HURLEY
MEDICAL CENTER

One Hurley Plaza
Flint, Michigan 48503

December 13, 2013

United States Nuclear Regulatory Commission
Region III, Materials Licensing
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: Amendment to NRC License No. 21-00338-02
Hurley Medical Center

Dear Madam or Sir:

We wish to amend our Materials License #21-00338-02

1. Add new authorized users
2. Change RSOs
3. Add Y90 Therasphercs

1. Please add Ambreen Sattar, M.D. and Anish Bansal, M.D. to our license as authorized users for Groups 35.100 and 35.200. We have enclosed their ABR certificates and NRC Forms 313.
2. Please change our Radiation Safety Officer from Dr. Mukkamala to Dr. Ege. Dr. Ege is currently an authorized user on our license and we have attaché NRC Form 313a(RSO).
3. We have attached documentation in support of the addition of Y90 to our license.

Thank you for your assistance with this matter. Please contact Dawn Sturk, Radiology Administrative Director at 810-262-9835 or our consultant, Tracy King at 734-662-3197 if you have any questions concerning this matter.

Sincerely,

Amy Benko, PharmD
Vice President for Patient Care Services

ITEM 3:

A. ADD BYPRODUCT MATERIAL Y-90 Microspheres for Brachytherapy

The enclosed supporting information is designed to follow the NRC licensing guidance "Microsphere Brachytherapy Sources and Devices" as revised June 2012.

Please Add:

Material:	Y-90
Form:	TheraSpheres
Quantity:	0.5 Ci Maximum
Purpose:	per 10 CFR 35.1000

B. ADD AUTHORIZED USERS FOR Y90

Anish Bansal, M.D. We have enclosed Dr. Bansal's ABR Diagnostic Radiology certificate and NRC Form 313.

Ambreen Sattar, M.D. We have enclosed Dr. Sattar's ABR Diagnostic Radiology certificate and NRC Form 313.

The manufacturer will train these individuals in the correct handling and administration of the Y90 TheraSpheres. Upon the completion of three(3) proctored/supervised by the manufacturer, we will submit the documentation of this training to your office for review within 30 days of the completion of training.

C. RADIATION SAFETY TRAINING

We confirm that training will be provided to all individuals involved in the preparation, measuring, handling, dosimetry calculations for, and administration of TheraSpheres. The training will be commensurate with their duties and will be documented.

D. WRITTEN DIRECTIVES

We commit to follow all the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy, except where replaced by the following licensing commitments.

1) We confirm that our written directive will include the patient name; the date; the signature of an AU for Y90 microspheres; the treatment site; the radionuclide(including the physical form "Y90 microspheres"; the prescribed activity/dose; the manufacturer and if appropriate for the type of microsphere used, the statement "or dose/activity delivered at stasis".

2) We confirm that the written directive, when possible, will specify the maximum dose(s)/activity(ies) that would be acceptable to specified site(s) outside the primary treatment site due to shunting(e.g. lung and gastrointestinal tract).
3) We confirm that the administration will be performed in accordance with the written directive. 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 should document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive should include the reason for not administering the intended dose/activity, the date, and the signature of an AU for Y-90 microspheres.
4) We will record the administered dose/activity delivered to the primary treatment site and to the other site(s), if any, which have been specified by the authorized user on the written directive. If the administration was terminated because of stasis, then the total dose/activity to the treatment site is the value of the total dose/activity administered when stasis occurred and the administration was terminated. We intend to prepare the record within 24 hours after the completion or termination of the administration and must include the name of the individual who made the assessment, the date, and the signature of an AU for Y-90 microspheres, if terminated due to stasis.
5) We commit to following the manufacturer's procedures for calculating/documenting the dose to the treatment area and other sites, preparing the dose for administration, and performing pre/post vial dose measurements.
6) We will perform semi-annual physical inventory of microsphere aggregates(eg.vials) including:
   a. The radionuclide and physical form; and
   b. Unique identification of each vial in which the microspheres are contained; and
   c. The total activity contained in each of the vials; and
   d. The location of the vials.
7) We will retain each semi-annual physical inventory record for three(3) years.
8) 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/her release in accordance with 10 CFR 35.75.
9) With regard to the use of vials, syringes, or radiation shields that are not labeled by the manufacturer:
   a. vials and shields will be labeled with the radionuclide and form(eg. Y-90 microspheres)
   b. syringes and syringe radiation shields with the radionuclide, form, and therapeutic procedure (eg. Y-90 microspheres, brachytherapy).
10) We will report any event, except for an event that results from intervention of a patient or human research subject, in which:

a. 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
b. the administration of Y-90 microspheres results in a dose
   i. that differs from the prescribed dose or the dose that would have resulted from the prescribed activity, as documented in the written directive, by more than 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue, and the total dose/activity administered differs from the prescribed dose/activity, as documented in the written directive, by 20 percent or more; or
   ii. that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from an administration to the wrong individual or human research subject, via the wrong route, or the wrong mode of treatment; or
   iii. to an organ or tissue other than the treatment site that exceeds by 0.5 Sv(50 rem) to an organ or tissue and by 50 percent or more of the prescribed dose/activity expected to that site from the administration of Y-90 microspheres, if carried out as specified in the written directive

10) We will comply with the medical event reporting and notification requirements as described by 10 CFR 35.3045(b)-(g).