

United States Nuclear Regulatory Commission  
Region I  
475 Allendale Road  
King of Prussia, PA 19406-1415

June 19, 2008

Attention: Medical Licensing Division

Re: Materials License 29-14017-01

Dear Sir or Madam:

Kimball Medical Center wishes to amend its materials license referenced above. We would like to add Dr. Lev Pukin and Dr. Alex Langman as authorized users for uses under 10CFR35.100 and 10CFR35.200.

Dr. Pukin was listed as an authorized user on the State of Florida license for the University Community Hospital, Inc. located in Tampa, Florida. A copy of the radioactive materials license for University Community Hospital is enclosed. Please note that uses 64E-5.626 and 64E-5.627 on the license correspond to uptake, dilution, and excretion studies and imaging and localization studies, respectively, for which a written directive is not required.

Please note the following materials enclosed in consideration of Dr. Langman's application for Authorized User status:

1. The completed NRC Form 313A, signed by Dr. Langman's preceptor, Dr. Leonard Freeman.
2. Documentation that the 1000 clock hours of work experience described in Item 6a of this form includes work experience under the supervision Leonard Freeman, M.D. involving:
  - 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.

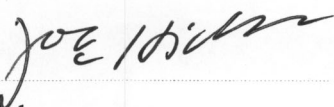
142564  
NMSS/RGN1 MATERIALS-002

Kimball Medical Center requests an exemption to the requirement in §§ 35.290, or 35.290(c)(1)(ii)(G) requiring experience 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. Kimball Medical Center orders only unit doses, and neither utilizes generators nor has any plans to do so.

3. A written attestation signed by Dr. Freeman that he (Dr. Freeman) meets the requirements of an authorized user in 10 CFR 35.190, and either 35.290.
4. A statement from Dr. Freeman that Dr. Alex Langman has satisfactorily completed the requirements in 10 CFR 35.290(c)(1) and has 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.
5. A copy of Dr. Freeman's, Montefiore Medical Center materials license which authorizes Dr. Freeman for the equivalent uses of 35.100 and 35.200 materials.

If you have any questions or require additional information in consideration of this amendment request, please do not hesitate to contact myself or our consultant Medical Physicist, Karen Wheeler, M.S., D.A.B.R. at (908) 788-9440 ext. 45 or via email at [kwheeler@biomedphysics.com](mailto:kwheeler@biomedphysics.com).

Sincerely,



Joe Hicks  
Executive Director

STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
BUREAU OF RADIATION CONTROL

RADIOACTIVE MATERIALS LICENSE  
SUPPLEMENTAL SHEET

UNIVERSITY COMMUNITY HOSPITAL, INC.  
3100 East Fletcher Avenue  
Tampa, FL 33612-4688

With reference to correspondence dated May 1, 2003, State of Florida Radioactive Materials License Number 549-1 is hereby amended.

TO CHANGE CONDITION 12 TO READ:

CONDITIONS

12. A. The following individuals or persons under their supervision are authorized for the materials and uses as indicated:

Authorized Materials and Uses as Described in Items 6, 7, 8, and 9	Names
64E-5.626, 64E-5.627, 64E-5.630 and xenon 133	Evan Wynne Harris, M.D. Robert K. Smith, M.D. Ralph E. Baker, M.D. Robert G. Carroll, M.D. Chester Kay, M.D. Jeffrey Bisker, M.D.
64E-5.626, 64E-5.627, 64E-5.630 and 64E-5.631(3)	Edward A. Eikman, M.D.
64E-5.630, 64E-5.631(3) and 64E-5.632	John Koval, M.D.
64E-5.626, 64E-5.627, 64E-5.630 (except gold 198 and iodine 131 for the treatment of thyroid carcinoma) and xenon 133	Joseph R. Patterson, M.D.
64E-5.626, 64E-5.627, 64E-5.630 (except gold 198, strontium 89, yttrium 90, samarium 153, phosphorus 32 and iodine 131 for the treatment of thyroid carcinoma) and xenon 133	Bryan I. Kaufman, M.D.

