



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

January 18, 2007

Docket No. 03036963
Control No. 139913

License No. 29-31058-01

Ashok Kumar, M.D.
Owner
1338 How Lane
North Brunswick, NJ 08902

SUBJECT: ASHOK KUMAR, M.D., REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL
NO. 139913

Dear Dr. Kumar:

This is in reference to your letter dated December 26, 2006 requesting to amend Nuclear Regulatory Commission License No. 29-31058-01. In order to continue our review, we need the following additional information:

1. As required in 10 CFR 35.290, the work experience involving 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, did not appear to be under the supervision of an authorized user who meets the requirements in 10 CFR 35.290, or 35.290(c)(1)(ii)(G), and 35.390, or equivalent Agreement State requirements. Additionally, the written attestation, signed by a preceptor authorized user who meets the requirements in 10 CFR 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, must state that you have satisfactorily completed this experience attribute. Please submit the name of the authorized user, who meets the requirements in 10 CFR 35.290, or 35.290(c)(1)(ii)(G), and 35.390, or equivalent Agreement State requirements who supervised you, along with their supporting documentation demonstrating that they are an authorized user, who meets the requirements in 10 CFR 35.290, or 35.290(c)(1)(ii)(G), and 35.390, or equivalent Agreement State requirements. If this experience attribute was satisfactorily completed as reviewed by your preceptor, Dr. Ajay Agarwala, then include this experience attribute in the preceptor's attestation statement.
2. The attestation statement from your preceptor, Dr. Ajay Agarwala, did not state that you could function **independently** as an authorized user. The attestation statement need to include that you have achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200 as required in 10 CFR 35.290.

A. Kumar
Ashok Kumar, M.D.

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3. Please include the dates and locations where the work experience attributes were obtained. If work experience was under the supervision of a different authorized user than your preceptor, Dr. Ajay Agarwala, please submit documentation demonstrating that they are an authorized user, who meets the requirements in 10 CFR 35.290, or 35.290(c)(1)(ii)(G), and 35.390, or equivalent Agreement State requirements.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Toolkit Index Page**. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 139913. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5366.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by James P. Dwyer

Dennis R. Lawyer
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:
Robert Tokarz, Radiation Safety Officer

A. Kumar
Ashok Kumar, M.D.

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SUNSI Review Complete: DLawyer

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DATE	1/18/2007						

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