



Frank Tran  
Health Physicist/License Reviewer  
NRC Region III/Division of Nuclear Materials Safety  
2443 Warrenville Rd, Suite 210  
Lisle, IL 60532-4352

Ref: Request for additional information regarding the renewal application for NRC License No. 13-32212-01

March 23, 2020

Dear Mr. Tran,

Thank you for your correspondence. Please find the response to the request for additional information.

- 1) **Provide a copy of the delegation of authority memorandum for the Radiation Safety Officer (RSO). For your reference, a sample of the memorandum is listed in NUREG-1556, Vol. 7, Rev. 1, Appendix E.**

Response:

A copy of the delegation of authority memorandum for the radiation Safety Officer (RSO) is attached.

- 2) **The application did not provide specific licensed materials and uses for each proposed authorized user. Please provide the specific licensed materials and uses for each user. If there are no changes to their authorization as listed in the previous amendment (No. 18), please state.**

Response:

Licensed material will be used by, or under the supervision of, the following individuals for the materials and uses indicated below:

Authorized Users	Material and Use
Le-Cun Xu, Ph.D.	For research and development use of all radionuclides permitted under this license
Christopher P. Leamon, Ph.D.	For research and development use of all radionuclides permitted under this license
Joseph A. Reddy, Ph.D.	For research and development use of all radionuclides permitted under this license
Nikki Parker	For research and development use of all radionuclides permitted under this license
Elaine Westrick	For research and development use of all radionuclides permitted under this license
Melissa Nelson	For research and development use of all radionuclides permitted under this license



- 3) **Your application did not address the following licensed material: phosphorus-32, phosphorus-33, sulfur-35, technetium-99, and radium-223. If you have never possessed them, please state. If you possessed them, please confirm that all of them have been properly disposed and you don't currently have any of their residue activities including in decay-in-storage.**

Response:

We never possessed phosphorus-32, phosphorus-33, technetium-99 and radium-223.

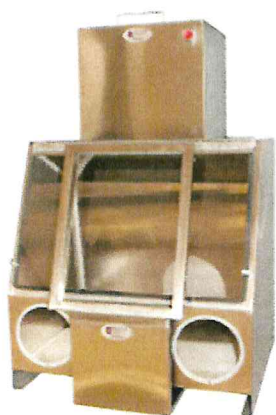
We possessed 0.25mCi of sulfur-35 which was transferred to a licensed radioactive waste disposal company, Bionomic Inc, on October 17, 2012. We don't currently have any of sulfur-35 residue activities.

- 4) **You request to possess and use many radionuclides in any physical and chemical form. Where radioactive materials may become airborne, please provide schematic descriptions of the ventilation systems with pertinent airflow rates, pressures, filtration equipment, and monitoring systems.**

Response:

We confirm that volatile radionuclides Iodine-125, Iodine-131 and Astatine-211 will be used in an iodination fume hood equipped with an activated charcoal filter to trap radioactive materials. The hood will be tested and approved prior to use. Bioassay will be performed after the use of volatile radionuclides to ensure that exposures remain ALARA.

### I-131 Fume Hood



*Front door hinges are placed forward for easy opening for cleaning*

- Used during the preparation of I-131 and other radiopharmaceuticals
- Designed to be used with an L-Block shield that slides under the front of the Fume Hood (L-Block not included)
- Constructed of stainless steel and rugged polycarbonate
- Provides a spacious work area with ample arm ports that allow easy access to the work area
- Hinged front door allows easy placement and retrieval of items
- Fan and air baffle assure even flow of air out of the hood
- Fan motor is 120 VAC, 60 Hz
- Two 12" x 12" x 1" disposable charcoal filters included
- Draws 135 CFM

#### Specifications:

Dimensions: O.D.: 24" W x 20" D x 36" H

Weight: 110 lb

Radiolabeling with other radionuclides will be performed in a certified radiation fume hood. Fume hood will be tested and certified annually. Air monitoring will not typically be performed since only bound form, non-volatile radionuclides will be used on laboratory benches.



Radiation fume hood



The ventilation system within temporary job site at 190 S. Russell Street, West Lafayette, Indiana has no recycled air, 10-15 room air exchanges/hour, pleated filter and HEPA exhaust prior to direct exit of building. This space has negative air pressure relative to surrounding space. Mice are housed in micro-isolators to minimize airborne exposure.

- 5) **With regarding to the radiation safety refresher training frequency for individuals working in or frequenting restricted areas, NUREG-1556, Vol. 7, Rev. 1, recommends an annual frequency. However, you proposed a radiation safety refresher training every two years. Please provide a justification for choosing the biennial radiation safety refresher training frequency.**

Response:

We confirm that radiation safety refresher training will be provided on an annual basis.

