NRC FORM 313 (03-2013) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 05/31/2015

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs,, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

OFFICE OF FEDERAL & STATE MATERIALS AND
ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

Br. 1

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

03030418

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

REC RG1 08-29-13 AM10:38

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER
- [x] C. RENEWAL OF LICENSE NUMBER 07-28154-01

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*

Alfieri Cardiology, P.A.
G-39 Omega Drive
Newark, Delaware 19713

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Alfieri Cardiology, P.A.
G-39 Omega Drive
Newark, Delaware 19713

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Joshua Mussaf

BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER
(302) 731-0001	

BUSINESS EMAIL ADDRESS
jmcnmt@yahoo.com

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number; b. chemical and/or physical form; and c. maiximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*) *(See 10 CFR 170 and Section 170.31)* FEE CATEGORY _____ AMOUNT ENCLOSED $ _____

13. CERTIFICATION. *(Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.*

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35 , 36, 39, AND 40, AND THAT ALL INFORMATION CONTANED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A C RIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Paul J. Alfieri, M.D. President and C.E.O.		7/26/2013

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY				DATE	581465

Item Number 5: Radioactive Materials:

Any byproduct material permitted by 10 CFR 35:200

We do not intend to use or possess any sealed sources that do not meet the criteria in 10 CFR 35.65 (e.g. .greater than 30 millicuries)

Item Number 6: Purpose(s) for which licensed materials will be used:

Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required by 10 CFR 35.200

Item Number 7: Individuals Responsible for Radiation Safety Program and Their Training and Experience:

The Radiation Safety Officer at Alfieri Cardiology, P.A. is Paul J. Alfieri, M.D.
He is currently listed on our license as the RSO

The Authorized Users at our facility are as follows:
Paul J. Alfieri, M.D. is currently authorized for use of material listed under 35.100; 35.200

Item Number 8: Training for Individuals Working in or Frequenting Restricted Areas
Alfieri Cardiology, P. A. Has established and implemented a training program consistent with NUREG 1556, Vol. 9, Revision 2, Appendix J for "Individuals Involved in the Medical Usage of Byproduct material" at the following intervals:

- **Nuclear Medicine Technologist** – Upon starting work with radioactive materials, annually thereafter or when there is a change in regulations or license conditions.
- **Ancillary Personnel** – Initially and when deemed necessary by the RSO.

The following will be documented:

- Date and duration of training
- Name of individual providing the training
- Name of individuals trained

Item Number 9: Facilities and Equipment

General

Alfieri Cardiology, P.A. operates at its current address site. Images of the diagram of the facility can be found in Attachment B.

Locations of Use

Radioactive material will be delivered to and stored in the Hot Lab. Radioactive material will be injected in either the treadmill room or the injection room and the patient will be imaged in the camera room.

Structural Shielding

Walls are constructed of 5/8" gypsum wall board on a wood frame. The building exterior is brick. The building is a single story, with no occupancy above or below the hot lab, injection room or camera room.

Additional Shielding

Radiopharmaceuticals and sealed sources will be stored in the manufacturers shielding until being used. Additional shielding will be available to maintain doses to occupationally exposed individuals and individual members of the public as low as reasonably (ALARA) achievable, specifically, the following shielding is available:

- Mfg Unit Dose shield
- Mfg Source shields
- Manufacture vial shield
- Syringe shields
- Rad waste Storage: 2" lead bricks around sharps container & lead lined waste container.
- L-Block

Item Number 10: Radiation Safety Program

1. **Audits of the program**

   We have developed and will implement and maintain written procedures in accordance with "NUREG 1556 vol. 9 rev. 2 Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses. Appendix L Model Licensee Audit"

2. **Dosimetry:**

   We have developed and will implement and maintain written procedures in accordance with "NUREG 1556 vol. 9 rev. 2 Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses. Appendix M Model Procedures for an Occupational Dose Program"

3. **Radiation Detection**

Below is a list of instruments available to make required measurements and perform required surveys...

Meter/Analyzer (Make & Model)	Probe/Detector (Make & Model)	NO. OF UNITS	RADIATION DETECTED (α, β, γ)	SENSITIVITY RANGE (mR/hr, cpm)
Ludlum 14C or equivalent	44-7	1	β, γ	0.01- 200 mR/hr
Ludlum 2200 Well Counter	NaI	1	γ	0 – 999,999 cpm
			β, γ	

Note: We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.

Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations.

Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Byproduct Material

A Capintec CRC –7 Dose Calibrator or equivalent will be used to measure patient dosages prior to administration and will be calibrated in accordance with nationally recognized standards or the manufacturer's instruction.

4. **Material Receipt and Accountability**

   We have developed and will implement and maintain written procedures for area surveys in

Accordance with "NUREG 1556 vol. 9 rev. 2 Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses. Appendix O Model Procedures for Ordering and Receiving Packages"

We have developed and will implement and maintain written procedures in Accordance with "NUREG 1556 vol. 9 rev. 2 Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses. Appendix P Model Procedures for Safely Opening Packages Containing Radioactive Material."

5. Occupational Dose Projections and Control Mechanisms

Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under "Criteria" in Appendix M, NUREG-1556, Vol. 9, Rev. 2.

6. Public Dose Projections and Control Mechanisms

Surveys performed in unrestricted areas indicate that it is unlikely that any individual member of the public will exceed regulatory limits from external sources. No volatile material is used on site; therefore, dose as a result of inhalation is remote.

