From: Donna Janda
To: joan_merton@midhosp.org
Date: Wed, Nov 8, 2006 6:57 PM
Subject: Additional information needed for request to add authorized user

Licensee: Middlesex Hospital
License No. 06-00649-03
Docket No. 03001242
Mail Control No.139399

Subject: Request to add Nancy Rini, M.D., to license as Authorized User

Please send an email to confirm receipt of this message.

To: Ms. Joan Merton, Radiation Safety Officer

In order to continue our review of the request to add Dr. Nancy Rini to your license as an Authorized User for uses under 10 CFR 35.100, 35.200, and 35.300, limited to oral administration of sodium iodide iodine-131 requiring a written directive in quantities less than or equal to 33 millicuries, please provide the following additional information to demonstrate that Dr. Rini meets the requirements of 10 CFR 35.190, 35.290, and 35.392:

1. Item 5 of NRC Form 313A, which was submitted with your letter dated August 11, 2006, documents 60 clock hours of classroom and laboratory training for Dr. Rini in the areas required by 10 CFR 35.290(c)(1)(i). Please clarify whether the number of clock hours includes 60 hours in each area listed in Item 5 or a total of 60 hours for all areas listed in Item 5. Please note that to be authorized for medical use under 10 CFR 35.200, Dr. Rini must have a minimum of 80 hours of classroom and laboratory training in all of the areas listed in 10 CFR 35.290(c)(1)(i).

2. According to Item 6a of NRC Form 313A, Dr. Rini has a total of 44 hours of supervised experience working with technecium-99m. 10 CFR 35.290(c)(1) requires that an authorized user of unsealed byproduct material for the uses authorized under 10 CFR 35.200 to be a physician who has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. In addition to the information discussed in Item 1 above, the training and experience must include work experience, under the supervision of an authorized user who meets the requirements in 10 CFR 35.190 and either 35.290 or 35.290(c)(1)(ii)(G) and 35.390, or equivalent Agreement State requirements, involving -

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging

and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs.

Please provide documentation that Dr. Rini has the required amount of supervised work experience in the areas described in (A) through (G) above.

3. In order for Dr. Rini to be authorized for 10 CFR 35.300 uses, limited to oral administration of sodium iodide iodine-131 requiring a written directive in quantities less than or equal to 33 millicuries, please provide documentation that Dr. Rini has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity;
(D) Radiation biology; and
(E) Chemistry of byproduct material for medical use

4. In addition to documentation of Dr. Rini's classroom and laboratory training as described in Item 3 above, please provide documentation of Dr. Rini's work experience under the supervision of an authorized user who meets the requirements in 10 CFR 35.390, 35.392, 35.394, or equivalent Agreement State regulations. A supervising authorized user who meets the requirements in 10 CFR 35.390(b) must also have experience in administering dosages as specified in 10 CFR 35.390(b)(1)(ii)(G)(1) or (2). The work experience must involve the areas listed in Item 2(A) through (E) above and administering dosages to patients or human research subjects that includes at least 3 cases involving the oral administration of less than or equal to 33 millicuries of sodium iodide I-131.

5. The preceptor attestation from Dr. Robert Quaife provided with your amendment request does not contain all of the required information needed to complete our review. Please provide the following:

(A) A written attestation signed by Dr. Quaife that he (Dr. Quaife) meets the requirements of an authorized user in 10 CFR 35.390 or equivalent Agreement State regulations;

(B) A statement from Dr. Quaife that Dr. Nancy Rini has satisfactorily completed the requirements in 10 CFR 35.290(c)(1) and 35.392(c)(1) and (c)(2) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100, 35.200, and 35.392; and

(C) A copy of the materials license which authorizes Dr. Quaife for the equivalent uses of 10 CFR 35.100, 35.200, and 35.392 materials.

Because your response will contain license commitments, please have your response signed and dated by an individual authorized to make binding commitments and sign official documents on behalf of Middlesex Hospital. Please be sure to include Mail Control No. 139399 in your response. Please note that you may not reply to this email by return email. Your reply must be in writing by letter or facsimile (610-337-5269). If we do not receive a reply from you within 30 calendar days from the date of this email, we will assume that you do not wish to pursue your application.

If you have any questions regarding these items, please call me at 610-337-5371.

Thank you for your attention to this matter.

Sincerely,

Donna Janda
Health Physicist, Medical Branch

Division of Nuclear Materials Safety
U.S. NRC Region I

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Subject:	Additional information needed for request to add authorized user
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midhosp.org
joan_merton (joan_merton@midhosp.org)

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