



Le-Cun Xu, Ph.D.
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United States Nuclear Regulatory Commission
Region III
2443 Warrenville Rd, Suite 210
Lisle, IL 60532-4352
ATTN: MATERIALS LICENSING

Re: Mail Control No. 601958: Request for additional information

Friday March 2nd, 2018

Dear Mr. Tran,

We appreciate the opportunity to be able to provide additional information to our recent amendment request to add Ge-68/Ga-68 generator to our U.S. Nuclear Regulatory Commission license #13-32212-01.

We request an exemption to the Decommissioning Funding Plan requirement to obtain a license to possess a Ge-68/Ga-68 generator. We will ensure that generators are returned to the supplier when they are exhausted. A purchase and return agreement between Endocyte and the generator supplier will be signed once this license amendment is approved.

We will provide \$225,000 in financial assurance for decommissioning. Our financial department is working to set up a trust fund. Once it is done, we will submit the financial assurance documents.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Le-Cun Xu' with a stylized flourish at the end.

Le-Cun Xu, Ph.D.
Radiation Safety Officer

Song, Taehoon

From: Tran, Frank
Sent: Friday, March 02, 2018 7:43 AM
To: Pavon, Sandy; Song, Taehoon
Cc: Tomczak, Tammy
Subject: FW: RE: Request for additional information regarding NRC License No. 13-32212-01
Attachments: 2Mar 2018 - additional information for adding a Ga-68 generator.pdf

Hi Sandy,

Please add this document to ADAMS for CN 601958 (13-32212-01/030-35228) and send me the ML number.

Thank you,
-Frank

From: Xu, Le-Cun [mailto:xul@Endocyte.com]
Sent: Friday, March 02, 2018 7:27 AM
To: Tran, Frank <Frank.Tran@nrc.gov>
Subject: [External_Sender] RE: Request for additional information regarding NRC License No. 13-32212-01

Hi Frank,
As requested, please find the additional information regarding your recent review of our amendment request.

Best Regards,
Le-Cun



Le-Cun Xu, Ph.D.
Senior Scientist
Endocyte, Inc.
3000 Kent Avenue, Suite A1-100
West Lafayette, IN 47906
Phone: 765-807-0606
Email: xul@endocyte.com

From: Tran, Frank [mailto:Frank.Tran@nrc.gov]
Sent: Friday, February 02, 2018 12:34 PM
To: Xu, Le-Cun
Subject: Request for additional information regarding NRC License No. 13-32212-01

Dear Dr. Xu:

We have reviewed your amendment request dated December 15, 2017. We will need the following to complete the review.

10 CFR 30.35 requires that:

(a)(1) Each applicant for a specific license authorizing the possession and use of unsealed byproduct material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in appendix B to part 30 shall submit a decommissioning funding plan as described in paragraph (e) of this section. ...

If an applicant is seeking a license to possess quantities of unsealed byproduct material less than 10^5 times the quantities set forth in 10 CFR Appendix B to Part 30 but greater than 10^3 times those quantities, then the applicant has the option of either submitting a decommissioning funding plan as described in paragraph 30.35(e) or a certification of financial assurance in the amount described in paragraph 30.35(d). The amount of financial assurance required at paragraph 30.35(d) is \$1,125,000.00 for quantities greater than 10^4 but less than or equal to 10^5 times the quantities in Appendix B to Part 30, and \$225,000.00 for quantities greater than 10^3 but less than or equal to 10^4 times the quantities in Appendix B.

For Ge-68, if the possession is from 0.1 to 1 millicurie, the required financial assurance is \$225,000.00. If the possession is from 1 to 10 millicuries, the required financial assurance is \$1,125,000.00. If the possession is greater than 10 millicuries, the applicant must provide a decommissioning funding plan and the associated financial assurance (§ 30.35).

Based on your request of 80 millicuries of Ge-68, you must provide a decommissioning funding plan and the associated financial assurance in accordance with 10 CFR 30.35. For your reference, the guidance regarding the decommissioning funding plan and decommissioning financial assurance can be found in NUREG-1757, Consolidated Decommissioning Guidance, which is posted on the NRC website at <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/>.

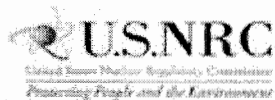
Please provide the response in writing with proper signature and date by March 2, 2018. Please reference Mail Control No. 601958 in your response to facilitate proper mail handling in our office. All correspondences can be mailed to Materials Licensing Branch, 2443 Warrenville Road, Suite 210, Lisle, IL 60532.

If you have any questions regarding the above, please do not hesitate to contact me at 630-829-9623 or reply to this email.

Sincerely,

Frank Tran

Health Physicist/License Reviewer
NRC Region III/Division of Nuclear Materials Safety
Phone: 630-829-9623
Fax: 630-515-1078
Email: Frank.Tran@nrc.gov



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