

From: Roldan, Lizette
Sent: Friday, April 30, 2010 11:02 AM
To: 'Brian Oyadomari'
Subject: REQUEST FOR ADDITIONAL INFORMATION REGARDING NEW LICENSE APPLICATION, CONTROL NO. 472613
Attachments: nrc313a(anp).pdf

Docket No. 030-38265
Control No. 472613

Dear Mr. Oyadomari:

This is in reference to your response dated April 9, 2010 to our request for additional information in e-mail dated March 23, 2010. Unfortunately, the proposed Authorized Nuclear Pharmacist (ANP), Dr. John Lim is not qualified to perform the duties as the ANP because he is not a pharmacist. In order to issue the license:

- 1) Please propose a qualified individual and provide a copy of the pharmacist license number and issuing entity. Also, choose **one** of the pathways outlined below and provide the following additional documents:
 - a) *For an individual previously identified as an ANP on an NRC or Agreement State license or permit or by a commercial nuclear pharmacy that has been authorized to identify ANPs (10 CFR 32.72(b)(2)(i)):*
 - i) Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC Master Material License broad-scope permittee on which the individual was named an ANP or a copy of an authorization as an ANP from a commercial nuclear pharmacy that has been authorized to identify ANPs, **OR**
 - b) *For an individual qualifying under 10 CFR 32.72(b)(4):*
 - i) Documentation that the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, **AND**
 - ii) Documentation that the individual practiced at a pharmacy, a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC, **OR**
 - c) *For an individual qualifying under 10 CFR 35.55(a):*
 - i) Copy of the certification(s) of the specialty board whose certification process has been recognized under 10 CFR 35.55(a), **AND**
 - ii) Written attestation, signed by a preceptor ANP, that training and experience required for certification have been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved, **AND**
 - iii) If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59, **OR**
 - d) *For an individual qualifying under 10 CFR 32.72(b)(2)(ii):*

- i) Description of the training and experience specified in 10 CFR 35.55(b) demonstrating that the proposed ANP is qualified by training and experience, **AND**
- ii) Written attestation, signed by a preceptor ANP, that training and experience required for certification have been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved, **AND**
- iii) If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

Please Note:

The attached NRC Form 313A (ANP), "Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation [10 CFR 35.55]," may be used to document training and experience for those individuals qualifying under 10 CFR 35.55(a) or (b).

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material; then Regulations, Guidance, and Communications**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region IV Office and refer to Mail Control No. 472613. Please note that you may reply to this letter by return e-mail if you send your response in the form of an attachment and it is signed by management. Your reply may be in writing by letter or facsimile (817-860-8263). If we do not receive a reply from you within **30 days (May 30, 2010)** from the date of this e-mail, we will assume that you do not wish to pursue your application and we will **VOID** your application.

If you have any technical questions regarding this deficiency letter, please call me at (817) 276-6596.

Sincerely,

Lizette Roldán, Ph.D.

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