



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

MAR 02 2018

Le-Cun Xu, Ph.D.
Radiation Safety Officer
Endocyte Incorporated
3000 Kent Avenue
West Lafayette, IN 47906

Dear Dr. Xu:

Enclosed is Amendment No. 15 to your NRC Material License No. 13-32212-01 in accordance with your request. Please note that we did not authorize Germanium-68/Gallium-68 Generator for your license because we have not secured adequate document related to your request. Specifically, we have not received information as discussed in the Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 Pharmacy Grade Generator Licensing Guidance. This guidance can be found at: <https://www.nrc.gov/docs/ML1707/ML17075A488.pdf>.

In addition, please maintain your unsealed byproduct material possession below the limit set forth in Title 10 Code of Federal Regulations Part 30, Section 35, "Financial assurance and recordkeeping for decommissioning" (10 CFR 30.35). Please note that, the possession limit authorized in your license includes all listed isotopes and the waste from your licensed activities (including decay products). Lutetium-177 has a half-life about 6.7 days and generates up to 0.05% of lutetium-177m as a decay product. Lutetium-177m has a half-life about 160 days which is more than 120 days; therefore, waste contained lutetium-177m is not authorized to dispose by decay in storage. Lutetium-177m has been created at the time lutetium-117 was made and its activity is increasing while lutetium-177 is decaying (at least for the first 22 days since lutetium-177 was created). Based on the current NRC regulations, any unsealed lutetium-177m alone with a quantity exceeding 100 micro-curies will need a decommissioning financial assurance and/or decommissioning funding plan (10 CFR 30.35).

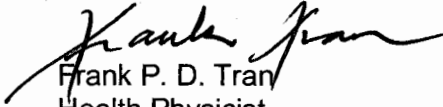
Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

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 Code of Federal Regulations 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,


Frank P. D. Tran
Health Physicist
Materials Licensing Branch

License No. 13-32212-01
Docket No. 030-35228

Enclosure: Amendment No. 15