DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
National Health Physics Program (NHPP)
2200 Fort Roots Drive
North Little Rock, AR 72114

In Reply Refer To: 598/115HP/NLR

April 3, 2018

Bryan Parker
Division of Nuclear Material Safety
Nuclear Regulatory Commission (NRC), Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Re: NRC Mail Control Number 594387
NRC Master Materials License (MML) No. 03-23853-01VA
NHPP Director Letter to NRC (Bryan Parker) dated May 8, 2017
NRC memorandum dated July 13, 2017, from Marc Dapas to the NRC Regional Administrators (ML No. 17075A487 in ADAMS)

Dear Mr. Parker:

With respect to the referenced items above and in order to ensure continued access and improvements to care for Veterans, we hereby revise our request of May 8, 2017, for an exemption from the requirement to submit a decommissioning funding plan (DFP) per 10 CFR 30.35(a)(1) for possession and use of Germanium-68 (Ge-68)/Gallium-68 (Ga-68) generators for Veterans Health Administration (VHA) permittees engaged in medical use under 10 CFR Part 35 and/or biomedical research under 10 CFR Part 30. The reason for revision is to use updated provisions of the revised NRC guidance memorandum dated July 13, 2017, and to enclose a legally binding agreement between Eckert & Ziegler Radiopharma GmbH (E&Z), signed February 5, 2018; the MML, signed February 6, 2018; and a representative of permittee management, and signed April 2, 2018. We understand this exemption would apply to the specific generator(s) referenced in the agreement and we would need to submit additional exemption requests for other vendors and generators.

We note that VHA, per 10 CFR 30.35(d), has filed a Certificate of Financial Assurance with the NRC in the amount of $1,125,000 for each VA facility identified as a permit holder under the MML. The certification is dated December 1, 2004.

We commit to follow the conditions in below subparagraphs when authorizing this exemption on a specific VHA permit, issued under our MML:

1. We will limit the number of generators authorized on a specific VA permit to less than 20 generators Ge-68/Ga-68 and less than 1000 millicuries (mCi) total. Two generators will typically be authorized with a 50-mCi maximum activity each.

2. We will require permittee management to provide a written and signed request to NHPP for an exemption from the requirement to submit a DFP per 10 CFR 30.35(a)(1) for possession and use of Ge-68/Ga-68 generators for medical use and/or biomedical research under their permit.

3. We will require a representative of permittee management to sign, date, and submit to NHPP, and maintain for NHPP/NRC inspection, a signature page that makes the permittee a party to the enclosed agreement between the MML and vendor such that the permittee agrees to return Ge-68/Ga-68 generators to the manufacturer or distributor when each generator expires and is no longer used to prepare Ga-68 radiopharmaceuticals for patients and/or biomedical research, or if the permittee ceases its use of Ga-68 radiopharmaceuticals from the generator.

4. We will add the following condition to a permit if we approve the exemption, subject to approval of this MML amendment:

> "Notwithstanding the requirements of 10 CFR 30.35 (a)(1), the permittee is exempt from the requirement to have a decommissioning funding plan needed for the possession and use of Germanium-68 (Ge-68)/Gallium-68 (Ga-68) medical use generators (GalliaPharm™ generators), based on the commitments between the VA Master Materials Licensee (MML), manufacturer (Eckert & Ziegler Radiopharma GmbH (E&Z)), and permittee. The permittee shall return the generators to the manufacturer/distributor in accordance with the "Master Return Agreement for GalliaPharm™ $^{68}Ge/^{68}Ga$ Generators" signed February 5, 2018, by E&Z, signed February 6, 2018, by the MML, and signed April 2, 2018, by a representative of permittee management."

5. In addition, for authorizing possession and medical use of Ge-68/Ga-68 generators, NHPP will use guidelines in the NRC document titled "Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 Pharmacy Grade Generator, Licensing Guidance," dated October 17, 2016 (NRC ML No. ML16287A403), or, if superseded, the most recent document published by NRC at the "Emerging Technologies and 10 CFR 35.1000" section of the NRC Web page. NHPP will require permittees to commit in writing to the items listed in Section 5 of the guidance document before granting an amendment to add these generators as an item on the permit. The permittee commitment will be incorporated by reference into the conditions of the permit.

NHPP received approval to request this amendment by the VHA National Radiation Safety Committee at its meeting held May 3, 2017. If you have any questions, please contact me at 410-642-2411, extension 6288.

