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To: bette.blankenship@hhchealth.org
Subject: NRC amendment request (HOCC)
Date: Wednesday, June 13, 2018 3:26:00 PM

Licensee: Hospital of Central Connecticut
License No. 06-02388-01
Docket No. 03001250
Mail Control No. 608439

**PLEASE CONFIRM
RECEIPT OF THIS
E-MAIL**

Ms Blankenship,

With regards to your request to add TheraSphere to your license, please provide the following commitments regarding your TheraSphere program:

Procedures for Administration

Manufacturer's procedures will be followed for calculating and documenting the dose or activity to the treatment site; preparing the dose for administration; determining shunting to non-treatment sites; and performing pre- and post-vial dose measurements. Otherwise, submit alternative methods.

Medical Event Reporting

Confirm that you will report any event, except for an event that results from intervention of a patient or human research subject, in which:

- 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 from the use of the wrong radionuclide; or
- the administration of byproduct material: to the wrong individual or human research subject; via the wrong route; or by the wrong mode of treatment; or
- the total dose or activity administered 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
- the administration of byproduct material results in dose or activity to an organ or tissue other than the treatment site, as documented in the written directive, except for shunting 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).

Inventory

A semi-annual physical inventory of microsphere aggregates (e.g., vials) will include:

- the radionuclide and physical form; and
- unique identification of each vial in which the microspheres are contained; and
- the total activity contained in each of the vial(s); and
- the location(s) of the vial(s).

Records of the semi-annual physical inventory will be retained for three years.

Labeling

Confirm that when the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer, you will:

- Label vials and vial radiation shields with radionuclide and form (e.g., Y-90 microspheres).
- Label syringes and syringe radiation shields with the radionuclide, form, and therapeutic procedure (e.g., Y-90 microspheres, brachytherapy).

Patient Release

Confirm that you have developed 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.

Radiation Protection Program Changes

If you wish to incorporate into your license a change process similar to 10 CFR 35.26.

Confirm that the following conditions will be met:

- the revision will be in compliance with the regulations;
- the revision will be based upon NRC's current guidance for TheraSphere Y-90 microspheres 35.1000 use posted on the [NRC Medical Use Toolkit](#);
- the revision will have been reviewed and approved by your Radiation Safety Officer and your management;
- the affected individuals will be instructed on the revised program before the change is implemented;
- you will retain a record of each change for five years, and
- 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 your management that reviewed and approved the change.

Such a change process may allow some future changes to your radiation safety program.

We will continue our review upon receipt of this information. Please submit the above information, signed by management, as a pdf to my email by June 27, 2018.

Thank you for your assistance,
Tara L. Weidner
Senior Health Physicist
USNRC