



ENDOCYTE

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Frank Tran
License Reviewer
NRC Region 3
Division of Nuclear Materials Safety
2443 Warrenville Rd, Suite 210
Lisle, IL 60532-4352
Ref: Mail Control Number 588347

August 5th, 2015

Dear Mr. Tran,

Thank you for your correspondence. Please find the answers to your questions below;

1) Please specify the chemical and/or physical form of gallium-67, gallium-68, and indium-111 (nonvolatile, oxide, etc.)

- a) Gallium-67 chloride in 0.1 M HCl solution
- b) Gallium-68 chloride in 0.05M HCl solution
- c) Indium-111 chloride in 0.1 M HCl solution

2) Provide names of proposed authorized user who will use gallium-67, gallium-68, and indium-111. Gallium-68 is more hazardous (in term of gamma emitter energy) than other radionuclides that are currently listed in your license, please provide information regarding training and experiences that are relative to the use of gallium-68 for the proposed users.

a) Dr. Le-Cun Xu, our resident radiochemist, will be the primary user and handler of these radionuclides and is listed as an authorized user on our current license. Dr. Xu has the following experience related to gallium-68;

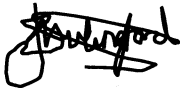
1. Ph.D. of Radiopharmaceutical Chemistry, trained to handle and use all pharmaceutical radioisotopes including gallium-68.
2. Is a member of Society of Nuclear Medicine and Molecular Imaging (SNMMI) since 2000 and has attended the SNMMI annual meeting almost every year since 2000, which has included updated knowledge of gallium-68
3. Directly handled and used many different radioisotopes in Kumamoto University, Purdue University, and Endocyte for the past 20 years
4. Visited the radiochemistry lab of NCM USA, LLC in New York, NY, and watched the handling and use of gallium-68, zirconium-89, and associated PET imaging studies in February, 2015
5. Visited the radiochemistry lab of Radiomedix in Houston, Texas, and watched the handling and use of gallium-68, zirconium-89, and associated PET imaging studies in February, 2015
6. Visited Dr. Mark Green's radiochemistry lab in Indiana University, School of Medicine and watched the handling and use of gallium-68 in April, 2015

August 5, 2015

b) Members of the biology group will be working with conjugates containing these radionuclides in animal studies under the supervision of Dr. Joe Reddy, also listed as an authorized user on our current license. As such, we would appreciate if you could add these radionuclides under Materials and Use associated with Dr. Reddy. Appropriate training will be given to all personnel that will be using these radionuclides according to the stipulations, compliance, and requirements of the NRC.

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

Sincerely yours,

A handwritten signature in black ink, appearing to read "J. Shillingford", written over a horizontal line.

Jonathan M. Shillingford, Ph.D.
Radiation Safety Officer

Tran, Frank

From: Shillingford, Jonathan <jshillingford@Endocyte.com>
Sent: Wednesday, August 05, 2015 9:57 AM
To: Tran, Frank
Subject: [External_Sender] RE: Request for additional information re NRC License No. 13-32212-01
Attachments: 5August2015 - NRC request for additional information.pdf
Importance: High

Good morning, Frank,

Please find enclosed a .pdf document that addresses your request for additional information, as listed below.

I would appreciate if you could confirm receipt of this e-mail for our records.

With kind regards,

Jonathan Shillingford, Ph.D.
Radiation Safety Officer



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From: Tran, Frank [mailto:Frank.Tran@nrc.gov]
Sent: Wednesday, August 05, 2015 8:44 AM
To: Shillingford, Jonathan
Subject: Request for additional information re NRC License No. 13-32212-01

Dear Dr. Shillingford:

We have reviewed your amendment request dated July 23, 2015. In order to complete our review, we will need additional information.

- 1) Please specify the chemical and/or physical form of gallium-67, gallium-68, and indium-111 (nonvolatile, oxide, etc.)
- 2) Provide names of proposed authorized user who will use gallium-67, gallium-68, and indium-111. Gallium-68 is more hazardous (in term of gamma emitter energy) than other radionuclides that are currently listed in your license, please provide information regarding training and experiences that are relative to the use of gallium-68 for the proposed users.

To continue review of your amendment request, we request that you submit your written response by September 1, 2015. Your response must be dated and signed by authorized personnel and please refer Mail Control Number 588347 in your response to facilitate proper mail handling in our office. To expedite the licensing process, you could fax your response to 630-515-1078 or scan and email your response as a pdf file to frank.tran@nrc.gov. If you have any questions or require clarification on any of the information stated above, please do not hesitate to contact me at 630-829-9887 or reply to this email.

Thank you,

Frank Tran

License Reviewer

NRC Region 3/Division of Nuclear Materials Safety

Phone: 630-829-9623

Fax: 630-515-1078

Email: Frank.Tran@nrc.gov



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