1C

License Number: 549-1  
Amendment No.: 101  
Control Number: 20030505-0660

HQ

Category: [5B]

Page 1 of 4 Page(s)

Expiration Date: 02/28/2005



STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
BUREAU OF RADIATION CONTROL

RADIOACTIVE MATERIALS LICENSE  
SUPPLEMENTAL SHEET

12. A continued:

Authorized Material and Uses as Described in Items 6, 7, 8, and 9	Name
64E-5.626, 64E-5.627, and 64E-5.630 (except gold 198 and iodine 131 for the treatment of thyroid carcinoma)	Albert Berje, M.D.
64E-5.630 and 64E-5.632	Jay L. Friedland, M.D.
64E-5.626, 64E-5.627 and xenon 133	Ellis B. Norsoph, M.D. J.L. Beauchamp, M.D. Douglas L. Eiland, M.D. David V. Jelaso, M.D. Daniel S. Williamson, M.D. Frederick J. Laufer, M.D. Brian H. Breslaw, M.D. Mark J. Timken, M.D. Maria Del Pilar Duque, M.D. Linwood James Henry, M.D. Joseph Charles, M.D. Yuvraj Singh, M.D. Jon Eric Anderson, M.D. Jonathan Berger, M.D. Upen Patel, M.D. Anil Patel, M.D. Beatrix Araiza, M.D. Theresa Witt-Tilton, M.D. Louis Bernhardt, M.D. Larry Hurst, M.D. James J. Okoh, M.D. Fredrick Carl Wendt, M.D. Kelly Seid, M.D. Paul Slawek, M.D. Beata Nowakowska, M.D.

27

License Number: 549-1  
Amendment No.: 101  
Control Number: 20030505-0660

HQ

Category: [5B]

Page 2 of 4 Page(s)

Expiration Date: 02/28/2005



STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
BUREAU OF RADIATION CONTROL

RADIOACTIVE MATERIALS LICENSE  
SUPPLEMENTAL SHEET

12. A. continued:

Authorized Materials and Uses as Described in Items 1, 2, 3, and 9	Names
64E-5.626, 64E-5.627 and xenon 133	Lev Pukin, M.D. Jay Torres, M.D. Frank Taylor, M.D. Michael Sorbello, D.O. Amit Gupta, M.D. Michael Hale, M.D. James W. Maurer, M.D. John Soong, M.D. James McDowall, M.D. Jerry Wayne Burke, M.D. Hulusi Ergun, M.D. Kuei-Tang Gordon Hsiang, M.D. Scott Raymond Shay, M.D. Luis A. Jimenez, M.D. Paul Hahn, M.D. Stewart M. Braunstein, M.D.
64E-5.627 for cardiac studies only	Robert Betzu, M.D. Ranchhod N. Khant, M.D. Mitch O'Hara, M.D. Stephen Mester, M.D. Arjumand Hashmi, M.D. Humberto Coto, M.D.
64E-5.627 for cardiac studies only (except generators and reagent kits)	Peter Berman, M.D. Mario Canedo, M.D. Vasco M. Marques, M.D. William Capo, M.D. Sami Elchahal, M.D. Juan Garcia, M.D. Lowell Gerber, M.D.

24

**STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
BUREAU OF RADIATION CONTROL**

**RADIOACTIVE MATERIALS LICENSE  
SUPPLEMENTAL SHEET**

12. A continued:

Authorized Medical Purposes Described in Items 1, 2, 3, and 9	Names
64E-5.627 for cardiac studies only (except generators and reagent kits)	Kevin Klein, D.O. Eduard Pascual, M.D. Rolando Rodriguez, M.D. Praveen Rohatgi, M.D. Hoshedar Tamboli, M.D. Aung Tun, M.D. Max F. Rattes, M.D. Raquel C. Martin, M.D. Shahid Malik, M.D. Arlene D. Lobo, M.D. Sunil Gupta, M.D.

- B. The radiation safety officer is Robert M. Sanders.
- C. Radiologic technologists who use and administer radioactive materials or perform brachytherapy or teletherapy procedures under the general supervision of an authorized user shall hold a valid certificate as required by Chapter 468, F.S.

