

Cardinal Health  
Nuclear Pharmacy Services  
Quality & Regulatory  
7000 Cardinal Place  
Dublin, OH 43017  
tel 614.757.4120  
fax 614.652.4598

www.cardinalhealth.com



**CardinalHealth**

Br. 2

December 9, 2015

Licensing Assistance Team  
Division of Nuclear Materials Safety  
U.S. NRC Region I DNMS  
2100 Renaissance Road  
King of Prussia, PA 19406

03038331

REC RG 1 12 17 15 AM 10 23

Re: Amendment Request for Radioactive Materials License number 34-32780-02, Cardinal Health PET Manufacturing Services, East Hartford, CT.

Licensing:

Cardinal Health 414, LLC (Nuclear Pharmacy Services and PET Manufacturing Services, hereafter Cardinal Health) requests an amendment for the above referenced license to remove Ryan Reganato as the Radiation Safety Officer (RSO) add Beau Dugas as the RSO. Beau Dugas is an authorized user (AU) cyclotron operator on this license and is familiar with the radiation safety program. Documentation of training is enclosed.

In addition, please add Tiandra Allen and John Taylor Vernon as a cyclotron operator AU's. Documentation of training is enclosed. Also, remove Donald Ford who is no longer employed.

If you have any questions regarding this request, please contact me at 614.757.9586.

Sincerely,

A handwritten signature in black ink, appearing to read "Glenn Sullivan".

Glenn Sullivan  
Manager, Health Physics  
Quality and Regulatory  
Nuclear Pharmacy Services

/dh

Enclosures: Training Documents

cc: Beau Dugas, MRSO loc. 5869  
Arshad Mehmood, loc. 5869  
John Taylor Vernon  
License File 5869 (3)

589751

NMSS/RGN1 MATERIALS-002

Cardinal Health  
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**CardinalHealth**

**TO:** All Employees, PMS Location 5869, East Hartford, Connecticut  
**FROM:** W. Scott Claunch, R.Ph., Corporate Radiation Safety Officer, Director, Pharmacy Safety & Practice, Nuclear Pharmacy Services  
**DATE:** November 18, 2015  
**SUBJECT:** Delegation of Authority

---

**Beau Dugas** has been appointed Manufacturing Radiation Safety Officer (MRSO) and is responsible for ensuring the safe use of radioactive materials. The MRSO is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The MRSO is hereby delegated the authority necessary to meet those responsibilities. This specifically includes having sufficient authority, organizational freedom, and management prerogative to:

1. Have unhampered access to all activities at his or her facility involving radioactive materials to identify radiation safety problems;
2. Immediately stop, without coordination with management, any activity at his or her facility involving the use of licensed materials by any user that might result in an unsafe situation or a violation of Agreement State requirements;
3. Initiate, recommend, or implement appropriate corrective actions; and
4. Verify the implementation of actions taken to correct radiation safety problems.

The MRSO is also responsible for assisting the Corporate Radiation Safety Committee and Corporate Radiation Safety Officer in the performance of their duties.

All of us have a critical responsibility in ensuring the safe use of radioactive materials. I refer you to one of our six values: "The health and safety of our employees, customers and community will never be compromised."

I understand and accept the responsibilities associated with being MRSO.

  
Beau Dugas, MRSO

12-11-15  
Date

  
W. Scott Claunch, CRSO

12/14/15  
Date

1 on 1 call completed 12/18/15 Date, CRSO Initials W.S.C.

Cardinal Health  
Nuclear Pharmacy Services  
Quality and Regulatory Department  
7000 Cardinal Place  
Dublin, OH 43017  
tel 614.757.5000  
fax 614.652.4588

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**CardinalHealth**

## DOCUMENTATION OF PET MANUFACTURING SERVICES RADIATION SAFETY OFFICER TRAINING

I hereby certify that the individual below has satisfactorily received 200 hours didactic training and 500 hours of practical radioisotope handling experience and that the individual has achieved a level of competency sufficient to independently operate as a PET Manufacturing Services radiation safety officer. This includes training as radiation safety officer under a current radiation safety officer.

