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Health Physicist
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U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

TELECON & FAX TRANSMITTAL

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CONVERSATION RECORD

TIME	DATE
04:54 am	January 11, 2012
(Follow-up: January 13, 2012 at 11:19 am)	

NAME OF PERSON(S) CONTACTED	TELEPHONE NO.	ORGANIZATION
Richard Keys Nuclear Med Consultant BJSP	636-248-0353	Barnes-Jewish St. Peter's Hospital

SUBJECT
License No.: 24-18968-01 Control No.: 576224

SUMMARY

We have reviewed your letter dated October 5, 2011, requesting an amendment to your byproduct materials license, specifically, that Punita Gupta, M.D. be added as an Authorized User (AU) on the license for 10 CFR 35.100, 35.200, and 35.300 (limited to Iodine-131 (I-131), oral administration of sodium iodide-131 in quantities less than or equal to 33 millicuries (mCi). The following additional information is needed:

1. The documentation submitted in support of that part of the request for 35.100 and 35.200 authorization for Dr. Gupta, specifically, Form 313A (AUD), indicates in Section 3.a. of Part I, a total of 700 hours of classroom and laboratory training obtained at Tufts Medical Center, (i.e., the total of the "clock hours" listed for each of the five basic radiation subject areas (ref. 10 CFR 35.290(c)(1)(i))); however, the statement in the first block under "Location of Training" describes that a "minimum of 80 hours of classroom and laboratory training in basic radionuclide handling techniques applicable to medical use" was obtained. In addition, Part II of the submitted form also indicates a minimum of 80 hours of classroom/laboratory training. Please address this discrepancy and provide necessary clarification and explanation as to whether Dr. Gupta obtained a minimum of 80 hours or 700 hours (approximately 15 – 17 weeks) of classroom/laboratory training in these subject areas. Note that any and all revisions or corrections made to NRC Form 313A for Dr. Gupta will need to be signed by the preceptor and submitted as complete forms.

2. Item 3.b of Part I of the Form 313A(AUD) specifies only 80 hours of actual supervised work experience for Dr. Gupta, which appears to be contrary to the statement included in Item 3.a of this form, which indicates 700 hours of total training and experience (80 of which was classroom/laboratory training). This point needs additional clarification. Please reference paragraph (c)(1) of 10 CFR 35.290, as well as Section 8.12 (Item 7) and Appendix D of NUREG-1556, Vol. 9, Rev. 2 for assistance in preparing your response. Appendix D may be found at:

   http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/sr1556v9r2-final.pdf#app-d

3. The documentation submitted in support of that part of the request for limited 35.300 authorization

(oral administration of I-131 in quantities less than or equal to 33 mCi) for Dr. Gupta, specifically, Form 313A (AUT), indicates in Section 3.a. of Part I, a total of 700 hours of classroom and laboratory training obtained at Tufts Medical Center, (i.e., the total of the "clock hours" listed for each of the five basic radiation subject areas (ref. 10 CFR 35.390(c)(1)(i)) and 10 CFR 35.392(c)(1))); however, the statement in the first block under "Location of Training" indicates that a "minimum of 200 hours of classroom and laboratory [training]" was obtained. In addition, Part II of the submitted form indicates both, a minimum of 200 hours of classroom/laboratory training ("Training and Experience" under 35.390, First Section, and a minimum of 80 hours of classroom/laboratory training, under 35.392, First Section. Please address these discrepancies and provide necessary clarification and explanations as to whether Dr. Gupta obtained 700 hours (approximately 15 – 17 weeks) of classroom/laboratory training in these subject areas, or a minimum of 200 hours, or 80 hours. Note that any and all revisions or corrections made to NRC Form 313A for Dr. Gupta will need to be signed by the preceptor and submitted as complete forms.

4. Item 3.b of Part I of the Form 313A(AUT) appears to specify completion of 80 hours of actual supervised work experience for Dr. Gupta, although a statement is included under the block for "Location of Experience/License" which indicates successful completion of 80 hours of classroom/laboratory training. (Item 3.a indicates 700 hours of (total) training and experience. This point needs additional clarification. Please reference paragraph (c)(1) of 10 CFR 35.392, as well as Section 8.12 (Item 7) and Appendix D of NUREG-1556, Vol. 9, Rev. 2, for assistance in preparing your response.

5. 10 CFR 35.59, "Recentness of Experience," requires that the training and experience specified in Subparts B, D, E, F, G, and H of Part 35 to 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. Based on the documentation submitted, including the cases involving personal participation for oral administration of I-131 in quantities less than or equal 33 mCi, additional information regarding continuing education for Dr. Gupta will need to be submitted in support of this request.

6. Please submit a copy of the Agreement State License for Tufts Medical Center, and other specific information, as applicable, to confirm that the preceptor is authorized for the uses requested by the proposed AU.

ACTION REQUIRED

As we cannot issue an amendment at this time we are "voiding" this request in order to enable you to prepare a quality application without time constraints. This is done without prejudice to the resubmission of your request at a later date. Upon receipt of your response we will resume our review. Address your written response to my attention at the above address, per the instructions above.

Please note that a "void" is an administrative procedure that puts your amendment request "on hold" (i.e., takes it out of our active casework database), until you reactive it via submission of a written response, thereby, affording you additional time to prepare a quality response that meets the requirements of 10 CFR 30.9, and other applicable regulations.

Please direct any questions you have to me at (630) 829-9573 or (800) 522-3025 ext. 9573.

Please also be reminded of the provisions in 10 CFR 30.9, "Completeness and accuracy of information." 10 CFR 30.9(a) specifies that "[I]nformation provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be *complete and accurate in all material respects.*"

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Dennis P. O'Dowd	Dennis P. O'Dowd	01/13/2012