



DEPARTMENT OF THE ARMY  
U.S. ARMY RESEARCH INSTITUTE OF ENVIRONMENTAL MEDICINE  
KANSAS STREET, BUILDING 42  
NATICK, MASSACHUSETTS 01760-5007

September 16, 2009

Br. 2

2009 SEP 18 PM 1:34

RECEIVED  
REGION 1

Licensing Assistance Team  
Division of Nuclear Materials Safety  
U.S. Nuclear Regulatory Commission Region 1  
475 Allendale Road  
King of Prussia, PA 19406-1415

Dear Sir/Ms.:

03036434

An amendment to Nuclear Regulatory Commission Materials License 20-30847-01 is requested in order to designate a new Radiation Safety Officer (RSO). We request approval to replace our current Radiation Safety Officer (RSO), Dr. Michael John Durkot, U. S. Army Research Institute of Environmental Medicine (USARIEM), Natick, MA with Mr. Michael Blaha. No other changes to our license are requested at this time.

Attached to this amendment you will find our revised NRC Form 313 which documents this request as well as Mr. Blaha's educational record and radiological work experience submitted as his qualifications to assume the RSO duties. Mr. Blaha has been one of the authorized users on our license for many years and has used radioisotopes while performing RIAs and cell assays as part of his research for over 25 years. Additionally, he has been designated as our Institute's alternate RSO since 2004 in order to learn these duties from Dr. Durkot. Finally, to complete his training, Mr. Blaha is scheduled this month to attend the 40-hour Radiation Safety Officer Course offered by Radiation Safety Academy.

The purpose of this action is to provide our Institute with a smooth transition of Radiation Safety Officers without any disruption to our research or suspension of our Radiation Program. I am confident that Mr. Blaha is well-qualified to conduct the RSO duties and oversee our Radiation Program. I can be reached at 508-233-4811 for additional information.

Sincerely,

Kevin N. Keenan  
Colonel, US Army  
Commander

Enclosure  
1. 2 copies of NRC Form 313

144173  
NRC/RCNI MATERIALS-002

NRC FORM 313  
(3-2009)  
10 CFR 30, 32, 33,  
34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 3/31/2012

### APPLICATION FOR MATERIALS LICENSE

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 Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to [infocollects.resource@nrc.gov](mailto: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.**

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. 2

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  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PA 19406-1415

03036434

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  
612 E. LAMAR BOULEVARD, SUITE 400  
ARLINGTON, TX 76011-4125

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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 20-30847-01
- C. RENEWAL OF LICENSE NUMBER \_\_\_\_\_

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

**COL Kevin N. Keenan, Commander USARIEM**  
**Kansas Street, BLD 42**  
**Natick, MA 01760**

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

**USARIEM**  
**Kansas Street, BLD 42**  
**Natick, MA 01760**

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

**COL Kevin N. Keenan**

TELEPHONE NUMBER

**(508) 233-4811**

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. maximum 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 (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 CONTAINED 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 CRIMINAL 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  
**COL Kevin N. Keenan, Commander USARIEM**

SIGNATURE 

DATE  
**09/09/2009**

#### FOR NRC USE ONLY

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

## Items 5 – 12 for NRC Form 313

5. Radioactive Material: Same as listed on Original License # 20-30847-01
6. Purpose for which licensed material will be used: Same as listed on Original License # 20-30847-01
7. Individual responsible for Radiation Safety Program and their training experience: change from Dr. Michael Durkot to Mr. Michael Blaha. Mr. Blaha's experience is detailed in the Original License as well as the amendment memorandum.
8. Training for individuals working in or frequenting restricted areas: Annual training and frequent monitoring will be performed by our RSO, as stated on original license.
9. Facilities and Equipment: new gamma counter (Perkin Elmer 10 channel Wizard).
10. Radiation Safety Program: Same as listed on Original License # 20-30847-01
11. Waste Management: Same as listed on Original License # 20-30847-01
12. License Fees Category: Same as listed on Original License # 20-30847-01

Reference NRC Form 313 Item #5

### RADIOACTIVE MATERIAL

<u>Element and Mass Number</u>	<u>Chemical and/or Physical Form</u>	<u>Maximum Activity</u>
Hydrogen - 3	Any	100 mCi
Carbon - 14	Any	100 mCi
Phosphorus - 32	Any	10 mCi
Phosphorus - 33	Any	10 mCi
Sulphur-35	Any	10 mCi
Iodine - 125	Radioimmunoassay Kits	20 mCi

Reference NRC Form 313 Item #6

**PURPOSE(S) for WHICH LICENSED MATERIAL WILL BE USED**

Research and development in laboratory analysis, exploration or experimentation; or the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, materials, and processes to include substrate analysis. This may include the internal or external administration of byproduct material, or the radiation therefrom into cell cultures and/or animal models. This **will not include** the administration of radioactive material to human beings.