RSO Name (Print) Ryan Regorato

RSO Signature: [Signature] Date: 16 Nov 15

RSO Designee Name (Print) Brian Dugas

RSO Designee Signature: [Signature] Date: 13 Nov 15

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## PET Manufacturing Services Training Authorization

January 5, 2015

I have reviewed the education and training documents listed below and they meet the training requirements outlined in the PET Manufacturing Services Radiation Safety Manual, Section 9.

G.E. PETtrace Cyclotron Training (30-60-90 Day Training Documentation)

Basic Radioisotope Handling Techniques Worksheet

Didactic Training Certificate

Therefore, I authorize **Beau Dugas** to act as a AU/Cyclotron operator on any PET Manufacturing License that grants self-approval for Authorized Users/Cyclotron Operators. A copy of this approval letter must be kept on file at all locations where the above named individual has worked for 5 years after the last date of employment.

A handwritten signature in black ink, appearing to read "Glenn Sullivan", written over a horizontal line.

Glenn Sullivan  
Manager, Health Physics  
Quality and Regulatory  
Nuclear Pharmacy Services

## Cardinal Health Manufacturing Training Summary

Beau Dugas has completed the following Cardinal Health Manufacturing training at the East Hartford, CT cyclotron site on December 8, 2014. This training was performed on a GE PETtrace cyclotron by an authorized user and cyclotron operator who received manufacturer or equivalent training on the GE PETtrace cyclotron.

### PET Trace Cyclotron Training

1. Health, General and Radiation Safety
2. Cyclotron Theory and Physics
3. Controls and Displays
4. Operating Instructions
5. Preventive Maintenance
6. Cyclotron Software
7. Cyclotron Shielding
8. Cyclotron Documentation

**100 hours**

### FDG Chemical Synthesis

1. Chemical Syntheses Theory
2. Materials Preparation
3. Chemical Preparation
4. Coincidence Synthesis Box Preparation
5. Coincidence Synthesis Box Operation
6. Handling up to 3 Ci of FDG
7. GMP Practices
8. Production Abnormalities

**60 hours**

### Quality Control

1. Radionuclidic Identification: Half-life test
2. Ph Testing
3. Chemical Purity of Fludeoxyglucose F-18 Injections: Gas Chromatography
4. Radiochemical Identity and Purity of Fludeoxyglucose F-18 Injection: Radio-TLC
5. Chemical Purity of Fludeoxyglucose F-18 Injection: Kryptofix TLC
6. Bacterial Endotoxin Testing
7. Membrane Filter Integrity Test
8. Radionuclidic Purity of Fludeoxyglucose F-18 injection
9. Sterility Testing

**80 hours**

### Radiation Testing and Equipment

1. Radiation Safety Training for Individuals Working in or Frequenting Restricted Areas
2. Portable Survey Meters and Wipe Tests
3. Transport and Receipt of Radioactive Materials
4. Dose Calibrator and Fume Hood

**25 hours**

### Component Materials Management

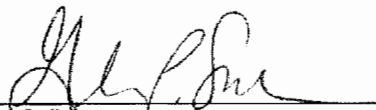
1. Receiving
2. Tracking
3. Batch Record Compliance
4. Record Retention
5. Inventory

**15 hours**

**TOTAL: 280 hours**

### Certification of Review of Training

I certify that I have reviewed the training and experience documentation of the above named individual and have determined that the individual has satisfactorily completed the training and experience requirements set forth in the PET Manufacturing Services Radiation Safety Training Manual.



Glenn Sullivan  
Manager, Health Physics  
Quality and Regulatory  
Nuclear Pharmacy Services

1/5/15  
Date

FIGURE 9-7

**RADIOISOTOPE HANDLING EXPERIENCE**

Name: *Beau Dugas*

Date *18 Nov 15*

Document the actual use/handling of radioactive material under the supervision of an Authorized User.

