HOT SHOTS NUCLEAR MEDICINE
3960 Patient Care Drive • Suite 105 • Lansing, Michigan 48911
Phone 517-887-3131 • Fax 517-887-3132 • www.HotShotsNM.com

December 5, 2017

Sara A. Forster, Health Physicist Licensing Reviewer
U. S. Nuclear Regulatory Commission, Region III
Division of Nuclear Materials Safety
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Subject: **Additional Information Request Response for CPI Pharmacy Services Holding, LLC, d/b/a Hot Shots Nuclear Medicine; CN600753**

Radioactive Material License Number - 21-26597-01MD

Ms. Forster:

I am responding to your email requesting additional information to add Yttrium-90 SIR-Spheres to our radioactive materials license. Below are the questions that you asked and my responses are in **BOLD** type:

1. Please state the maximum per vial activity (i.e. 189 mCi/vial) that will be received at your facility. Please also confirm that no more than 1 patient will be designated per incoming vial.
   According to the *Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance*, we would expect that the maximum per vial activity will be 189 mCi/vial. No more than one patient dose will be administered per vial.

2. Please describe any handling, including associated safety precautions, laminar flow hoods that would be used, etc., and/or manipulation of the microspheres that is planned
   All manipulation of the Yttrium-90 SIR-Spheres will be handled within a laminar flow hood that includes a dose calibrator. Quality control procedures will be performed on the dose calibrators being used to assure proper calculating and measuring of the activity. The Yttrium-90 SIR-Spheres will be transferred from the manufacturer's vial into a single patient unit dose container. All handlers will use the procedures learned from the manufacturer training to control and to contain spilled byproduct material from the Yttrium-90 SIR-Spheres and follow proper decontamination procedures.

3. Please describe any repackaging of microspheres (including transfer to syringes and labeling) that is planned.
   The Yttrium-90 SIR-Spheres will be transferred from the manufacturers vial to a unit dose container in accordance with the manufacturer's instructions. The dose will have a label attached that includes the prescription number, medical licensee's name, radiopharmaceutical, procedure, ordered activity, calibration date/time and patient name. The dose will be shielded for transport with an appropriate dose shielding container.

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4. Please expand your description of any decay-in-storage practices, including storage locations, and plans to survey any items and deface labels, prior to disposal.
   All Yttrium-90 SIR-Spheres that remain following repackaging will be kept in the original manufacturer's vial and placed in a shielded waste area until the vial survey is background. Once the survey is background, the product labeling will be defaced and the vial will be disposed of in the daily waste barrels for final disposal with Stericycle. Any spilled byproduct material from the Yttrium-90 SIR-Spheres will also be placed in the same shielded waste area until the survey is background and then disposed of in the daily waste barrels.

5. Please confirm that any Authorized Nuclear Pharmacists (ANPs) and associated staff that will be involved in the activities described will receive training from the manufacturer prior to first use, under this license.
   The training described below in the original amendment document will be completed by each Authorized Nuclear Pharmacist or additional handler prior to their first use:
   1. **All Authorized Nuclear Pharmacists and additional handlers on the pharmacy staff will be provided training by the manufacturer, Sirtex, for manipulating doses. Which includes but is not limited to:**
      a. **Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys**
      b. **Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres**
      c. **Performing checks for proper calculating and measuring of the activity and safely preparing the Y-90 microspheres to be delivered to the client**
      d. **Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, and safely using proper decontamination procedures**

If you have any questions or require further information about the additional information, please do not hesitate to contact me at (517) 887-3131.

Sincerely,

Matthew D. Kazmierski

Matthew D. Kazmierski, R.Ph., RSO

Pavon, Sandy

From: Forster, Sara
Sent: Tuesday, December 05, 2017 6:00 PM
To: Sandrik, Lauren; Pavon, Sandy; Song, Taehoon
Subject: FW: RE: Additional Information Request for CPI Pharmacy Services Holding, LLC, NRC Lic. No. 21-26597-01MD, CN600753 (resending from Dec. 1)
Attachments: 2017.12.05 NRC License Amendment - Additional Information Response.pdf

Please scan in and return to me.

Thank you!

Sara x9892

From: Matthew Kazmierski [mailto:M.Kazmierski@HotShotsNM.com]
Sent: Tuesday, December 05, 2017 3:33 PM
To: Forster, Sara <Sara.Forster@nrc.gov>
Subject: [External_Sender] RE: Additional Information Request for CPI Pharmacy Services Holding, LLC, NRC Lic. No. 21-26597-01MD, CN600753 (resending from Dec. 1)

Hello Ms. Forster –

Attached is the response for additional information required for our license amendment CN 600753.

If you have any questions please let me know.

Have a great night –

Matthew Kazmierski

Matthew Kazmierski
Matthew Kazmierski, R.Ph. – Pharmacy Manager
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Email: **M.Kazmierski@HotShotsNM.com**

From: Forster, Sara [mailto:Sara.Forster@nrc.gov]
Sent: Monday, December 04, 2017 2:10 PM
To: m.kazmierski@HotShotsNM.com
Subject: Additional Information Request for CPI Pharmacy Services Holding, LLC, NRC Lic. No. 21-26597-01MD, CN600753 (resending from Dec. 1)

Dear Mr. Kazmierski:

As discussed last week, we have reviewed your August 31, 2017 letter (ML17250A340) requesting the addition of an yttrium-90 microspheres to your license. As promised, this email is a follow-up to our conversation. Please respond to the items below, as noted, as soon as possible; preferably by close of business on Monday, December 4, 2017:

1. Please state the maximum per vial activity (i.e. 189 mCi/vial) that will be received at your facility. Please also confirm that no more than 1 patient will be designated per incoming vial.

2. Please describe any handling, including associated safety precautions, laminar flow hoods that would be used, etc., and/or manipulation of the microspheres that is planned.

3. Please describe any repackaging of microspheres (including transfer to syringes and labeling) that is planned.

4. Please expand your description of any decay-in-storage practices, including storage locations, and plans to survey any items and deface labels, prior to disposal.

5. Please confirm that any Authorized Nuclear Pharmacists (ANPs) and associated staff that will be involved in the activities described will receive training from the manufacturer prior to first use, under this license.

If you are unable to respond by Monday, please let us know when you will be able to provide a response. Additional guidance may be found in NUREG 1556, Vol. 13, rev. 1, "Program Program-Specific Guidance about Commercial Radiopharmacy Licenses," which may be found at:

http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v13/r1

Submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. Any response must be submitted under a signed and dated cover letter. 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
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