Training in Radiation, Formal Courses:

1. Principles and Practices of Radiation use and Protection- The Pennsylvania State University- Graduate Course 1975
2. Medical Research application of Radioisotopes- Harvard Medical School/Massachusetts General Hospital 1978
3. Principles of Radioimmunoassays methods.- New England Nuclear Corporation- 1978
4. Radioactive Waste Packaging, Transportation and Disposal Seminar 1978
5. Radioactivity Measurements, Standardization, Monitoring Techniques and Instruments
6. Annual Radiation Safety Course

**Radioisotopes worked with:**

1) Carbon-14 (C-14-glucose, lactate, glycerol, FFA used in in vivo infusion studies) in these studies I used uCi amounts.

2) Hydrogen-3 (H-3-glucose, lactate, glycerol, inulin and water used in in vivo infusion studies) in these studies I used uCi amounts

3) Iodine-125 (used in Radioimmunoassays, uCi amounts)

4) Sodium-24 (used to measure sodium space) uCi amounts

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Reference NRC Form 313 Item #8

## **TRAINING for INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS**

Individuals who receive, transfer, store or use radioactive materials, and ancillary personnel shall **annually** be trained of the precautions or procedures to minimize exposure, health protection problems associated with exposure to radioactive materials, the purposes and functions of protective devices employed, the applicable provisions of NRC regulations. **Annual training** will be IAW NRC Regulatory Guide 8.29 (Instruction Concerning Risks from Occupational Radiation Exposure) for their protection from exposure to ionizing radiation. Training will be before duties with or in the vicinity of radioactive materials and will be re-instructed whenever there is a significant change in duties, regulations or terms of NRC License. **Annual training will be conducted by both Dr. Michael Durkot, Radiation Protection Officer, who has 25 years experience using radioisotopes and a contracted licensed Health Physicist who specializes in training. Training is to be assessed by course content exams.**

This training will also include:

Waste Management, see Reference NRC Form 313 Item #10, section 13.

Installation's ALARA Policy, see Reference NRC Form 313 Item #10, section 6, and their appropriate response to an unusual occurrence or emergency that may involve radioactive material contamination with or without injuries, see Reference NRC Form 313 Item #10, Appendix B.

## FACILITIES and EQUIPMENT

### Facilities:

Locations within the U.S. Army Research Institute of Environmental Medicine (USARIEM) where radioactive materials are stored or used are conventional chemical, biological, and physical science laboratories. Laboratories are equipped with laboratory hoods where necessary, lockable refrigerators or freezers for storage of radioactive materials, sinks connected to the municipal sanitary sewerage system, impervious laboratory bench top working areas, etc. There are no changes in the locations and characteristics of the laboratories where radioactive materials will be stored or used, or in the receiving area for the Institute.

Low Level Radioactive Waste (LLRW) is held in a LLRW secure enclosure, located on the Penthouse fourth floor of USARIEM.

### Radiation Detection Instrumentation:

#### Portable Survey Instruments

<u>Manufacture</u>	<u>Model #</u>	<u>Qty.</u>	<u>Radiation Measured</u>
Eberline Instrument Corp	E-530	2	Gamma Monitor

We reserve the right to upgrade our survey instruments as necessary.

#### Radiation Laboratory (counting room) Instrumentation

<u>Manufacture</u>	<u>Model #</u>	<u>Detector</u>	<u>Radiation Measured</u>
Packard	1900 TR	Tri CarbLiquid Scintillation Analyzer	Beta
Packard	Cobra II	Constant Quanta	Gamma

We will use instruments that meet the radiation monitoring instrument specifications published in Appendix M to NUREG-1556, Volume 7.

### Calibration Frequency:

Portable Survey Instruments will be calibrated at least annually commercially, after a repair or as determined necessary by the RSO. Radiation Laboratory instruments will be calibrated as required for usage. See Reference NRC Form 313 Item #10, Appendix C. We will implement the model survey meter calibration program published in Appendix M to NUREG-1556, Volume 7.

Reference NRC Form 313 Item #10

Monitoring and Radioactive Contamination.

We have done a prospective evaluation and determined that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10CFR 20 or we will monitor individuals in accordance with the criteria in the section entitled "Radiation Safety Program-Occupational Dose" in NUREG-1556, Volume 7".

We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG-1556, Volume 7. Leak tests will be performed at the intervals approved by the NRC or an Agreement State and specified in the Sealed Source and Device Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State, to provide leak tests kits to other licensees and according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instruction. As an alternative, we will implement the model leak test program published in Appendix R to NUREG-1556, Volume 7.

We will develop and maintain procedures for ensuring material accountability

Emergency Procedures.

The procedures for safe use, including security of material, and emergencies have been developed. These procedures may be revised only if 1) changes are reviewed and approved by the licensee management and the RSO in writing; 2) the staff is provided training in the revised procedures prior to the implementation; 3) the changes are in compliance with the NRC regulations and the license; and 4) the changes do not degrade the effectiveness of the program.

Dr. Michael Durkot  
USARIEM Radiation Protection Officer

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Reference NRC Form 313 Item #11.

