

ASHOK KUMAR, M.D., F.A.C.C.

Member American College Physicians
Diplomat American Board of Internal Medicine
Diplomat American Board of Cardiovascular Disease
Clinical Assistant Professor of Medicine, UMDNJ - Rutgers Medical School

M816

J-6

February 12, 2007

Dennis R. Lawyer
Health Physicist
Commerical and R&D Branch
Division of Nuclear Safety
475 Allendale Road
King of Prussia, PA. 19408

29-31058-01

DOCKET NO: 03036963
CONTROL NO: 139913

**SUBJECT: REQUEST FOR ADDITIONAL INFORMATION CONCERNING
APPLICATION FOR AMENDMENT TO LICENSE**

Dear Mr. Lawyer:

Enclosed please find the information you requested in order to continue your review.

Sincerely,


A. Kumar, M.D., F.A.C.C., F.A.C.P.

RECEIVED
REGION 1

2007 FEB 13 AM 10:30

139913

NMSS/RCM MATERIALS-002

January 23, 2007

USNRC, Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415
ATTN: Dennis R. Lawyer

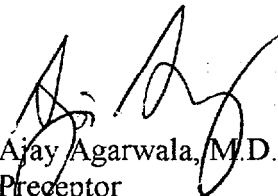
RE: Control # 139913

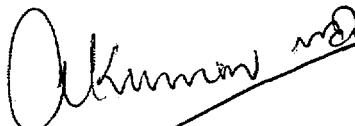
Dear Dennis Lawyer:

As the Preceptor supervisor of Ashok Kumar, I attest that as part of his training, Ashok Kumar, M.D. did provide documentation that he satisfactorily completed the experience attribute of Elution of a generator 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. I also attest that Ashok Kumar has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10CFR35.200. I am enclosing a copy of NRC license. I am enclosing a copy of license 29-31058-01 listing me as an authorized user for 10CFR35.200 medical uses.

Ashok Kumar received under my supervision his work experience at his facility located at 1338 How Lane, North Brunswick, New Jersey from Jan 17th 2006 to NOV 29th 2006.

Sincerely,


Ajay Agarwala, M.D.
Preceptor


Ashok Kumar, M.D./owner

NRG FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 of 2 PAGES

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Ashok Kumar, M.D.	3. License No. 29-31058-01
2. 1338 How Lane North Brunswick, New Jersey 08902	4. Expiration Date: July 31, 2015
	5. Docket No. 090-36963

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material permitted by 10 CFR 35.200	Any	A. As needed

9. Authorized use:

A. Any imaging and localization as permitted by 10 CFR 35.200.

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at 1338 How Lane, North Brunswick, New Jersey.
- 11. The Radiation Safety Officer (RSO) for this license is Robert J. Tokarz.
- 12. Licensed material is only authorized for use by, or under the supervision of:
 - A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
 - B. Authorized user and use: Ajay K. Agarwala, M.D. 35.200
- 13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.


HEALTHExcel CARDIOLOGY ASSOCIATES
906 OAKTREE ROAD, SUITE J
SOUTH PLAINFIELD, NEW JERSEY 07080
Phone (908) 222-8700
Fax (908) 222-8770

This is to attest that Ashok Kumar, M.D., F.A.C.C. has presented evidence that he has satisfactorily completed the following training and experience as stipulated in 10 §35.290. The doctor has:

1. Completed 100 hours of classroom and laboratory training in basic radionuclide handling techniques applicable to be medical use of unsealed byproduct material for imaging and localization studies that included:
 - a) Radiation Physics and instrumentation
 - b) Radiation Protection
 - c) Mathematics pertaining to the use and measurement of radioactivity
 - d) Chemistry of byproduct material for medical use
 - e) Radiation Biology

2. Completed 600 hours of work experience, under the supervision of an authorized User who meets the requirement of 10 §35.290, if an authorized user trained before 24 October 2005, 10 §35.290 or equivalent Agreement State requirements. This work experience included, but was not limited to:
 - 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.

The classroom and laboratory training and work experience should provide a level of knowledge to permit the doctor to function, with regards to these areas, as an authorized user for diagnostic imaging and localization studies.


Preceptor Signature

Date 12/19/06

29-31058-01
Materials License #

Ajay Agarwala, M.D.
Preceptor Full Name (Print or Type)

US Nuclear Regulatory Commission
Issued By



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

FW Mm

January 18, 2007

Docket No. 09036969
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.]*

*CHR **

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

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) 337-6366.

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,



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

cc:
Robert Tokarz, Radiation Safety Officer