ISOTOPE	MAXIMUM ACTIVITY HANDLED	USE See key below: 1,2,3,4,5,6,7	EXPERIENCE Actual clock hours (Include date range of experience)	WHERE EXPERIENCE GAINED
<i>Co-57</i>	<i>0.0100 mCi</i>	<i>1 + 2 + 4 + 5 + 6 + 3 + 7</i>	<i>April 2014 - present &gt; 300 hrs</i>	<i>CAH</i>
<i>F-18</i>	<i>10,000 mCi</i>	<i>3 + 7 + 1 + 2 + 4 + 5 + 6</i>	<i>April 2014 - present &gt; 300 hrs</i>	
<i>Na-22</i>	<i>0.1022 mCi</i>	<i>+1 + 2 + 3 + 4 + 5 + 6</i>	<i>April 2014 - present &gt; 300 hrs</i>	
<i>N-13</i>	<i>500 mCi</i>	<i>1 + 2 + 4 + 5 + 6 + 3 + 7</i>	<i>April 2014 - present &gt; 300 hrs</i>	

Key for "Use": the number, or numbers, entered under "Use" should correspond to the handling experience for each isotope.

1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys
2. Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides
3. Calculating, assaying and safely preparing dosages for patients or human research subjects
4. Using appropriate internal controls to avoid mistakes in the labeling and/or administration of by product or accelerator material
5. Using procedures to prevent or minimize contamination and using proper decontamination procedures
6. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests
7. Production of radioactive materials via bombardment in a nuclear reaction.

## TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: Beau Dugas

Location of Training	Date(s) of Accordance	Course Title	Total Clock Hours of Course	BREAKDOWN OF COURSE CONTENT IN CLOCK HOURS*				
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radioactivity	Radiation Biology	Radiopharmaceutical Chemistry
CARDINAL HEALTH DUBLIN, OH	9/8/2014- 10/20/2014	CARDINAL HEALTH AUTHORIZED USER EDUCATION PROGRAM	200	85	58	25	32	0
*Note: Show a breakdown of hours by institution, dates, and subjects. List each hour only once (i.e., under the most applicable subject category)		<b>TOTAL HOURS</b>	200	85	58	25	32	0

Signature:

  
 Corporate Radiation Safety Officer

Date: 10/20/2014



# Central Connecticut State University

New Britain, Connecticut



In recognition of fulfillment of the prescribed course of study authorized by the Board of Regents for Higher Education, and upon the recommendation of the faculty, we hereby confer upon

## Beau Edwin Dugas

PERSONAL INFORMATION WAS REMOVED  
BY NRC. NO COPY OF THIS INFORMATION  
WAS RETAINED BY THE NRC.

the Degree of  
**Bachelor of Science**  
in **Biomolecular Sciences**

with all the honors, rights, and privileges appertaining thereunto.

In Witness thereof, the undersigned have affixed and subscribed their names  
on this the [REDACTED]

Chairman  
Board of Regents for Higher Education

Interim President  
Board of Regents for Higher Education

President  
Central Connecticut State University





## PET Manufacturing Services Training Authorization

December 7, 2015

I have reviewed the education and training documents listed below and they meet the training requirements outlined in the PET Manufacturing Services Radiation Safety Manual, Section 9.

G.E. PETtrace Cyclotron Training (30-60-90 Day Training Documentation)

Basic Radioisotope Handling Techniques Worksheet

Didactic Training Certificate

Therefore, I authorize **Tiandra Allen** to act as a AU/Cyclotron operator on any PET Manufacturing License that grants self-approval for Authorized Users/Cyclotron Operators. A copy of this approval letter must be kept on file at all locations where the above named individual has worked for 5 years after the last date of employment.



---

Glenn Sullivan  
Manager, Health Physics  
Quality and Regulatory  
Nuclear Pharmacy Services

## Cardinal Health Manufacturing Training Summary

Tiandra Allen has completed the following Cardinal Health Manufacturing training at the East Hartford, CT cyclotron site on November 30, 2015. This training was performed on a GE PETtrace cyclotron by an authorized user and cyclotron operator who received manufacturer or equivalent training on the GE PETtrace cyclotron.