- 6) **Provide a description of the hands-on training program which will be provided to individuals who will be working with animals that licensed material were administered, including who will provide the instructions. Please see NUREG-1556, Vol. 7, Rev. 1, Appendix D for reference.**

Response:

Employees who will be working with animals that licensed material is administered will be sufficiently trained. Training will consist of principles of radiation protection, radioactivity measurements, monitoring techniques, calculations basic to using radioactivity and biological effects of radiation.

Hands-on training will be provided by authorized users/biologists who have sufficient experience in animal studies. Hands-on training will consist of the following:

- Observing authorized users perform licensed activities with animals, including administration of the radioactive material to the animal, using survey equipment, proper contamination control techniques, and proper methods for disposal of radioactive material.
- Performing licensed activities with animals under the supervision of authorized users. Dry run will be done prior to performing licensed activities. Activities will include the administration of radioactive material to an animal, use of survey equipment, proper contamination control techniques, and proper disposal of radioactive material.





- Training that is specific to the radionuclides used under the license, the procedures that will be performed, the animals used, and the surveys and contamination control activities necessary for the materials used and procedures performed.

- 7) **Provide the following statement: “We will use instruments that meet the radiation monitoring instrument specifications published in Appendix I in NUREG-1556, Vol. 7, Rev. 1, ‘Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.’ We reserve the right to upgrade our survey instruments as necessary. Instruments will be calibrated before first use, at least annually thereafter, and after any repair, by a vendor that the NRC or an Agreement State has licensed to perform instrument calibration.”**

Response:

We confirm that we will use instruments that meet the radiation monitoring instrument specifications published in Appendix I in NUREG-1556, Vol. 7, Rev. 1, ‘Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.’ We reserve the right to upgrade our survey instruments as necessary. Instruments will be calibrated before first use, at least annually thereafter, and after any repair, by a vendor that the NRC or an Agreement State has licensed to perform instrument calibration.

- 8) **Provide the following statement: “We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times.”**

Response:

We confirm that we will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times.

- 9) **If you will possess any sealed source containing licensed material (not for use as in a general license device or as exempt quantity source), provide the following statement: “Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license. Records of inventory will be maintained for a period of 3 years from the date of each inventory, and will include the radionuclides, quantities, manufacturer’s name and model numbers, and the date of the inventory.” If you will not possess any sealed source under the authorization of this license, please state.**

Response:

We will not possess any sealed source containing licensed material under the authorization of this license.

- 10) **If the leak test will be required for the sealed sources discussed in Question 8 above, please specify who will perform the leak test and associated information (see NUREG-1556, Vol. 7, Rev. 1, Section 8.10.7, “Surveys and Leak Tests” for reference.)**



Response:

Leak test is not required since we will not possess any sealed source containing licensed material under the authorization of this license.

**11) Provide a description of how licensed material will be secured at your facility to prevent an unauthorized access and theft.**

Response:

Our facility is a locked facility. All visitors must enter through the front door that is monitored by a staff member. All other access doors are equipped with electronic key fob access. Our laboratory is also locked. Radioactive materials will be kept under direct supervision and stored in locked laboratory.

**12) Provide the following statement: "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix M in NUREG-1556, Vol. 7, Rev. 1, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.'"**

In addition, please address the following:

- a) Item 10.6 (1) stated that the licensee will perform ambient radiation survey to ensure they meet the requirement in 10 CFR 20. It mentioned about a threshold for a dose rate of 32 mR/hr. Please provide a justification for this threshold or a correction if necessary.
- b) Item 10.6 (3) stated that an area with less than 200 microcuries of licensed material was used at one time will be surveyed on a monthly basis. However, NUREG-1556, Vol. 7, Rev. 1, recommends in Appendix M that if a quantity of licensed material equal to or greater than an annual limit for intake (ALI) which has been used at any one time at any particular location, that location should be surveyed daily. For your information, an ALI for I-131 listed in 10 CFR 20 is 50 microcuries. Provide a justification or correction if necessary.
- c) Item 10.6 (4) stated that your criteria for surface contamination for release of facility or equipment is 5000dpm/100cm<sup>2</sup> (average), 15000dpm/100cm<sup>2</sup> (maximum) or 1000dpm/100cm<sup>2</sup> (removable). However, for such as I-125 as authorized in your license NUREG-1556, Vol. 7, Rev. 1, Appendix M, Table M-2 recommends the release criteria as 100dpm/100cm<sup>2</sup> (average), 300dpm/100cm<sup>2</sup> (maximum) or 20dpm/100cm<sup>2</sup> (removable). Provide a justification or correction if necessary.

