



June 18, 2018

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

Attn: Materials Licensing Branch

RE: Addition of Radionuclides and Sr82/85-Rb82 generators

License Reviewer,

In reference to license number 13-32726-01 MD: I would like to amend the following conditions.

- A. Add to the license an increase for the possession of Molybdenum-99/Technetium-99m generator possession limit to 20 curies (Ci) any form. Waste and storage will be kept separate from the PET products and waste.
- B. Add to the license an increase of the Technetium-99m possession limit to 20 curies (Ci) in any form.
- C. Add to the license an increase in the Uranium (depleted) possession limit to 100 kg.
- D. Add to the license an increase in the Lutetium (Lu-177) possession limit to 15.0 curies (Ci) in any form. Because of the over six (6) day half-life of this product and the production of "Betas" I will have separate storage and waste areas.
- E. Add to the license Actinium-225 with a possession limit of 300 milli-curies (mCi). Because of the over ten (10) day half-life of this product I will have separate storage and waste areas.
- F. Add to the license an increase to the Sr82/85-Rb82 generator to 3.0 curies (Ci). The
- G. Add to the license Astatine-211 with a possession limit of 300 mCi.
- H. Add to the license an increase of Zirconium-89 to 2000 mCi.

Medical Radiolotope Center
17490 Dugdale Drive * South Bend * Indiana
574-271-2800

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PURPOSE:

All of the added radionuclides are to provide unique radionuclides for contract manufacturing for new proteins and related ligands as well as being made available for redistribution to licensed facilities allowed to receive the radionuclide being purchased.

The Sr82/Rb82 generator has been increased to allow Spectron to redistribute unopened, unexpired generators intended for human use. These generators will be FDA approved generators, such as the Drax Ruby Fill, and the generator will not be opened, breached or physically modified by Spectron employees prior to being shipped to the end user.

SPECIAL HANDLING:

Spectron mrc, LLC will provide a separate storage and waste areas/containers for Lu-177, At-211, Ac-225, Zr-89 so that there is control over the various radionuclides with their different half-lives. Disposal of decayed radionuclides will follow the protocol described in the current license's waste management program.

Additionally, Spectron will utilize glove boxes with charcoal filtration or hot cells during the handling of Actinium-225 and/or Astatine-211 when that additional protection is needed. Generally, the individual patient doses are low enough that normal radiation safety technique will be adequate to control exposure and contamination.

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: TAROY@sbcglobal.net

Yours truly,



Gregory S. Hiatt R.Ph/ RSO



Spectron
mrc l.l.c.

From:	Gregory S. Hiatt R.Ph., RSO
Fax:	574-271-3523
Phone:	574-298-9616

FAX

Nuclear Regulatory Commission

To: MATERIALS LICENSING BRANCH

Fax: 630-515-1078

Phone: 630-829-9607

Pages: 3 INCLUDING COVER

Re: License amendment for license #: 13-32726-01MD

~~CONFIDENTIAL~~

A very special consideration in approving this amendment sooner would be greatly appreciated.

*TX
Greg Hiatt*

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