



Mr. Bryan A. Parker
Senior Health Physicist
USNRC Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

November 21, 2017

RE: License No. 13-32726-01MD
Docket No. 030-38044
Control No. CN601366

Additional information for control number: CN601366

Mr. Parker:

A. As we discussed on 11/20/2017, I am confirming that I no longer wish to add Ali Abassi, PharmD, MD to my license as an authorized user.

B. Spectron mrc, LLC pharmacy's proposed authorized uses of Cu-64 include redistribution, compounding and dispensing pharmaceuticals that are approved to contain Cu-64, research and development of new radiopharmaceuticals that are to incorporate Cu-64 and to possess and store prepared products for the subsequent chance of a physician request for the product. The redistribution will be for Cu-64 solution, radiopharmaceuticals that use Cu-64 as the radionuclide, and investigational radiopharmaceuticals and/or preparations made using Cu-64.

Spectron mrc, LLC's pharmacy intends to use Cu-64 in the following processes:

1. In preparation of FDA approved kits that include the need to add Cu-64 in the compounding and/or preparation procedures. A couple of current examples include but are not limited to: Cu-64 DOTATATE and Cu-64 PSMA.
2. For filling a physician's order for a pharmaceutical that includes the addition of Cu-64.
3. For the delivery of the physician's orders of C-64 radiopharmaceuticals
4. In the development of new radiopharmaceuticals for either diagnostic or therapeutic uses. This work could be for a third party contract or for a local physician's IND or for internal development.
5. To sell and deliver the Cu-64 as a radiochemical to any party that is authorized to receive Cu-64 and has an interest in purchasing Cu-64. Such customer could be affiliated research facilities, other radiopharmacies, along with hospitals and Universities having a need for Cu-64.

A handwritten signature in black ink, appearing to be "B. Parker", is located at the bottom left of the page.

C. Spectron mrc, LLC pharmacy's proposed authorized uses of cyclotron produced Ga-68 include redistribution, compounding and dispensing pharmaceuticals that are approved to contain Ga-68, research and development of new radiopharmaceuticals that are to incorporate Ga-68 and to possess and store prepared products for the subsequent chance of a physician request for the product. The redistribution will be for Ga-68 solution, radiopharmaceuticals that use Ga-68 as the radionuclide, and investigational radiopharmaceuticals and/or preparations made using Ga-68.

Spectron mrc, LLC's pharmacy intends to use Ga-68 in the following processes:

1. In preparation of FDA approved kits that include the need to add Ga-68 in the compounding and/or preparation procedures. Radiopharmaceuticals that incorporate Ga-68 include Ga-68 DOTATATE and Ga-68 PSMA.
2. For filling a physician's order for a pharmaceutical that includes the addition of Ga-68 along with physician orders for Ga-68 as a radiopharmaceutical.
3. For the delivery of the physician's orders of Ga-68 radiopharmaceuticals
4. In the development of new radiopharmaceuticals for diagnostic use. This work could be for a third party contract or for a local physician's IND or for internal development. Internal development could include Ga-68 MAA and/or microspheres for hepatobiliary assessment.
5. To sell and deliver the Ga-68 as a radiochemical to any party that is authorized to receive Ga-68 and has an interest in purchasing Ga-68. Such customer could be affiliated research facilities, other radiopharmacies, along with hospitals and Universities having a need for Ga-68.

I hope I have answered your questions adequately but if there is any additional information that you need please feel free to call or email me.

My cell phone number is: 574-298-9616

My email address is: tarqv@sbcglobal.net

Sincerely,



Gregory S. Hiatt R.Ph/RSO
President