Response:

We confirm that we will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix M in NUREG-1556, Vol. 7, Rev. 1, Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.





- a) Dose rate surveys will be performed to ensure that operations which involve licensed material do not exceed a dose rate of 2 millirem/hour or result in an effective dose equivalent of 100 millirem in any one year.
  - b) Daily survey will be performed when greater than 50 microcuries of licensed material is used. When a small quantity of licensed material (less than 50 microcuries at a time) is used, monthly survey will be performed.
  - c) Criteria for acceptable surface contamination for release of facility or equipment is below:
    - Beta-gamma emitters: 5000dpm/100cm<sup>2</sup> (average), 15000dpm/100cm<sup>2</sup> (maximum) or 1000dpm/100cm<sup>2</sup> (removable).
    - I-131: 1000dpm/100cm<sup>2</sup> (average), 3000dpm/100cm<sup>2</sup> (maximum) or 200dpm/100cm<sup>2</sup> (removable).
    - Ac-225 and I-125: 100dpm/100cm<sup>2</sup> (average), 300dpm/100cm<sup>2</sup> (maximum) or 20dpm/100cm<sup>2</sup> (removable).
- 13) **Provide the following statement: “Pursuant to 10 CFR 30.35(g) we will maintain records important to decommissioning and transfer these records to an NRC or Agreement State licensee before licensed activities are transferred or assigned, in accordance with 10 CFR 30.34(b). Furthermore, pursuant to 10 CFR 30.51(f), prior to license termination, we will forward the records required by 10 CFR 30.35(g) to the appropriate NRC Regional Office.”**

Response:

We confirm that pursuant to 10 CFR 30.35(g) we will maintain records important to decommissioning and transfer these records to an NRC or Agreement State licensee before licensed activities are transferred or assigned, in accordance with 10 CFR 30.34(b). Furthermore, pursuant to 10 CFR 30.51(f), prior to license termination, we will forward the records required by 10 CFR 30.35(g) to the appropriate NRC Regional Office.

We appreciate your time in reviewing our request. Should you have any additional questions, please do not hesitate to contact me.

Sincerely yours,

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

Advanced Accelerator Applications  
3000 Kent Ave, Suite A1-100  
West Lafayette, IN 47906  
Direct: 765-807-0606  
Cell phone: 765-337-8239  
[le-cun.xu@adacap.com](mailto:le-cun.xu@adacap.com)



## Delegation of Authority to RSO

To: Radiation Safety Officer

From: Indiana Site Head, Advanced Accelerator Applications

Subject: Delegation of Authority

You, Dr. Le-Cun Xu, have been appointed Radiation Safety Officer (RSO) and are responsible for ensuring the safe use of radiation. You are responsible for managing the Radiation Protection Program (RPP), identifying radiation protection problems, initiating, recommending, or providing corrective actions, verifying implementation of corrective actions, stopping unsafe activities, and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations, when justified, to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the U.S. Nuclear Regulatory Commission at any time. It is estimated that you will spend approximately 10 hours per week conducting radiation protection activities.

Leamon  
Christopher

Digitally signed by Leamon Christopher  
DN: dc=com, dc=Novartis, ou=people,  
ou=PH, serialNumber=2319377,  
cn=Leamon Christopher  
Date: 2020.03.23 10:59:35 -04'00'

March 23, 2020

Signature of Management Representative

Christopher P. Leamon, Ph.D.

Indianan Site Head and VP Discovery Research

I accept the responsibilities as stated above,

Signature of Radiation Safety Officer

Date

Name

Title

## Song, Taehoon

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**From:** Tran, Frank  
**Sent:** Monday, March 23, 2020 3:25 PM  
**To:** Pavon, Sandy; Song, Taehoon  
**Cc:** Tomczak, Tammy  
**Subject:** FW: RE: Request for additional information regarding the renewal application for NRC License No. 13-32212-01  
**Attachments:** Response to NRC request for additional information.pdf

Dear IM Center:

Please add the attachment to ADAMS for CN 616030.

Thank you,  
-Frank

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**From:** Le-Cun Xu <Le-Cun.Xu@adacap.com>  
**Sent:** Monday, March 23, 2020 3:11 PM  
**To:** Tran, Frank <Frank.Tran@nrc.gov>  
**Subject:** [External\_Sender] RE: Request for additional information regarding the renewal application for NRC License No. 13-32212-01

Hi Frank,

Please find the response to the request for additional information. Should you have any additional questions, please do not hesitate to contact me.

Thanks,

Le-Cun

Le-Cun Xu, Ph.D.  
Radiation Safety Officer  
Research Advisor  
Endocyte, Inc.

***Endocyte is now part of Advanced Accelerator Applications, the Radioligand business of Novartis***

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