September 7, 2018

DNMS/Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Attn: Mr. Bryan Parker

Pertaining to license number: 13-32726-01 MD; Control No. CN609116; Docket No. 030-38044

ADDITIONAL INFORMATION CN 609116

Dear Mr. Parker,

In Response to your request for more information from your email dated September 6, 2018.

Spectron mrc continues to receive requests from various companies to provides clinical doses for various medical applications, usually to treat cancer. As a result, we are getting requests to label various ligands with isotopes that are not widely utilized. The initial use for these isotopes will be for Clinical trials, but the near-term anticipated need would be for wide ranging treatment for patients either via an Investigational New Drug or as a New Drug Approval. In either case, the need exists for high quality, licensed, nuclear pharmaceutical services. This need will continue to grow due to the fact that several more drugs are being developed with similar isotopes.

Many of the isotopes that are being used for clinical trials are only produced on a limited schedule. This causes the need for a higher possession limit to accommodate the decay.
Please see the following pages for answers to your 4 items.

Item 1.

Use: Spectron mrc is providing Lu-177 for clinical trials to various researchers. Lu-177 has become one of the therapeutic isotopes of choice. We utilize our facility to process the Lu-177 into GMP, pharmaceutical grade material either shipped as an isotope or as labeled to a customer's ligand. Typical use is with a PSMA molecule for prostate cancer, however, there are uses for Neuroendocrine tumors as well.

Possession limit: The request for 15 Curies is to address the current supply options from various reactors, as well as, the anticipated customer volume and anticipation of future supply options. We need to receive the product in bulk from various reactors monthly in certain cases. With a 6-day half-life, we may need to decay the isotope for up to 5 half-life's. Assuming a 200 mCi patient dose, 15 Curies after 5 half-life's is only two doses. Some reactors only provide isotopes one time per month with Lu-177.

Received: The material will be received either via Fed-Ex or a private carrier from licensed suppliers.

Form: The material is in liquid or solid.

Special Handling: The product is not volatile. However, as a precaution, a vented glove box, fume hood or Hot Cell will be utilized for handling. The air in the vented glove box, fume hood or Hot Cell will be filtered to capture any vapors.

Bioassays: Non-needed.

Dosimetry: Appropriate dosimetry will be deployed to detect exposure to the surrounding area and staff.

Breathing Zone monitoring: Non-needed. Each vented glove box, fume hood or Hot Cell will be checked at a minimum of every 6 months to ensure proper operation.

Effluent Monitoring: Spectron has a stack monitor that provides continuous monitoring of effluents. No release is expected due to filtration and the lack of volatility.

Item 2.

Use: Ac-225 is for clinical trials to various researchers. Ac-225 has become one of the therapeutic isotopes of choice and is difficult to obtain. We utilize our facility to process the Ac-225 into GMP, pharmaceutical grade material either shipped as an isotope or as labeled to a customer's ligand. Typical use is with a PSMA molecule for prostate cancer, however, there are other cancers being targeted with Ac-225.

Possession limit: The request for 300 mCi is to address the supply options from various producers of Ac-225, as well as, the anticipated customer volume. We need to receive the product in bulk usually on a monthly or longer interval. With a 10-day half-life, we may need to decay the isotope for up to 4 half-life's meaning 300 mCi's we would have under 20 mCi during the last week.

Received: The material will be received either via Fed-Ex or a private carrier from licensed suppliers.

Form: The material is in liquid or solid.
Special Handling: The product is not volatile. However, as a precaution, a vented glove box, fume hood or Hot Cell will be utilized for handling. The air in the vented glove box, fume hood or Hot Cell will be filtered to capture any vapors. Spectron mrc gets its Ac-225 as a distributor for Global Morpho. Global Morpho will provide training for handling the Ac-225.
Bioassays: Non needed.
Dosimetry: Appropriate dosimetry will be deployed to detect exposure to the surrounding area and staff.
Breathing Zone monitoring: Non needed. Each vented glove box, fume hood or Hot Cell will be checked at a minimum of every 6 months to ensure proper operation.
Effluent Monitoring: Spectron has a stack monitor that provides continuous monitoring of effluents. No release is expected due to filtration and the lack of volatility.

Item 3.
Use: At-211 is used for clinical trials to various researchers. At-211 is in extremely short supply but has significant promise as a therapeutic. We utilize our facility to process the At-211 into GMP, pharmaceutical grade material either shipped as an isotope or as labeled to a customer's ligand. Several cancers are being targeted with Ac-225.
Possession limit: The request for 300 mCi is to address the supply options from various producers of At-211, as well as, the anticipated customer volume. We need to receive the product in bulk daily. With a 7.2 hours half-life, we may need to decay the isotope for up to 5 half-life's meaning with 300 mCi's we would have under 10 mCi for patient dose within a 3-hour drive from South Bend.
Received: The material will be received either via Fed-Ex or a private carrier from licensed suppliers.
Form: The material is in liquid or solid.
Special Handling: The product is not volatile. However, as a precaution, a vented glove box, fume hood or Hot Cell will be utilized for handling. The air in the vented glove box, fume hood or Hot Cell will be filtered to capture any vapors.
Bioassays: Non-needed.
Dosimetry: Appropriate dosimetry will be deployed to detect exposure to the surrounding area and staff.
Breathing Zone monitoring: Non-needed. Each vented glove box, fume hood or Hot Cell will be checked at a minimum of every 6 months to ensure proper operation.
Effluent Monitoring: Spectron has a stack monitor that provides continuous monitoring of effluents. No release is expected due to filtration and the lack of volatility.

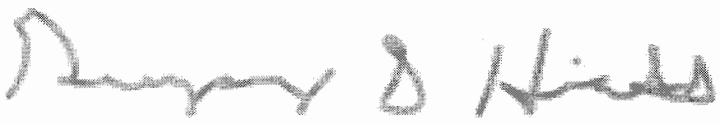
Item 4.

Use: Spectron mrc is providing Zr-89 for clinical trials to various researchers. Zr-89 has become one of the isotopes of choice. We utilize our facility to process the Zr-89 into GMP, pharmaceutical grade material either shipped as an isotope or as labeled to a customer's ligand. Zr-89 has many uses.
Possession limit: The request for 2 Curies is to address the current supply options from various cyclotrons, as well as, the anticipated customer volume and anticipation of future supply options. We need to receive the product in bulk, typically twice per month. With a 3.27-day half-life, we may need to decay the isotope for up to 5 half-life's. 2 Curies after 4 or 5 half-life's is approximately 100 mCi for use.
Received: The material will be received either via Fed-Ex or a private carrier from licensed suppliers.
Form: The material is in liquid or solid.
Special Handling: The product is not volatile. However, as a precaution, a vented glove box, fume hood or Hot Cell will be utilized for handling. The air in the vented glove box, fume hood or Hot Cell will be filtered to capture any vapors.
Bioassays: Non-needed.
Dosimetry: Appropriate dosimetry will be deployed to detect exposure to the surrounding area and staff.
Breathing Zone monitoring: Non-needed. Each vented glove box, fume hood or Hot Cell will be checked at a minimum of every 6 months to ensure proper operation.
Effluent Monitoring: Spectron has a stack monitor that provides continuous monitoring of effluents. No release is expected due to filtration and the lack of volatility.

If you need additional information, please feel free to call or email me.

My cell phone number is: 574-298-9616
My email address is: TARQY@sbcglobal.net

Yours truly,



Gregory S. Hiatt R.Ph/ President