



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

March 24, 2020

Le-Cun Xu, Ph.D.
Radiation Safety Officer
Advanced Accelerator Applications
(formerly Endocyte, Inc.)
3000 Kent Ave.
Ste. A1-100
West Lafayette, IN 47906

Dear Dr. Xu:

Enclosed is Amendment No. 19 renewing your NRC Materials License No. 13-32212-01 for Advanced Accelerator Applications (formerly Endocyte, Inc.) in accordance with your request. Please note that former License Condition No. 13 regarding the decommissioning financial assurance was deleted because it does not apply to your license based on the licensed possession limit. In addition, based on the NRC licensing policy License Condition No. 14 regarding the experimental animals and their products was added to your license. We also listed thorium-227 in Item No. 6.O. as solid or liquid (not dispersible).

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.

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.

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures

The enclosed document contains sensitive security-related information.
When separated from this cover letter this letter is uncontrolled.

[REDACTED]

L. Xu

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that potentially sensitive information is not made publicly available through ADAMS, the NRC's electronic document system. Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390, the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability. The RIS may be located on the NRC Web site at: <https://www.nrc.gov/docs/ML1619/ML16196A237.pdf> and the link for frequently asked questions regarding protection of security related sensitive information may be located at: <https://www.nrc.gov/reading-rm/sensitive-info/faq.html>.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice," a copy of this letter 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. 19

[REDACTED]