Issuance Date: MAY 20 2003

For the Bureau of Radiation Control:

**ORIGINAL SIGNED BY:  
MARK LUNDBERG**

Mark Lundberg  
Environmental Specialist  
4052 Bald Cypress Way, Bin C21  
Tallahassee, FL 32399-1741  
(850) 245-4545

License Number: 549-1  
Amendment No: 101  
Control Number: 20030505-0660

HQ

Category: [5B]

Page 4 of 4 Page(s)

Expiration Date: 02/28/2005

TOTAL P. 04

**MEDICAL USE TRAINING AND EXPERIENCE  
AND PRECEPTOR ATTESTATION**APPROVED BY OMB: NO. 3150-0120  
EXPIRES: 10/31/2008**PART I - TRAINING AND EXPERIENCE****Note:** Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulation (10 CFR Part 35)

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

ALEX LANDEMAN, M.D.

2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed

NJ

**3. CERTIFICATION**

- a. Provide a copy of the board certification. (Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a); continue if applying under other subparts.)
- b. Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); 35.51(c); 35.290(c)(1)(ii)(G) for AU seeking 35.200 authorization; 35.390(b)(1)(ii)(G); 35.396(d)(1) and 35.396(d)(2); 35.590(c); or 35.690(c).
- c. Provide completed Part II Preceptor Attestation, Items 11a through 11d.
- Stop here after completing items 3a, 3b, and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements.

**4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO),  
AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR  
AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS**

- a. Provide a copy of the license or broadscope permit listing the current authorization and (b) or (c)
- b. Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c).
- c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).

**5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)**

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	Montefiore Med. Center 111 EAST 210 ST. BRONX, NY 10467	200	7/98-6/02
Radiation Protection	"	150	"
Mathematics Pertaining to the Use and Measurement of Radioactivity	"	150	"
Radiation Biology	"	100	"
Chemistry of Byproduct Material for Medical Use	"	50	"
OTHER			





## MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

## 6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.690(c)

Training Element	Type of Training *	Location and Dates
1000 HOURS DURING DIAGNOSTIC RADIOLOGY Residency	Diagnostic RadioLOGY	Montefiore Med. Center 111 EAST 210 ST. BRONX, NY 10467

\* Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic, or vendor training.

## 7. FORMAL TRAINING

Physicians (for uses under 35.400 and 35.600) and Medical Physicists

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)
Residency in DIAGNOSTIC RADIOLOGY	NYC Licence # 75-28805-01	7/98-6/02	ACGME

## 8. RADIATION SAFETY OFFICER (RSO) – ONE-YEAR FULL-TIME EXPERIENCE

- ☐ YES Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervision.  
☒ N/A of \_\_\_\_\_ the RSO for License No. \_\_\_\_\_

## 9. MEDICAL PHYSICIST – ONE-YEAR FULL-TIME TRAINING/WORK EXPERIENCE

- ☐ YES Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics  
(35.961) or medical physics (35.51) under the supervision of \_\_\_\_\_  
☒ N/A who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51);

and

- ☐ YES Completed 1 year of full-time work experience (at location providing radiation therapy services described  
and for topics identified in item 6a) for (specify use or device) \_\_\_\_\_  
☒ N/A under the supervision of \_\_\_\_\_ who is a medical physicist (35.961) or meets  
requirements for Authorized Medical Physicists (35.51) (specify use or device) \_\_\_\_\_

## MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

## 10. SUPERVISING INDIVIDUAL -- IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in 10 CFR Part 35, provide the following information for each):

A. Name of Supervisor

LEONARD M. FREEMAN,  
MD

B. Supervisor is:

☒ Authorized User☐ Authorized Medical Physicist☐ Radiation Safety Officer☐ Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s)

for medical uses in Part 35, Section(s)

D. Address

DEPT. OF NUCLEAR MEDICINE  
MONTEFIORE MED. CENTER  
111 EAST 210 ST.  
BRONX, NY 10467

E. Materials License Number

NY CITY #  
75-28805-1

## PART II -- PRECEPTOR ATTESTATION

**Note:** This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet training requirements in 35.590 or Part 35, Subpart J (except 35.980).

