The Hospital of Central Connecticut
Connect to healthier.™

To: Tara L. Weidner
Senior Health Physicist
U.S. Nuclear Regulatory Commission
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406

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

Dear Ms. Weidner;
In response to your email and request for additional information regarding the implementation of the Y90 Theraspheres program for the Hospital of Central Connecticut:

Procedures for Administration

The Manufacturer's procedures will be followed for:

- Calculating and documenting the dose or activity administered
- Preparing the dose for administration
- Determining shunting to non-treatment sites
- Performing the pre- and post-vial dose measurements.

Medical Event Reporting

The Hospital of Central Connecticut will report any event, except for an event that results from intervention of a patient or human research subject, in which:

- The Theraspheres administration 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
- The administration the byproduct material is to the wrong individual or human research subject, via the wrong route, or by the wrong mode of treatment
- 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
- The Theraspheres administration 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.

The Hospital of Central Connecticut will comply with the medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g).

Semi-Annual Microsphere Aggregates Inventory

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

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

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

Bradley Memorial 81 Meriden Avenue Southington, CT 06489 860 276 5000 tel
New Britain General 100 Grand Street New Britain, CT 06050 860 224 5011 tel www.thocc.org

The Hospital of Central Connecticut
Connect to healthier.™

Labeling

If the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer, Hospital of Central Connecticut 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

Post-procedure patient release measurements ensure that radiation emissions from each patient or human research subject allow patient release in accordance with 10 CFR 35.75.

Radiation Protection Program Changes

Adding the Y90 Theraspheres procedure to the radiation protection program, the Hospital of Central Connecticut confirms:

- The program change will be in compliance with the regulations
- The program change will be based upon NRC's current guidance for TheraSphere Y-90 microspheres 35.1000 use posted on the NRC Medical Use Toolkit;
- The program change has been reviewed and approved by the Hospital of Central Connecticut Radiation Safety Officer
- Affected staff and physicians will be instructed on the revised program before the change is implemented

Thank you,

Janette Edwards

Janette Edwards
Vice President of Operations
Hartford HealthCare Central Region
100 Grand Street New Britain, CT 06050
860-224-5272