December 22nd, 2015

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 items;

1. In April 2014, David J. Burkart, M.D. was previously on this license as an Authorized User and approved for Authorized Uses 10 CFR 35.100, 35.200, 35.300. Recently, David J. Burkart, M.D. has re-joined this facility as a member of the Medical Staff.

   We are requesting that Dr. Burkart be re-instated onto this license renewal application as an Authorized User for Authorized Uses 10 CFR 35.100, 35.200, 35.300. As reference, David J. Burkart, M.D. was on License # 24-02704-01 Docket # 030-02310 Amendment #67.

Should you have any additional questions or need additional information, please contact our Health Physics Specialist, Subby Anzalone at 402-290-2391 or email at sebastiano.anzalone@cardinalhealth.com.

Your attention in this matter is greatly appreciated.

Sincerely,

Patrick O'Toole, M.D.
Radiation Safety Officer

December 22nd, 2015

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 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.

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

The applicant shall 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 should 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 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.

- The licensee shall 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 should 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 shall 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 shall retain each semi-annual physical inventory record for three years.

- The licensee should 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 shall retain each semi-annual physical inventory record for three years.

- The licensee should 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 shall 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 shall comply with the medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g).

Should you have any additional questions or need additional information, please contact our Health Physics Specialist, Subby Anzalone at 402-290-2391 or email at sebastiano.anzalone@cardinalhealth.com.

Your attention in this matter is greatly appreciated.

Sincerely,

Patrick O'Toole, M.D.
Radiation Safety Office

Item 10e **Safe Use of Unsealed Licensed Material**

We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

Please see the attached documentation in Item 8A

Safe Use of TheraSphere and SIRSpheres Yttrium-90 Microspheres Licensed Material

We have developed and will implement and maintain procedures for safe use of TheraSphere and SIRSpheres Yttrium-90 Microspheres that meet 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 and statements surrounding the use of Yttrium-90 microspheres, as originally provided in you on February 6, 2013 Amendment ML13042A415 .

Forster, Sara

From: Anzalone, Sebastiano <Sebastiano.Anzalone@cardinalhealth.com>
Sent: Wednesday, December 23, 2015 8:57 AM
To: Forster, Sara
Subject: [External_Sender] RE: Additional Information Inquiry re Prime Healthcare Services, NRC Lic. No. 24-02704-01, CN589393
Attachments: Sined Amend y-90 and urkart.pdf

Ms. Forster
Attached is the additional items as requested. Please let me know if there is any additional items I can assist with.
Kind Regards
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: Tuesday, December 22, 2015 2:01 PM
To: Anzalone, Sebastiano
Subject: RE: Additional Information Inquiry re Prime Healthcare Services, NRC Lic. No. 24-02704-01, CN589393

Dear Mr. Anzalone:

Thank you for the update concerning U.S. NRC License No. 24-02704-01. Please note that our review of the renewal application is ongoing, and a second request for additional information may be issued at a later time.

At this time, to request to add the Authorized User (AU) David J. Burkhart., M.D., please provide a signed and dated letter stating the information provided in your email message ,below. In addition to the request to add the AU, please confirm statements surrounding the use of yttrium-90 microspheres, as originally provided in your February 6, 2013 letter (ML13042A415). Do not hesitate to contact me with any questions you may have.

Please provide additional requested information within 14 days (on or before January 3, 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,

Sara A. Forster, Health Physicist Licensing Reviewer
U.S. Nuclear Regulatory Commission - Region III
Division of Nuclear Materials Safety
2443 Warrenville Rd. - Ste. 210
Lisle, IL 60532-4352
sara.forster@nrc.gov

Direct: (630) 829-9892
Facsimile: (630) 515-1078

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

From: Anzalone, Sebastiano [mailto:Sebastiano.Anzalone@cardinalhealth.com]
Sent: Tuesday, December 22, 2015 9:37 AM
To: Forster, Sara
Subject: [External_Sender] Addition of AU to Ram Licenese Renewal

Good Morning Ms. Forster,
My name is Subby Anzalone and I am a Health Physics Specialist with Cardinal Health.
This correspondence is regarding the RAM License Renewal Application License #24-02704-01 Control # 589393 (Prime Healthcare Services-Kansas City, LLC d/b/a/ St. Joseph Medical Center) that has been assigned to you.
The reason for my correspondence, is that the facility recently informed me that that there is an Authorized User (David J. Burkart, M.D.), that was previously on this license (April 2014), that has since returned. They are requesting that he be re-instated on the this license renewal application as an Authorized User for Authorized Uses 10 CFR 35.100, 35.200, 35.300.
As reference, David J. Burkart, M.D. was on License # 24-02704-01 Docket # 030-02310 Amendment #67.

Should you need any addition please do not hesitate in contacting me on my mobile phone (402-290-2391)
I would greatly appreciate if you could response to this email as to if this request has been approved or denied so I can update the facility.
Thank you again for your attention to this matter.
Happy Holidays
Subby Anzalone

CardinalHealth

Subby Anzalone, BS, NMTCB, ARRT(N)
Regional Health Physics Specialist
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No SUNSI contained herein - as of 5/2/2016