I attest the individual named in Item 1:

11a.  
☒has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s)  
as documented in section(s) of this form.CONFORMS TO NYC ARTICLE  
175.01 - 175.116 OF THE  
rules of NY  
CITY

11b. Select one

☐  
☒ N/Ameets the requirements in ☐ 35.50(e) ☐ 35.51(c) ☐ 35.390(b)(1)(ii)(G) ☐ 35.690(c) for  
types of use, as documented in section(s) of this form.

11c.

☐  
☒has achieved a level of competency sufficient to independently operate a nuclear pharmacy (for 35.980); **OR**has achieved a level of competency sufficient to function independently as an authorized **USER OF**  
**RADIOPHARMACEUTICALS** for **General Diagnostic** (or units); **OR**☐has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety  
Officer for a medical use licensee; **OR**☐ N/A

11d.

☐  
☒I am an Authorized Nuclear Pharmacist; **OR** I am a Radiation Safety Officer; **OR**

I meet the requirements of

section(s) of 10 CFR Part 35

or equivalent Agreement State requirements to be a preceptor

☐ AU

or

☐ AMP

for the following byproduct material uses (or units):

NYCITY # 75-2885-01

A. Address

111 EAST 210 ST  
BRONX, NY 10467

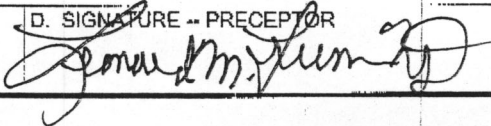
B. Materials License Number

NYC # 75-2885-01

C. NAME OF PRECEPTOR (print clearly)

LEONARD M. FREEMAN MD

D. SIGNATURE -- PRECEPTOR



E. DATE

3/6/06



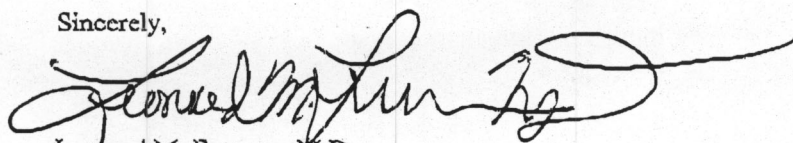
December 13, 2007

Re: Dr. Langman's Training & Experience

I attest that Dr. Langman satisfied the required training and experience during his residency training as detailed below:

- 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.
- G. Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs.

Sincerely,



Leonard M. Freeman M.D.  
Montefiore Medical Center  
111 East 210<sup>th</sup> Street  
Bronx, NY 10467



MONTEFIORE MEDICAL CENTER  
The University Hospital  
for the Albert Einstein  
College of Medicine

DEPARTMENT OF NUCLEAR MEDICINE



ALBERT EINSTEIN  
COLLEGE OF MEDICINE  
OF YESHIVA UNIVERSITY

LEONARD M. FREEMAN, M.D.  
Professor and Vice Chairman  
Professor of Radiology  
Director, Henry and Lucy  
Moses Division  
718-920-0060 Office  
718-920-2629 Fax  
E-mail: lfreesman@montefiore.org

10/13/06

To Whom it may concern

This is to certify that I meet  
the requirements of an authorized user in 10 CFR  
35.190 and 35.290

I also certify that Dr. Alex Langman  
has satisfactorily completed the requirements in  
10 CFR 35.290(c)(1) and has 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

Leonard M. Freeman MD

MONTEFIORE MEDICAL CENTER  
The University Hospital  
for the Albert Einstein  
College of Medicine

Henry and Lucy Moses Division

111 East 210th Street  
Bronx, New York 10467-2460  
(718) 920-5012  
(718) 920-2629 Fax

SHERMAN L. HELLER, Ph. D.  
Radiation Safety Officer  
Physicist, Nuclear Medicine

MONTEFIORE



October 12, 2006

To Whom It May Concern:

Leonard Freeman, M.D. has been authorized for medical use of radioisotopes and is being authorized for material permitted by our broad scope Human Use Radioactive Material License (license No. 75-2885-01). Attached is a copy of the cover sheet for the application for renewal of our Human Use Radioactive Material License as well as item 9.1 in the application.

