Nuvance Health

Norwalk Hospital/Radiation Safety

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September 20, 2022

U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

Licensee: Norwalk Hospital, #06-06941-01
Docket No. 03001267
Mail Control No. 632329

Dear Mr. Hann,

Please find below our response to your request for additional information concerning our amendment request to add Y-90 SIR-Spheres to our NRC license.

1. We confirm that we will commit to meeting the general requirements in 10 CFR Part 35, Subpart A, "General Information;" Subpart B, "General Administrative Requirements;" Subpart C, "General Technical Requirements;" Subpart L, "Records;" and Subpart M, "Reports," except as specified in the "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance, April 20, 2021, Revision 10.2." Additionally, we will meet applicable requirements of 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations;" Part 20, "Standards for Protection Against Radiation;" and Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material."

2. We confirm that we will provide training in our 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. The NRC recognizes that, if an authorized user (AU) satisfies the Training and Experiences listed in NRC's licensing guidance for Y-90 microspheres and is currently listed on a Commission or Agreement State medical use license or permit for a specific type of microsphere, the AU should be allowed to work under a different license for the medical use of the same type of microsphere. We confirm that we would like to request authorization to notify the NRC in the future that Norwalk Hospital has permitted an AU to work at its facility without requesting an additional license amendment, provided the following conditions are met:

i. the AU satisfies the T&E listed in this licensing guidance for Y-90 microspheres; and
ii. the AU is currently listed for the same type of Y-90 microsphere use on a Commission or Agreement State license, a permit issued by a Commission master materials licensee, a permit issued by a Commission

or Agreement State licensee of a broad scope, or a permit issued by a Commission master materials license broad scope permittee; and
iii. the licensee provides the NRC a copy of the license or permit on which the AU is listed for the specific Y-90 microsphere use; and
iv. the licensee provides the NRC documentation of the completion of three patient cases if previously not submitted to the NRC; and
v. the licensee provides documentation of the above listed conditions to NRC for each AU no later than 30 days after the date that the licensee allows the AU to work as an AU for the specific type of Y-90 microsphere.

If this authorization is approved, these notification conditions will be incorporated as license conditions on the license.

4. We confirm that we would like to request to incorporate into our 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:

i. the revision is in compliance with the regulations; and
ii. the revision is based upon NRC's current guidance for TheraSphere® and SIR-Spheres® Y-90 microspheres 35.1000 use posted on the NRC's Medical Uses Licensee Toolkit Web site; and
iii. the revision has been reviewed and approved by the licensee's RSO and licensee's management; and
iv. the affected individuals are instructed on the revised program before the change is implemented; and
v. the licensee will retain a record of each change for five years; and
vi. 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.

If approved, these conditions for use of the updated guidance will be incorporated as license conditions in the license.

5. We confirm that we will follow all the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use, except where replaced by the following licensing commitments:

i. We will develop, implement, and maintain written procedures for administration requiring a written directive 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, we will 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. We commit to following the manufacturer's procedures or will submit alternative methods for calculating and documenting the dose or activity to the treatment site; preparing the dose for administration; determining shunting to non-treatment 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). For the purpose of this guidance, shunting is defined as blood flow through pathway or bypass due to patient vasculature causing the Y-90 microspheres to flow to an unwanted location. Unexpected dose or activity to an organ or tissue other than the treatment site that is caused by catheter placement during delivery of the Y-90 microspheres is not considered shunting and should be evaluated as a possible medical event.

Administration of Y-90 microspheres must be performed in accordance with the written directive. We shall record the dose or activity delivered to the treatment site. The records 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 dose or administered activity and the date the record is completed.
ii. We must complete the 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). We shall retain a copy of the written directive in accordance with 10 CFR 35.2040.

Due to the unique properties of Y-90 microsphere brachytherapy, the following written directive condition will be used instead of 10 CFR 35.40(b):
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 or 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."
For the purpose of written directive and medical event reporting requirements in the Y-90 microsphere guidance, "prescribed dose" means the total dose (rad or Gy). Alternatively, prescribed activity (mCi or GBq) may be used in lieu of prescribed dose. If prescribed activity is used in lieu of prescribed dose, the activity shall be used for all documentation and evaluations. As described in 10 CFR 35.2, "treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive. For instance, the treatment site may be described as the lobe or segment that is intended to receive the Y-90 microspheres and the tissue that is expected to receive Y-90 microspheres due to shunting. For the purpose of this guidance, stasis is defined as a stoppage or slowdown in the flow of blood. The inability to complete administration due to clogging or kinking of the catheter is not considered stasis.
iii. 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.

iv. 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.

v. In place of 10 CFR 35.3045(a), we 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 action 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
o An administration of the wrong radionuclide or type of microsphere; or
o An administration to the wrong individual or human research subject; or
o An administration by the wrong route of administration; or
o 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, we shall comply with the medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g).

vi. We commit to use only yttrium-90 microspheres for therapeutic medical uses as approved in the Sealed Source and Device Registries for SIR-Spheres, including maximum activity per vial limit.

vii. We 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. SIR-Spheres, TheraSphere); and
• Label syringes and syringe radiation shields with the radioactive device.

viii. We commit to developing 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. Guidance for release of patients or human research subjects following administration of radioactive materials may be found in Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials."

ix. As the Y-90 microspheres are too small to be seen, we will 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 retain a record of each survey for three years and the record will 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. We understand that we do not need to perform surveys in an area(s) where patients or human research subjects are confined when they cannot by released under 10 CFR 35.75.

x. If the physical conditions of use exceed those reported in the Sealed Source and Device (SSD) certificate, we shall request an amendment for the new conditions.

6. We have reviewed Revision 10.2 of the "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance" dated April 20, 2021 (located here https://www.nrc.gov/docs/ML2108/ML21089A364.pdf), and commit to following all criteria and guidance specified within.

Please contact ruth.shanley@nuvancehealth.org (203-739-7182) with any further questions. Thank you.

Sincerely,

Peter Cordeau
President, Norwalk Hospital

Fatejeet S. Sandhu, M.D.
Radiation Safety Officer, Norwalk Hospital
Jeet.Sandhu@nuvancehealth.org

Ruth Shanley, MS, RT(R), RDMS
Radiation Safety Coordinator, Nuvance Health
Ruth.shanley@nuvancehealth.org