7. Safe Use of Radionuclides and Emergency Procedures. Include the ALARA Program and all Applicable Procedures.

We have developed and will implement and maintain written procedures in Accordance with "NUREG 1556 vol. 9 rev. 2 Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses. Appendix N Model Emergency Procedures."

We have developed and will implement and maintain written procedures in Accordance with "NUREG 1556 vol. 9 rev. 2 Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses. Appendix N Model Procedures for Developing, Maintaining, and Implementing Written Directives"

We have developed and will implement and maintain written procedures in Accordance with "NUREG 1556 vol. 9 rev. 2 Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses. Appendix T Model Procedures for Safe Use of Unsealed Licensed Material"

We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.110.

We have developed and will implement and maintain procedures for safe use of unsealed Byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

8. Surveys and Their Frequency

We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70. Radiation and contamination limits from Appendix R of NUREG 1556 Vol 9, Rev 2 will be used on survey forms.

Semi-annual sealed source inventory and leak testing will be performed consistent with procedures in Appendix Q of NUREG 1556, Vol. 9. Rev. 2.

9. Transportation

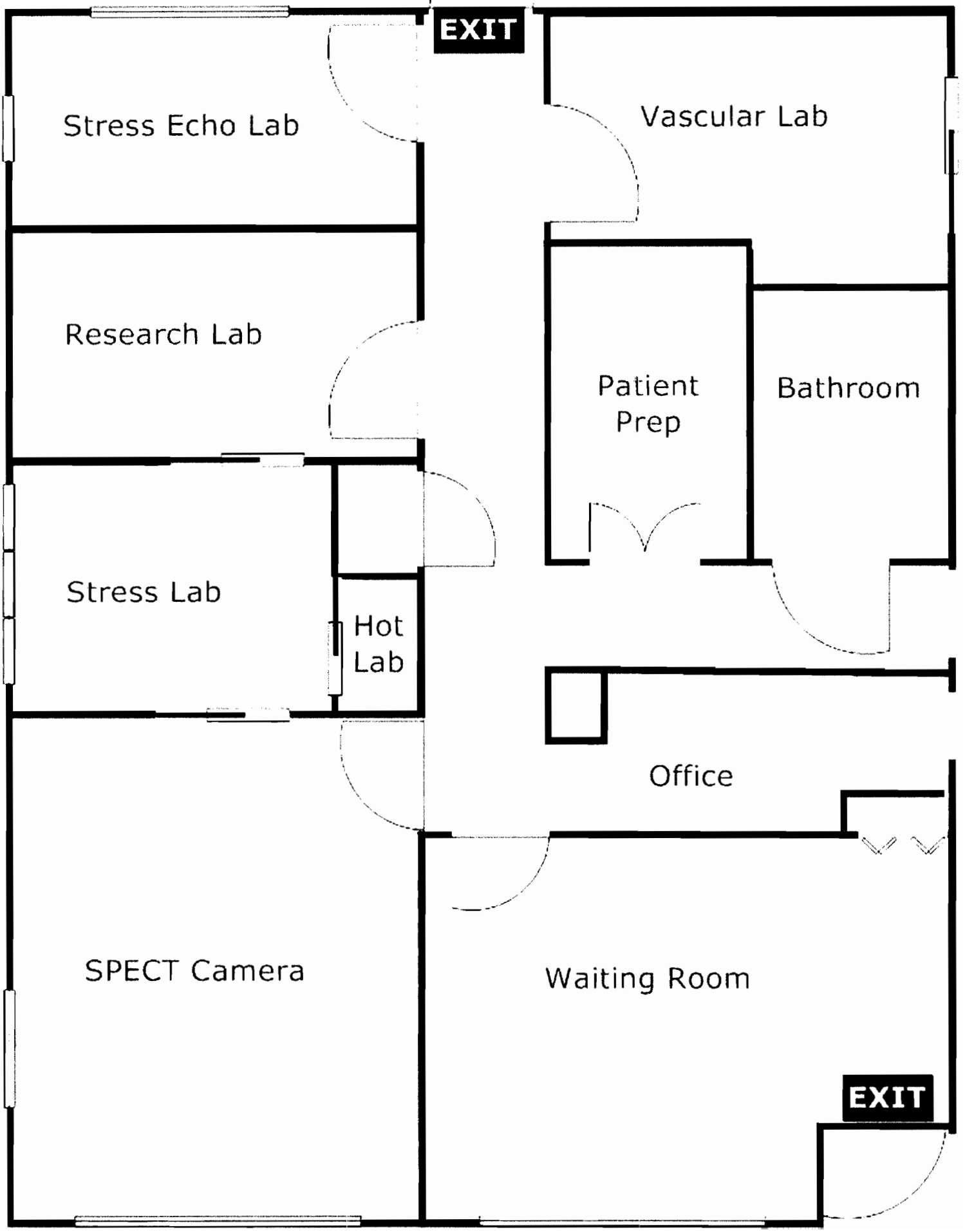
Radioactive material shall be transported in accordance with the provisions of 10 CFR Part 71. Manufacturer's procedures for return of radiopharmaceuticals and sealed sources will be adhered to.

Item Number 11: Waste Management

We have developed and will implement and maintain written waste disposal procedures For licensed material, in accordance with 10 CFR 20.1101, that also meets the requirements of the applicable section of Subpart K to 10 CFR Part 20 and of 10 CFR 35.92.

Alfieri Cardiology

Attachment B



This is to acknowledge the receipt of your letter/application dated 7/26/13, and to inform you that the initial processing which includes an administrative review has been performed.

Renew (07-28154-01)

[X] 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

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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** 581465.
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