

From: Sandra Gabriel
To: Larry.Johnston@LPNT.net
Date: Fri, Jan 19, 2007 7:20 PM
Subject: Additional information for NRC license amendment request, mail control 139923

Licensee: Raleigh General Hospital
License No.: 47-18046-01
Docket No.: 03014390
Control No.: 139923

To: Larry Johnston, CNMT, RT(N)

This refers to the letter dated January 2 2007. Please provide the following additional information within 30 days. If you do not respond within 30 days, we will presume that you do not wish to pursue your application. You may mail your signed response or fax it to 610-337-5269, referencing mail control 139923. You may wish to leave a voicemail or e-mail message to alert me when you send the fax.

Please send an e-mail to confirm receipt of this message.

1) You requested to extend the authorizations for Dr. Mercedes Ramas to include 35.300 uses. Please note that there are now 4 subcategories under 35.300 and it is necessary to document supervised cases in each requested subcategory. The submitted preceptor statements indicate that Dr. Ramas completed supervised experience administering I-131 to treat hyperthyroidism. The subcategories under 35.300 are now defined by the radiopharmaceuticals administered rather than by patient diagnosis. The category under which hyperthyroidism treatments typically fall is 35.392: "Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries." Please confirm that your request is to authorize Dr. Ramas for "oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries."

2) Current NRC regulations require a preceptor attestation to be provided in a specified format, as indicated in Part II of the NRC Form 313(AUT) that you submitted with your letter. Because the copy that you submitted was blank please submit a statement that provides the information required by 10 CFR 35.392(c)(3), signed by a 35.300 authorized user who is familiar with Dr. Ramas' training and experience and believes the statement to be accurate. For example: "I attest that Mercedes Ramas, M.D. has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.392(c)(1) and the supervised work and clinical case experience required in 10 CFR 35.392(c)(2) and has achieved a level of competency sufficient to function independently as an authorized user for oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries."

Thank you for your help. If you have any questions, you may e-mail me or call at 610-337-5182. Please note that I will be out of the office from January 22-24.

Sandy Gabriel
Senior Health Physicist
Medical Branch
NRC Region I

Mail Envelope Properties

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From: Sandra Gabriel
Created By: SLG2@nrc.gov

Recipients

LPNT.net
Larry.Johnston (Larry.Johnston@LPNT.net)

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Route
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MESSAGE	3566	Friday, January 19, 2007 7:20 PM

Options

Expiration Date: None
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