



Spectron
mrc l.l.c.

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. 13-32726-02
Docket No. 030-38045
Control No. CN600619

ADDITIONAL INFORMATION FOR CONTROL NO.: CN600619

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 manufacturing's proposed authorized uses of Cu-64 include distribution, compounding and preparation of 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 or pharmacy request for the product. The distribution 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 intends to use Cu-64 in the following processes:

1. In preparation of FDA approved compounds that include the need to add Cu-64 in the manufacturing and/or preparation procedures. A couple of current examples include but are not limited to: Cu-64 DOTATATE and Cu-64 PSMA.
2. In the development and manufacturing 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.
3. 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.

C. Spectron mrc, LLC manufacturing's proposed authorized uses of cyclotron produced Ga-68 include distribution, compounding and preparation of 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 or pharmacy request for the product. The distribution 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 intends to use Ga-68 in the following processes:

1. In preparation of FDA approved compounds that include the need to add Ga-68 in the manufacturing and/or preparation procedures. Radiopharmaceuticals that incorporate Ga-68 include Ga-68 DOTATATE and Ga-68 PSMA.
2. In the development and manufacturing 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.
3. 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.

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