Commit to completing a written directive, which must be dated and signed by an AU before the administration in accordance with 10 CFR 35.40(a) and 10 CFR 35.40(c) unless a delay in order to provide a written directive would jeopardize the patient's health, as allowed under 10 CFR 35.40(c)(1).

The licensee shall retain a copy of the written directive in accordance with 10 CFR 35.2040. The written directive shall include the patient or human research subject's name; the treatment site; the radionuclide (including the physical form [Y-90 microspheres]); the model of spheres (e.g. TheraSphere® SIR-spheres®) or manufacturer; the prescribed dose or activity; and, if appropriate for the type of microsphere used, the statement "or dose or activity delivered at stasis."

Termination due to Stasis:
If the administration was terminated because of stasis, then the total dose or activity to the treatment site is the value of the total dose or activity administered when stasis occurred, and the administration was terminated. The record shall be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual who determined the administered dose or activity, the signature of an AU for Y-90 microspheres, and the date signed.

Emergent Patient Conditions:
If the procedure must be modified due to emergent patient conditions that prevent administration in accordance with the written directive (e.g., artery spasm or sudden change in blood pressure), the AU shall document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive shall include the reason for not administering the intended dose or activity, the signature of an AU for Y-90 microspheres, and the date signed.

Response: We will continue to complete a written directive, which must be dated and signed by an AU before the administration in accordance with 10 CFR 35.40(a) and 10 CFR 35.40(c) unless a delay in order to provide a written directive would jeopardize the patient's health, as allowed under 10 CFR 35.40(c)(1).

Saint Luke's
HEALTH SYSTEM

4401 Wornall Road
Kansas City, MO 64111
816-932-2000

5. Medical Event Reporting

In place of 10 CFR 35.3045(a), the licensee shall commit to report any event, except for an event that is caused by shunting as described in the criteria below, or as a result of patient intervention, as defined in 10 CFR 35.2 as an actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration. The criteria for event reporting is:

• the administration of byproduct material results in a dose that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue; and

- an administration of the wrong radionuclide or type of microsphere; or
- an administration to the wrong individual or human research subject; or
- an administration by the wrong route of administration; or
- an administration by the wrong mode of treatment; or

• the total dose or activity delivered differs from the prescribed dose or activity, as documented in the written directive, by 20 percent or more, except when stasis or emergent patient conditions are documented and resulted in a total dose or activity administered that was less than that prescribed; or

• A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding shunting as defined in Section 6.1 when shunting was evaluated prior to the treatment in accordance with the manufacturer's procedures.)

Additionally, the licensee shall comply with the medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g).

Response: We will continue to report any event, except for an event that is caused by shunting as described in the criteria below, or as a result of patient intervention, as defined in 10 CFR 35.2 as an actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration. The criteria for event reporting is:

• the administration of byproduct material results in a dose that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue; and

- an administration of the wrong radionuclide or type of microsphere; or
- an administration to the wrong individual or human research subject; or
- an administration by the wrong route of administration; or
- an administration by the wrong mode of treatment; or

• the total dose or activity delivered differs from the prescribed dose or activity, as documented in the written directive, by 20 percent or more, except when stasis or emergent patient conditions are documented and resulted in a total dose or activity administered that was less than that prescribed; or

Saint Luke's
HEALTH SYSTEM

4401 Wornall Road
Kansas City, MO 64111
816-932-2000

• A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding shunting as defined in Section 6.1 when shunting was evaluated prior to the treatment in accordance with the manufacturer's procedures.)
We will also continue to comply with the medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g).

6. Labeling
Commit to the following when the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer:

- Label vials and vial radiation shields with the radioactive device (i.e. SIRspheres®, TheraSphere®); and
- Label syringes and syringe radiation shields with the radioactive device.

Response: We will continue to ensure that the following is done when the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer or third-party Radio-pharmacy contracted by the manufacturer to draw up unit doses.

- Label vials and vial radiation shields with the radioactive device (i.e. SIRspheres®, TheraSphere®); and
- Label syringes and syringe radiation shields with the radioactive device.

7. Patient Release
Commit to develop procedures that describe measures taken to ensure that radiation emissions, which may include bremsstrahlung, from each patient or human research subject permits his or her release in accordance with 10 CFR 35.75.

