From: Donna Janda
To: cchipley@srmedicalcenter.org
Date: Wed, Aug 9, 2006 11:01 AM
Subject: Additional information needed for amendment request

Licensee: Schneider Regional Medical Center
License No. 55-17986-01
Docket No. 03013764
Mail Control No. 139076
ATTN: Charles Chipley III, Radiation Safety Officer

Subject: Additional information needed for license amendment request to add authorized user

Dear Mr. Chipley:

In your letter dated June 13, 2006, you requested to authorize Dante P. Galiber, M.D. for 35.100, 35.200, 31.11, and oral administration of sodium iodide iodine-131 for imaging and localization studies. Dr. Galiber is currently listed on NRC license 55-25547-01 for 35.100, 35.200, and 31.11 authorizations; therefore, he can be authorized for these uses on Schneider's NRC license. In accordance with 10 CFR 35.392(c)(1), (c)(2), and (c)(3), in order to approve Dr. Galiber for oral administration of sodium iodide iodine-131 for imaging and localization studies, please provide the following:

A. Documentation of successful completion of 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide iodine-131 for procedures requiring a written directive. The training must include:

(i) radiation physics and instrumentation;
(ii) radiation protection;
(iii) mathematics pertaining to the use and measurement of radioactivity;
(iv) chemistry of byproduct material for medical use; and
(v) radiation biology; and

B. Documentation of work experience, under the supervision of an authorized user who meets the requirements in 10 CFR 35.390(a), 35.390(b), 35.392, 35.394, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in 35.392(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 -

(i) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(ii) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
(iii) calculating, measuring, and safely preparing patient or human research subject dosages;
(iv) using administrative controls to prevent a medical event involving the use of byproduct material;
(v) using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
(vi) 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 iodine-131; and

C. Provide a written attestation that the individual has satisfactorily completed the requirements described in paragraphs A and B above and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 10 CFR 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in 10 CFR 35.390, 35.392, or 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in 35.390(b), must also have experience in administering dosages as specified in 10 CFR

35.390(b)(1)(ii)(G)(1) or (2). A link to NRC Form 313A, Medical Use Training and Experience and Preceptor Attestation, is provided: http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a.pdf .

Please note that the training and experience described above must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed. If Dr. Galiber's training and experience was obtained before June 2006, please submit documentation of related continuing education and experience.

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 the licensee. Please be sure to include Mail Control No. 139076 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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