Sincerely,

Paul L. Yurko 400994

Digitally signed by Paul L. Yurko 400994
Date: 2018.04.03 14:27:46 -04'00'

Paul L. Yurko, MS
Interim Director

Enclosure

Eckert & Ziegler

MASTER RETURN AGREEMENT FOR GalliaPharm™ $^{68}Ge/^{68}Ga$ GENERATORS

This Master Return Agreement (**Agreement)** is made as of February 1, 2018, by and among Eckert & Ziegler Radiopharma GmbH organized and existing under the laws of Germany, address Robert-Rössle-Str. 10, 13125 Berlin, Germany (**E&Z**) and the U.S. Department of Veterans Affairs (VA), organized and existing under the laws of the United States of America, address 810 Vermont Avenue, NW Washington DC 20420, United States. "Licensee" as used in this agreement is "Department of Veterans Affairs, Under Secretary of Health."

Recitals

Licensee is holder of Master Materials License NRC Lic. No. 03-23853-01VA issued by the United States Nuclear Regulatory Commission. Licensee has currently 116 permittees across the United States who are in possession of respective local facility permits issued under the authority of the Licensee's Master Materials License (**Permittees)**.

Licensee intends to amend its Master Materials License with the NRC to add $^{68}Ge/^{68}Ga$ to their permit and, if requested by any of the Permittees, to subsequently subissue a $^{68}Ge/^{68}Ga$ permit amendment to the respective local facility permits of Permittees.

In case of successful amendment of Licensee's Master Materials License with the NRC, E&Z is willing to accept and conduct returns of GalliaPharm™ from any of Licensee's Permittees provided that Licensee provides E&Z prior any intended delivery of a GalliaPharm™ to a Permittee with

a) a copy of the $^{68}Ge/^{68}Ga$ permit amendment to the local facility permit of the respective Permittee, the Permittees name and Permittees delivery address, and

b) the executed Permittee signature page to this Master Return Agreement.

NOW, in consideration of the foregoing recitals, it is agreed as follows:

1. Background

As regular users of radioactive substances and radiopharmaceuticals, we assume that you are aware that possession and use of both are subject to several regulatory requirements to ensure public health and safety.

These considerations include the final return of these materials and products.

Hence, purchases and deliveries of GalliaPharm™, Eckert & Ziegler's $^{68}Ge/^{68}Ga$ generator, have to undergo a standard return procedure.

This Agreement applies to deliveries of GalliaPharm™ from E&Z to site(s) that are authorized by the United States Nuclear Regulatory Commission or Agreement states to possess the required maximum radioactive quantity of $^{68}Ge/^{68}Ga$ contained in GalliaPharm™ .

The GalliaPharm™ $^{68}Ge/^{68}Ga$ generator has been approved by the FDA (DMF #28741) for use in the radiolabeling of NETSpot® and certain restrictions on its use apply – see GalliaPharm™ Instructions for Use.

2. General Handling, Safety and Return:

2.1 The Licensee is obligated to return each GalliaPharm™ and E&Z (directly or through its subsidiaries, affiliates and/or distributors) is obligated to accept the return of these GalliaPharm™ by the Licensee to the terms and condition of this Agreement.

2.2 The Licensee will contact E&Z to obtain a returned materials authorization (RMA).

2.3 Any returns shall be accomplished in accordance with E&Z's instructions. In the case of GalliaPharm's™ shelf-live expiry, return has to take place at the latest sixty (60) days following the expiry date. The Licensee shall contact E&Z in due time for return guidance and instructions (phone: +1 508-497-0060 or GalliaPharm@ezag.com).

2.4 If the Licensee fails to facilitate due return of GalliaPharm™, does not inform E&Z in due time and/or deviates from any guidance and instructions given by E&Z, the Licensee will be responsible for all costs up to a maximum of $ 125,000 per incident for loss, damage and expense incurred by E&Z in relation to the inadequate or delayed return including cost of return freight and all labor and third party associated costs, fees or penalties.

2.5 If prior to the expiry date of the GalliaPharm™, the RAM license expires, is terminated or withdrawn for whatever reason or in case of the Licensee's insolvency, receivership or bankruptcy or its dissolution or ceasing to do business, E&Z is entitled to directly or indirectly through qualified representatives package and effect return of the GalliaPharm™ according to its return guidelines.