Response: We will continue to maintain procedures that describe measures taken to ensure that radiation emissions, which may include bremsstrahlung, from each patient or human research subject permits his or her release in accordance with 10 CFR 35.75.

8. Surveys
Commit to surveying, with an appropriate radiation detection survey instrument, all areas that the Y-90 microspheres are prepared for use or administered. The survey should be conducted immediately following each preparation and administration in unrestricted areas and by the end of the day for restricted areas. A licensee should retain a record of each survey for three years and the record should include the date of the survey, the results of the survey, the instrument used to perform the survey, and the name of the individual who performed the

Saint Luke's
HEALTH SYSTEM

4401 Wornall Road
Kansas City, MO 64111
816-932-2000

survey. Licensees do not need to perform surveys in an area(s) where patients or human research subjects are confined when they cannot be released under 10 CFR 35.75.

Response: We will continue to survey, with an appropriate radiation detection survey instrument, all areas that the Y-90 microspheres are prepared for use or administered. The survey will be conducted immediately following each preparation and administration in unrestricted areas and by the end of the day for restricted areas. We will continue to retain a record of each survey for three years and the record should include the date of the survey, the results of the survey, the instrument used to perform the survey, and the name of the individual who performed the survey.

9. Radiation Protection Program Changes

Licensee's may request to incorporate into their license a change process similar to 10 CFR 35.26. Such a change process can allow some future changes to radiation safety programs without a license amendment provided that the change process requires the following conditions to be met for revisions to the radiation safety program:

a.) the revision is in compliance with the regulations; and
b.) the revision is based upon NRC's current guidance for TheraSphere® and SIRSpheres® Y-90 microspheres 35.1000 use posted on the NRC's Medical Uses Licensee Toolkit Web site; and
c.) the revision has been reviewed and approved by the licensee's RSO and licensee's management; and
d.) the affected individuals are instructed on the revised program before the change is implemented; and
e.) the licensee will retain a record of each change for five years; and
f.) the record will include a copy of the appropriate website guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

Response: SLH request that the original request for additional flexibility for program changes in Item 7 of the license renewal dated April 13, 2023 to include the additions (E and F) below continue to apply to the responses in this letter related to Y-90 microspheres procedures. With the addition of any revision to the radiation safety program regarding Y-90 microspheres that the revision will be based upon NRC's current guidance for TheraSphere and SIRSphere Y-90 microspheres 35.1000 use posted on the NRC's Medical Uses Licensee Toolkit Web site.

Item 7 of the license renewal dated April 13.2023 (*copied for reference*)

SLH is requesting additional flexibility for program changes and changes to procedures. In these cases:

Saint Luke's
HEALTH SYSTEM

4401 Wornall Road
Kansas City, MO 64111
816-932-2000

A. The proposed revision will be documented, reviewed, and approved by the RSC in accordance with the procedure Outlined in the Radiation Safety Committee Charter.
B. The proposed revision will be in accordance with regulatory requirements, will not change license conditions, and will not decrease the radiation safety program effectiveness.
C. Affected personnel will be trained in the revised procedure prior to implementation.
D. The RSC will evaluate the effectiveness of the change and its implementation.

SLH wishes to amend Item 7 of the license renewal dated April 13, 2023, to include:

E. A record of any program change will include a copy of the appropriate website guidance (if applicable), the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.
F. The licensee will retain a record of each change for five years.

If you have any questions, please contact me at (816) 932-6262.

Thank you for your consideration.

Roy Sions
Radiation Safety Officer

Martha Pavon

From: Laura Cender
Sent: Friday, October 13, 2023 12:32 PM
To: Martha Pavon
Subject: File for ADAMS - Saint Luke's Health System
Attachments: Response to Request for Additional Information 10.13.2023.pdf

Hello Martha,

Could you please add the attached file to ADAMS for Saint Luke's Health System?

Licensee: Saint Luke's Health System
License No. 24-00889-01
Docket No. 030-02286
Control No. 635317

Thank you,
Laura

Laura Cender
Pronouns: She/Her
U.S. Nuclear Regulatory Commission
Materials Licensing Branch
E-mail: Laura.Cender@nrc.gov
Phone: (630) 829-9712