



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

APR 12 2018

Gregory S. Hiatt, R.Ph.
Owner - Radiation Safety Officer
Spectron mrc, LLC
17490 Dugdale Dr.
South Bend, IN 46635

Dear Mr. Hiatt:

Enclosed is Amendment No. 03 to your NRC Materials License No. 13-32726-01MD in accordance with your request dated September 20, 2017.

Please note that your license is now in landscape format. Also, some conditions were revised to meet current NRC policy and other standard conditions were added related to your research and development activities.

As requested, we have amended your license to allow increased possession of copper-64 and gallium-68. However, we did not authorize the possession and use of an IRE germanium-68/gallium-68 (Ge-68/Ga-68) Galli-Eo™ generator as requested in Item B of your letter dated September 20, 2017. The reasons for this are outlined below:

- 1) The IRE Ge-68/Ga-68 generator requested has not yet been approved for human use by the FDA. It may only be used for research purposes. If you still wish to seek authorization for non-human use of the IRE Ge-68/Ga-68 Galli-Eo™ generator, please specify this in your re-submittal.
- 2) To date, you have not provided adequate financial assurance (FA). The NRC cannot issue an authorization for Ge-68/Ga-68 generators before receipt and review of adequate FA documentation, as required by 10 CFR 30.35. If you still wish to seek authorization for the IRE Ge-68/Ga-68 Galli-Eo™ generator, please provide adequate FA information. You may contact Ms. Jennifer Bishop of our office to discuss specific details related to your FA needs. Ms. Bishop can be reached at 630-829-9607 or by email at jennifer.bishop@nrc.gov.

Please be reminded that until you have appropriate FA in place, you must maintain your possession limits below those levels specified in 10 CFR 30.35, as described in Condition 13 of your license.

- 3) Although your September 20, 2017 request for the IRE Ge-68/Ga-68 generator contained a copy of a return agreement between Spectron mrc and IRE, that agreement was unclear as to the legally binding effect on IRE and the licensee, with respect to the above-referenced license.

Accordingly, if you still wish to seek authorization for the IRE Ge-68/Ga-68 Galli-Eo™ generator, please re-submit a request following the NRC guidance for Ge-68/Ga-68 generators entitled "Eckert & Ziegler GalliaPharm™ Germanium-68/Gallium-68 Pharmacy Grade Generator," Revision 1 dated July 13, 2017. (This guidance may be found at: <https://www.nrc.gov/docs/ML1707/ML17075A488.pdf>)

Also, please submit a legally binding agreement between the manufacturer and the licensee. At a minimum, in addition to information already contained in the submitted generic agreement, the document should:

- a. Include the licensee's name and license number;
- b. Be signed and dated by a duly authorized representative of Spectron mrc, including an organizational chart or description explaining that individual's authority to sign on behalf of the licensee;
- c. Be co-signed and dated by a duly-authorized IRE representative, including a legibly printed or typed full name and title;
- d. Be supported by a U.S. NRC or Agreement State license showing that the manufacturer (IRE) is authorized to receive Ge-68/Ga-68 generators as described in the agreement.
- e. Include a manufacturer or distributor commitment to accept expired generators from the licensee, regardless of the licensee's financial status or shipping specifications, etc. (any "return guidelines" that are required as part of the agreement should be included with the agreement for NRC review); and
- f. Include any additional requirements specified in NRC's July 29, 2016 exemption memo and enclosure. This document can be found in the Agencywide Documents Access and Management System (ADAMS) under Accession No. ML16082A415.

Please review the enclosed documents carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U. S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

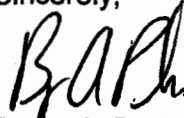
You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We

strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

In accordance with Title 10 of the *Code of Federal Regulations* Section 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,



Bryan A. Parker
Senior Health Physicist
Materials Licensing Branch

License No. 13-32726-01MD
Docket No. 030-38044

Enclosure: Amendment No. 03