If there are any questions, please feel free to contact me at 718-920-5012.

Sincerely,

Sherman Heller, Ph.D.  
Radiation Safety Officer



# CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

Pursuant to the New York City Charter and Article 175 of the New York City Health Code and in reliance on statements and representations heretofore made by licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive, possess and use the radioactive material(s) designated below; and to use such radioactive materials for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders now or hereafter in effect of all appropriate regulatory agencies and to any conditions specified below.

In accordance with letters dated 2 March 2006 and 21 March 2006 from Sherman Heller, Ph.D, Radiation Safety Officer, Montefiore Medical Center; License number 75-2885-01 is hereby amended to change Items 3b, Conditions 9(N), 10, 29, to add Items 6(KK), 7(KK), 8(KK), Condition 9(KK), and to read:

## LICENSEE

		<b>3a. License Number:</b>	75-2885-01
<b>1. Name:</b>	Montefiore Medical Center	<b>3b. Amendment Number:</b>	21
<b>2. Address:</b>	111 East 210th Street Bronx, New York 10467	<b>4. Expiration Date:</b>	31 December 2008
		<b>5. Reference Number:</b>	188-7

6. Radioactive materials (element number)	7. Chemical and/or physical form	8. Maximum quantity licensee may possess at any one time
(A) Any radioactive material with atomic number 3-83, inclusive, except as listed below	(A) Any	(A) 3.7 Gigabecquerels each, except as listed below
(B) Hydrogen-3	(B) Any	(B) 7.4 Gigabecquerels
(C) Strontium-90	(C) Sealed Sources Mold (Atlantic Research, Model B)	(C) 7.4 Gigabecquerels
(D) Molybdenum-99	(D) Generators with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(D) 333 Gigabecquerels
(E) Technetium-99m	(E) Generators with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA *****	(E) 333 Gigabecquerels

## Item 9.1

## Authorized Users for Medical Use

## Nuclear Medicine

Leonard M. Freeman, M.D.  
Jennie Chun, M.D.  
Mark Travin, M.D.  
David Milstein, M.D.  
Ping Lu, M.D.  
M. Donald Blaufox, M.D.  
Renee Moadel, M.D.  
Suman Jana, M.D.  
Anna Valdivia, M.D.

## Radiation Therapy

Shalom Kalnicki, M.D.  
Chandan Guha, M.D.  
Giridhar Gorla, M.D.  
Madhar Garg, M.D.  
James Butler, M.D.

The above Nuclear Medicine and Radiation Therapy physicians have been previously authorized (BHR License No. 75-2885-01) for medical use of radioisotopes and are being authorized for material permitted by our previous license. The only exception is Shalom Kalnicki, M.D. He will be the new chairman for Radiation Therapy Department. All of the physicians' CVs, Supplement I, and NYS licenses are attached (Att. 9.1)

## Item 9.2

## Authorized users for non-medical use

Joan Uelinger, M.D. is the director of the blood bank at Montefiore Medical Center and one of the authorized users under our present blood irradiator license. Her CV, Supplement I, Director Certificate, authorization letter and Clinical Lab Certificate are attached (Att. 9.2.1)

Mrs. Leana J. Serrano is the Blood Bank Supervisor and is responsible for supervising the use of the irradiator. A copy of her ASCP Certificate is attached (Att. 9.2.2)

Ravindra Yaparpalvi is authorized Radiation Therapy physicist for our Human Use License No. 75-2885-01 and our Linac Registrations, No. 77000012 and 77000030. A copy of his CV, Supplement I, Board Certification is attached. (Att. 9.2.3)

This is to acknowledge the receipt of your letter/application dated

6/19/2008, and to inform you that the initial processing which includes an administrative review has been performed.

☒ AMEND. 29-4017-01  
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 142564.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)  
(6-96)

Sincerely,  
Licensing Assistance Team Leader