St. Joseph Medical Center

April 22nd, 2016

U.S. Nuclear Regulatory Commission Region III
Materials Licensing Branch
2443 Warrenville Road
Lisle, IL 60532-4352

Ms. Forster:

This correspondence is in regards to RAM License Renewal Application License #24-02704-01 Control # 589393 (Prime Healthcare Services-Kansas City, LLC d/b/a/ St. Joseph Medical Center) to include the following revised items. We are requesting that this supplemental information be included with our license renewal application.

1. In regards to the use of Microsphere Brachytherapy Sources and Devices, our facility has developed and will implement and maintain procedures for safe use of TheraSphere and SIRSpheres Yttrium-90 Microspheres that surround the requirements of 10 CFR 1000 and as stated in the Emerging Technologies License Guidance –Microsphere Brachytherapy Sources and Devices; Section- License Commitments - Written Directives, Inventory, Patient Release, Labeling, & Medical Event Reporting (as stated below) and statements surrounding the use of Yttrium-90 microspheres, as originally provided in you on February 6, 2013 Amendment ML13042A415.

A. License Commitments - Written Directives, Inventory, Patient Release, Labeling, & Medical Event Reporting

The applicant **will** commit to follow all the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use, except where replaced by the following licensing commitments:

• For the purpose of written directives 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.

• The written directive shall include the patient or human research subject's name; the date; the signature of an AU for Y-90 microspheres; the treatment site; the radionuclide (including the physical form [Y-90 microspheres]); the prescribed dose/activity; the manufacturer; and, if appropriate for the type of microsphere used, the statement "or dose/activity delivered at stasis."

• The written directive **will** specify the maximum dose(s)/activity(ies) that would be acceptable to the specified site(s) outside the primary treatment site due to shunting (e.g. lung and gastrointestinal tract).

• Administration of Y-90 microspheres must 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 **will** document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive **will** include the reason for not administering the intended dose/activity, the date, and the signature of an AU for Y-90 microspheres.

• The licensee **will** record the administered dose/activity delivered to the primary treatment site and to the other specified site(s). 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. The record **will** be prepared 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.

• The licensee **will** commit to following the manufacturer's procedures for calculating/documenting the dose to the treatment and other sites, preparing the dose for administration, and performing pre/post vial dose measurements; or submit alternative methods.

• The semi-annual physical inventory of microsphere aggregates (e.g. vials) should include:

1) the radionuclide and physical form; and

2) unique identification of each vial in which the microspheres are contained; and

3) the total activity contained in each of the vial(s); and

4) the location(s) of the vial(s).

• The licensee **will** retain each semi-annual physical inventory record for three years.

• The licensee **will** commit to develop 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.

• The following additional guidance applies when the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer:

1) Label vials and vial radiation shields with radionuclide and form (e.g., Y-90 microspheres).

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

• The licensee **will** retain each semi-annual physical inventory record for three years.

• The licensee **will** commit to develop 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.

• The following additional guidance applies when the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer:

1) Label vials and vial radiation shields with radionuclide and form (e.g., Y-90 microspheres).

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

• The licensee **will** commit to report any event, except for an event that results from intervention of a patient or human research subject, in which:

1) 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

2) the administration of Y-90 microspheres results in a dose

a) 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

b) 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 by the wrong mode of treatment; or

c) 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

• Additionally, the licensee **will** comply with the medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g).

B. Training for the use of Yttrium-90 microspheres: Prime Healthcare Services-Kansas City, LLC d/b/a/ St. Joseph Medical Center **will** provide training in this facilities 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. For your records, I have included a revised page 13 of the application which includes the commitment of this training.

C. Authorized User: We are requesting that Ronald R. Weis, M.D. remain on this license as an Authorized User. For your records, I have included a revised page 6 of the application which includes Dr. Ronald R. Weis, M.D.

Should you have any additional questions or need additional information, please do not hesitate in contacting me at 402-290-2391 or email at sebastiano.anzalone@cardinalhealth.com.

Your attention in this matter is greatly appreciated.