3. Documentation:

3.1 The Licensee may not permit any person reasonably within the Licensee's control to

(i) open, breach or modify the GalliaPharm™ and/or

(ii) copy, clone, reverse engineer any hardware GalliaPharm™ components or

(iii) copy, modify or decompile any documents accompanying the GalliaPharm™ without E&Z's prior written consent.

3.2 Non-compliance with the above, in particular if a return GalliaPharm™ has not been prepared according to the E&Z return guidance and/or applicable legislation including residual activity estimation of GalliaPharm™, exposure rate and Transport Index measurements on the package, correct packaging assembly, labeling and documentation, can result in rejection of the respective return consignment until the irregularities are corrected and the GalliaPharm™ is resubmitted for return.

4. No Resale or Transfer:

The Licensee acknowledges that due to its FDA approved status, any delivered, unpacked and commissioned GalliaPharm™ generator may not be sold, leased or otherwise locally transferred to or utilized by any third parties, end-users or Permittee at any other location other than the original delivery location holding the respective license. If the Licensee violates this section, the GalliaPharm™ warranty will be violated and E&Z will not be responsible for any loss, damage and expense incurred by such unauthorized use.

5. Addition of Permittee(s) to this Agreement

Upon the delivery to E&Z of an executed Permittee signature page to this Agreement, Permittee is hereby added to the Agreement as an additional party hereunder, and will thereupon have all the rights and obligations of a "Party" hereunder.

Licensee shall remain a Party to this Agreement and the addition of Permittee as Party to the Agreement shall not relieve Licensee of responsibility of any obligations that accrued prior to and after the addition of Permittee.

For the avoidance of doubt, the purchase and sale of a GalliaPharm™ and all related commercial aspects will be subject to a separate order procedure between E&Z and the individual Permittee.

6. Miscellaneous:

This Agreement constitute the full and entire understanding and agreement between the parties regarding the subject matter hereof and supersedes and cancels all prior agreements, negotiations, correspondence, undertakings and communications of Licensee, E&Z and any Permittee(s), oral or written, respecting such subject matter.

This Agreement may be amended or terminated by either Party if the current return policies and guidelines regarding GalliaPharm™ generators are amended, modified or explicitly codified. This

will not influence the return of GalliaPharm™ already delivered by E&Z to the Licensee or a Permittee prior to any such changes in applicable laws and regulations.

Signature for accepting the above:

Licensee:

Name: Dr. Michael P. Hagan, MD, PhD

Title: Chair of the National Radiation Safety Committee

Signature: 2/6/18

Date: Michael P. Hagan

Eckert & Ziegler Radiopharma GmbH:

Name: Dr. André Heß Martina Leplow

Title: General Manager Authorized Signatory

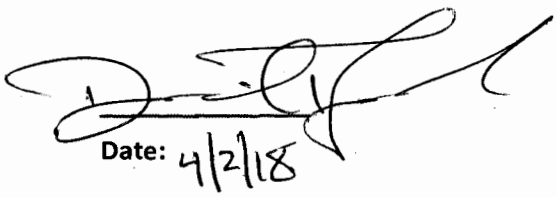
Signature:

Date: February 5, 2018

[Permittee Signature Page to Master Return Agreement]

By signature of this Master Return Agreement, [ ] Permittee) shall become a Party to the Agreement:

Permittee:



Date: 4/2/18

Name: DAVID ISAACKS, FACHE

Title: Director

UPS Internet Shipping: View/Print Label

1. **Ensure there are no other shipping or tracking labels attached to your package.** Select the Print button on the print dialog box that appears. Note: If your browser does not support this function select Print from the File menu to print the label.

2. **Fold the printed label at the solid line below.** Place the label in a UPS Shipping Pouch. If you do not have a pouch, affix the folded label using clear plastic shipping tape over the entire label.

3. **GETTING YOUR SHIPMENT TO UPS**
   Customers with a Daily Pickup
   Your driver will pickup your shipment(s) as usual.

   Customers without a Daily Pickup
   Take your package to any location of The UPS Store®, UPS Access Point(TM) location, UPS Drop Box, UPS Customer Center, Staples® or Authorized Shipping Outlet near you. Items sent via UPS Return Services(SM) (including via Ground) are also accepted at Drop Boxes. To find the location nearest you, please visit the 'Find Locations' Quick link at ups.com.
   Schedule a same day or future day Pickup to have a UPS driver pickup all of your Internet Shipping packages. Hand the package to any UPS driver in your area.

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