## **WASTE MANAGEMENT**

**We will use the model Decay-in-Storage and Disposal of liquids into Sanitary Sewer model waste procedures that are published in Appendix T to NUREG-1556, Volume 7.**

## AUTHORIZED USERS

1) **Dr. Michael J. Durkot**, U.S. Army Institute of Environmental Medicine, Radiation Safety Officer

Training in Radiation, Formal Courses:

- 1) Principles and Practices of Radiation use and Protection- The Pennsylvania State University- Graduate Course 1975
- 2) Medical Research application of Radioisotopes- Harvard Medical School/Massachusetts General Hospital 1978
- 3) Principles of Radioimmunoassays methods.- New England Nuclear Corporation- 1978
- 4) Radioactive Waste Packaging, Transportation and Disposal Seminar 1978
- 5) Radioactivity Measurements, Standardization, Monitoring Techniques and Instruments
- 6) Soldier System Command Annual Radiation Safety Course

Radioisotopes worked with:

- 1) Carbon-14 (C-14-glucose, lactate, glycerol, FFA used in in vivo infusion studies) in these studies I used uCi amounts.
- 2) Hydrogen-3 (H-3-glucose, lactate, glycerol, inulin and water used in in vivo infusion studies) in these studies I used uCi amounts
- 3) Iodine-125 (used in Radioimmunoassays, uCi amounts)
- 4) Sodium-24 (used to measure sodium space) uCi amounts

2) **Bradley C. Nindl, Ph.D.**

Training in Radiation, Formal Courses:

- 1) Principles and Practices of Radiation use and Protection- The Pennsylvania State University- Graduate Course 1995
- 2) Soldier System Command Annual Radiation Safety Course
- 3) Iodine-125 (used in Radioimmunoassays, uCi amounts)

3) **Michael D Blaha**

College coursework related to radionuclides: Physics (1yr), Biochemistry (1 1/2yr), Nutritional Biochemistry (Food Irradiation).

On-the-job training and experience since 1975 with the following radionuclides:

P<sup>32</sup> isotope exchange determinations

C<sup>14</sup>

H<sup>3</sup>

S<sup>35</sup>

I<sup>125</sup>

[All the above were in µCi activities as part of laboratory assays or kits]

As Lab Manager for 20 years I have trained numerous military and civilian employees in how to safely handle and conduct assays involving radionuclides.

Attended approximately 12 annual Radiation Safety Training sessions run by the Radiation Safety Officer Mr. Paul Angelis

Have been a participating member of the Natick Soldier Systems Center's Radiation Safety Committee since 1994, a group tasked with upholding the NRC license requirements for all Principal Users and Radiation Workers at the Natick Facility.

Have an outstanding safety record and reputation for working neatly.

**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	In accordance with the letter dated June 29, 2009,
1. Department of the Army U. S. Army Soldier Research Institute of Environmental Medicine (USARIEM)	3. License number 20-30847-01 is amended in its entirety to read as follows:
2. Building 42 Kansas Street Natick, Massachusetts 01760	4. Expiration date January 31, 2014
	5. Docket No. 030-36434 Reference No.

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. Hydrogen 3	A. Any	A. 100 millicuries
B. Carbon 14	B. Any	B. 100 millicuries
C. Phosphorus 32	C. Any	C. 10 millicuries
D. Phosphorus 33	D. Any	D. 10 millicuries
E. Sulfur 35	E. Any	E. 10 millicuries
F. Iodine 125	F. Any	F. 20 millicuries

9. Authorized use:

A. through F. Research and development as defined in 10 CFR 30.4; animal studies.

**CONDITIONS**

10. Licensed material may be used or stored only at the licensee's facilities located at Building 42, Kansas Street, Natick, Massachusetts.
11. Licensed material shall be used by, or under the supervision of, Michael John Durkot, Ph. D. or Michael D. Blaha. Licensed material listed in Item F. shall be used by, or under the supervision of, Bradley C. Nindi, Ph.D.
12. The Radiation Safety Officer for this license is Michael John Durkot, Ph. D.
13. The licensee shall not use licensed material in or on human beings.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
20-30847-01Docket or Reference Number  
030-36434

Amendment No. 1

14. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.
15. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
16. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
  - A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
  - B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and
  - C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.
17. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
20-30847-01Docket or Reference Number  
030-36434

Amendment No. 1

18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Letter dated January 9, 2004 [ML040360196]
  - B. Letter received January 28, 2004 [ML040430143]
  - C. Letter dated June 29, 2009 [ML091900407]

For the U.S. Nuclear Regulatory Commission

***Original signed by Elizabeth Ullrich***Date July 27, 2009

By

Elizabeth Ullrich  
Commercial and R&D Branch  
Division of Nuclear Materials Safety  
Region I  
King of Prussia, Pennsylvania 19406

This is to acknowledge the receipt of your letter application dated

9/16/09, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (20-30847-01) 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 144173.  
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 (R1)  
(6-96)

Sincerely,  
Licensing Assistance Team Leader