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MATERIALS LICENSING BRANCH



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CONVERSATION RECORD

	TIME	DATE
	1:30 p.m.	December 16, 2011
NAME OF PERSON(S) CONTACTED	TELEPHONE NO.	ORGANIZATION
Christopher Durbin, Ph.D.	(314) 205-6218	St. Luke's Hospital 232 S. Woods Mill Road Chesterfield, MO 63107
REPRESENTED PERSON or PERSONS		ORGANIZATION
SUBJECT		
License No.: 24-01570-03		Control No.: 576099

SUMMARY

SUBJECT: Request to add Amit Kirit Bhatt, M.D. for 35.300, 35.400, 35.600 materials/uses to NRC License No. 24-01570-03.

Informed Dr. Durbin that we have completed review of their request, and have noted the following deficiencies:

RE: Submitted NRC Form 313A (AUT) dated June 9, 2011 (relative to 35.300 materials/uses, specifically parenteral administration of beta-emitting nuclides):

(1) Part I, Item 3.a. specifies 670 total hours of didactic classroom and laboratory training; Part I, Item 3.b. indicates 225 hours of supervised work experience using radionuclides (check boxes for 35.390, 35.392, 35.354, and 35.396 indicated). 10 CFR 35.390 requires a total of 700 hours of training and experience, a minimum of 200 hours of which must be classroom and laboratory-based basic radiation safety-related training and the remainder actual supervised work experience. Although not stated explicitly in 35.390, it is implicit that the individual undergoing training have approximately 500 hours of supervised work experience. The classroom and laboratory hours indicated equal 17 weeks (at full 40-hours) of basic radiation training.

The licensee was requested to address the disparity between hours indicated under Item 3.a and 3.b, to ensure that they are accurate.

(2) Part II – Preceptor Attestation, First Section. Check boxes for 35.392 and 35.394 are checked, attesting to completion of 80 hours of classroom/laboratory training for these uses; however, these have no relevance to this particular preceptor attestation, and should not have been checked, since both of these sections pertain exclusively to oral administration of iodine-131, and not to satisfying the requirements for authorization in parenteral administration of beta-emitting and low-energy gamma radionuclides. (Also reference Part II – Preceptor Attestation, Second Section and Third Section of this particular Form 313A (AUT) as well).

The licensee was requested to make the necessary corrections to the submitted Form.

(3) Part II, Fourth Section: The check box for 35.396 under "Board Certification" was checked and should not have, as it was stated and established that Dr. Bhatt is not certified by a medical specialty board recognized by the NRC.

The licensee was requested to make the necessary corrections to the submitted Form.

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- (4) Part II, Fifth Section: Supporting information for the preceptor, Kristin Bradley, was not provided in this application nor was it indicated that this individual is a physician. The licensee was requested to provide a copy of Wisconsin License No. 24-123-01, University of Wisconsin Radiation Oncology, and, assuming it is a broadscope license, a copy of the permit that names Kristin Bradley as an authorized user for the materials and uses for which this individual is preceptoring proposed authorized user, Dr. Bhatt.

RE: Submitted NRC Form 313A(AUT) dated August 30, 2011, (relative to 35.300 materials/uses, specifically oral administration of sodium iodide iodide-131, in quantities less than and greater than 33 millicuries (mCi):

- (1) Part I, Item 3.a. specifies 670 total hours of didactic training obtained; Part I, Item 3.b. indicates 225 hours of experience using radionuclides. However, none of the check boxes for 3.b were checked. 10 CFR 35.390 requires a total of 700 hours, a minimum of 200 hours of which must be classroom and laboratory-based basic radiation safety training, and the remainder actual supervised work experience.

The licensee was requested to address the disparity between hours indicated under Item 3.a and 3.b, to ensure that they are accurate.

- (2) Item 3.b. of Part I of the form is not completed (No check boxes are checked).

The licensee was requested to make the necessary correction to the submitted Form.

- (3) The Supervising Individual for Supervised Work Experience (Part I, Item 3.b) is not indicated on this NRC Form 313A (AUT), nor is a referenced license number if the supervising individual was an authorized user.

The licensee was requested to make the necessary corrections to the submitted Form. It was also pointed out to the licensee that it is reasonable to assume that Kristin Bradley is not authorized for Oral NaI-131 uses, based on the previous Form 313A (AUT), and therefore, could not be the Supervising Individual for this block of 3.b., nor could Dr. Butler, the preceptor for this Form, as he does not appear to be associated with University of Wisconsin Radiation Oncology, the location indicated as where the supervised work experience took place.

- (4) According to Part I, Item 3.c. of this form, supervised clinical case experience was received by the proposed authorized user in the oral administration of I-131 in quantities greater than 33 mCi at University of Wisconsin, and there is no indication as from whom this supervised case experience was received (See note in (3) above relative to Kristin Bradley. If supervised clinical casework involving I-131 was received at University of Wisconsin, the supervising individual will need to be indicated.

These points were brought to the licensee's attention with a request that they be addressed.

- (5) Part II – Preceptor Attestation, First Section: The check boxes for 35.392 and 35.394 are checked. This may not be necessary, but is likely not a significant issue.

- (6) Part II – Preceptor Attestation, Third Section is required to be checked for the requested authorization, and is not, which is a significant omission that must be corrected for action to proceed.

The licensee was requested to make the necessary correction to the submitted Form.

RE: Submitted NRC Form 313A (AUS) dated June 8, 2011, relative to 35.400 and 35.600 (remote afterloader unit(s)):

- (1) Part 1, Item 3.a. specifies 610 total hours of didactic classroom and laboratory training completed. Part I, Item 3.b. indicates 230 hours of supervised work and clinical experience related to 35.400 materials and uses. 10 CFR 35.490 requires a total of 700 hours, 200 hours of which is classroom/laboratory training in basic radiation safety, and the 500 hours of supervised work experience pertaining to 35.400 materials/uses. The 230 hours indicated does not meet the regulatory requirement.

The licensee was requested to address this point.

- (2) A copy of Wisconsin License 25-1323-01, identifying Kristin Bradley as an authorized user/supervising individual for the supervised work experience, was not provided in the application.

A copy of this license, along with the sub-license or permit naming Kristin Bradley as an authorized user was requested.

Dr. Durbin agreed to provide necessary information, clarifications and corrections. He stated that would take several weeks to obtain the information, review it and submit it. It was agreed that this requested action would be closed at this time in order to provide the licensee the time needed to resubmit all the information necessary to demonstrate compliance with the requirements of Part 35 for adding Dr. Bhatt to the license for the authorizations requested.

Based on this conversation, the requested action [Control No. 5760999] will be issued only in part, (i.e., to delete Drs. Weyman and George from the license).

NAME OF PERSON DOCUMENTING CONVERSATION

Dennis P. O'Dowd

Dennis P. O'Dowd

|SIGNATURE

|DATE December 16, 2011

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