ST JOHN PROVIDENCE HEALTH SYSTEM
ST. JOHN MACOMB-OAKLAND HOSPITAL
Macomb Center

January 12, 2017

U. S. NUCLEAR REGULATORY COMMISSION
Region III
Materials Licensing Branch
2443 Warrenville Road, Ste 210
Lisle, IL 60532-4352

RE: Additional information for license amendment for #21-01190-05, CN592221

Ms. Sara Forester,

Thank you for your time reviewing our license amendments. In regards to the Y90 request.

(1) We Confirm concerning procedures for administration:

a. That we shall 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 non-treatment sites; and performing pre- and post-vial dose measurements; or submit alternative methods; and

b. That administration of Y-90 microspheres must be performed in accordance with the written directive. The licensee shall record the dose or activity delivered to the treatment site. The record should 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 and the date.

c. In cases where the licensee's commitments may deviate from the guidance, please highlight and explain those deviations.

(2) We confirm concerning documentation of termination due to stasis as part of the written directives: 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 should 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 date, and the signature of an AU for Y-90 microspheres.

(3) We confirm that:

a. Dr. Jain will complete at least the first three hands-on patient cases supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which authorization is sought.

b. The licensee will submit documentation from the manufacturer to the NRC Region III Office within 30 days of when Dr. Jain's first three patient cases have been satisfactorily completed.

(4) We cannot confirm Dr. Linda Rissman's training during the last 7 years, I was told that information would be made available to me, but it has not. Therefore we wish to take back this request for Dr. Linda Rissman as an Authorized User. We do not plan on submitting her again for Authorized User status at our facility.

If you have any questions or concerns, feel free to email me as it is a quick way to get a response from me.

Thank you,

Laura T Smith

Laura T. Smith, MS, DABR
Radiation Safety Officer