Sincerely,

Sebastiano Anzalone, B.S., CNMT, ARRT(N)

Regional Health Physics Specialist

Item 7a Authorized Users

The radioactive materials listed previously will be used by the following physicians for the materials or groups and uses indicated. Please remove all Authorized Users highlighted in RED. These individuals are no longer affiliated with this R.A.M. License. Please add the

Please see the attached NRC License #40-16775-01

James R. Bergh, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11
~~Timothy Blackburn, M.D.~~	~~10 CFR 35.200~~
Corey W. Chopra, M.D.	10 CFR 35.100 and 35.200
~~Daniel H. Dunker, M.D.~~	~~10 CFR 35.200~~
Charles W. Horner, M.D.	10 CFR 35.100, 35.200 and 35.300
Kenneth L. Koontz, M.D.	10 CFR 35.100, 35.200 and 35.300
Richard G. Kuckelman, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11
Michael W. Matchette, M.D.	10 CFR 35.100, 35.200, 35.300 (Limited to the Oral Administration of Sodium Iodide-131 in Quantities less than or equal to 33 millicuries)
Marco S. Mazzella, M.D.	10 CFR 35.200
Patrick M. O'Toole, M.D.	10 CFR 35.100, 35.200 and 35.300
James Sear, M.D.	10 CFR 35.200
D. Christopher Walker, M.D.	10 CFR 35.1000 (Limited to Yttrium-90 as SIR-Spheres)
Ronald R. Weis, M.D.	**10 CFR 35.100, 35.200 and 35.300**

Item 8b **Training for Individuals Working in or Frequenting Restricted Areas**

Additional, this facility has developed and will implement and maintain written procedures for initial and annual refresher Radiation Safety Training to meet NRC requirements.

1. Training for employees working in, or frequenting, the restricted areas of our license where radioactive materials will be used will receive annual instruction on radiation protection.

2. The extent of this instruction will be commensurate with the potential radiological hazards associated with the employee's job.

3. Radiation workers will be classified as Occupationally Exposed Workers.

4. Non-occupationally Exposed Workers will include custodial personnel, security personnel and ancillary personnel (such as housekeeping and nurses). The Radiation Safety Officer will designate these individuals.

5. Documentation of the Radiation Safety Program will be maintained.

6. Initial training will consist of a review of:
   Federal Guide 8.29
   Federal Guide 8.13
   Applicable Regulations CFR 19 & 20
   Areas where radioactive material is used or stored
   Potential hazards associated with radioactive materials
   Radiation Safety Procedures

7. Follow-up training will consist of an annual review of applicable regulations, potential hazards and appropriate radiation safety procedures.

   Please see the attached the Cardinal Health Pharmacy and Verification of Completion Forms

8. **This facility will provide training in the facilities 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.**

Forster, Sara

From: Anzalone, Sebastiano <Sebastiano.Anzalone@cardinalhealth.com>
Sent: Wednesday, April 27, 2016 7:58 AM
To: Forster, Sara
Subject: [External_Sender] RE: Additional Information Request re Prime Healthcare Services - Kansas City, LLC d/b/a St. Joseph Medical Center, NRC Lic. No. 24-02704-01, CN 589393
Attachments: licenseapp Nov 2015 Page 6.pdf; licenseappPage 13 Nov 2015.pdf; RAM APP Revision Apr 2016.pdf

Ms. Forster,
Attached is the requested information as discussed. Lease review and contact me with any question or concerns (402-290-2391)
Thank you and have a great day
Subby

CardinalHealth

Subby Anzalone, BS, NMTCB, ARRT(N)
Regional Health Physics Specialist
Cardinal Health Medical & Health Physics Services
5840 F Street, Omaha, NE 681
402.734.8045 opt #6 office | 402.290.2391 mobile |402.553.3033 fax

From: Forster, Sara [mailto:Sara.Forster@nrc.gov]
Sent: Friday, April 22, 2016 2:19 PM
To: Anzalone, Sebastiano
Subject: Additional Information Request re Prime Healthcare Services - Kansas City, LLC d/b/a St. Joseph Medical Center, NRC Lic. No. 24-02704-01, CN 589393

Dear Mr. Anzalone:

As discussed, please see the attached conversation record.

Please refer to NUREG 1556, Vol. 9, rev. 2, "Program-Specific Guidance About Medical Use Licenses," when preparing your response. The volume may be found at the website: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/.

Please provide additional requested information within 14 days of our conversation (on or before May 5, 2016), via a signed and dated cover letter. Submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. Do not hesitate to call me with any questions you may have, or if you will need additional time to complete your response.

Sincerely yours,

Sincerely,

Sara A. Forster, Health Physicist Licensing Reviewer
U.S. Nuclear Regulatory Commission - Region III
Division of Nuclear Materials Safety