### PET Trace Cyclotron Training

1. Health, General and Radiation Safety
2. Cyclotron Theory and Physics
3. Controls and Displays
4. Operating Instructions
5. Preventive Maintenance
6. Cyclotron Software
7. Cyclotron Shielding
8. Cyclotron Documentation

100 hours

### FDG Chemical Synthesis

1. Chemical Syntheses Theory
2. Materials Preparation
3. Chemical Preparation
4. Coincidence Synthesis Box Preparation
5. Coincidence Synthesis Box Operation
6. Handling up to 3 Ci of FDG
7. GMP Practices
8. Production Abnormalities

60 hours

### Quality Control

1. Radionuclidic Identification: Half-life test
2. Ph Testing
3. Chemical Purity of Fludeoxyglucose F-18 Injections: Gas Chromotography
4. Radiochemical Identity and Purity of Fludeoxyglucose F-18 Injection: Radio-TLC
5. Chemical Purity of Fludeoxyglucose F-18 Injection: Kryptofix TLC
6. Bacterial Endotoxin Testing
7. Membrane Filter Integrity Test
8. Radionuclidic Purity of Fludeoxyglucose F-18 injection
9. Sterility Testing

80 hours

### Radiation Testing and Equipment

1. Radiation Safety Training for Individuals Working in or Frequenting Restricted Areas
2. Portable Survey Meters and Wipe Tests
3. Transport and Receipt of Radioactive Materials
4. Dose Calibrator and Fume Hood

25 hours

### Component Materials Management

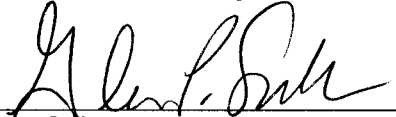
1. Receiving
2. Tracking
3. Batch Record Compliance
4. Record Retention
5. Inventory

15 hours

**TOTAL: 280 hours**

### Certification of Review of Training

I certify that I have reviewed the training and experience documentation of the above named individual and have determined that the individual has satisfactorily completed the training and experience requirements set forth in the PET Manufacturing Services Radiation Safety Training Manual.



Glenn Sullivan  
Manager, Health Physics  
Quality and Regulatory  
Nuclear Pharmacy Services

11/7/15  
Date

## RADIOISOTOPE HANDLING EXPERIENCE

Name: Tiandra Allen

Date 12/04/15

Document the actual use/handling of radioactive material under the supervision of an Authorized User.

ISOTOPE	MAXIMUM ACTIVITY HANDLED	USE See key below: 1,2,3,4,5,6,7	EXPERIENCE Actual clock hours (Include date range of experience)	WHERE EXPERIENCE GAINED
Co-57	0.0100 mCi	1,2,3,4,5,6,7	Jan - Dec 2015 > 300 hrs	CAH
F-18	11,000 mCi	1,2,3,4,5,6,7	Jan - Dec 2015 > 300 hrs	
Na-22	0.1022 mCi	1,2,3,4,5,6,7	Jan - Dec 2015 > 300 hrs	
N-13	500 mCi	1,2,3,4,5,6,7	Jan - Dec 2015 > 300 hrs	

Key for "Use": the number, or numbers, entered under "Use" should correspond to the handling experience for each isotope.

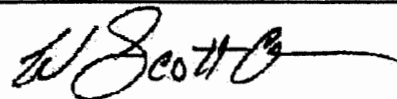
1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys
2. Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides
3. Calculating, assaying and safely preparing dosages for patients or human research subjects
4. Using appropriate internal controls to avoid mistakes in the labeling and/or administration of by product or accelerator material
5. Using procedures to prevent or minimize contamination and using proper decontamination procedures
6. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests
7. Production of radioactive materials via bombardment in a nuclear reaction.

## TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: Tiandra Allen

Location of Training	Date(s) of Accordance	Course Title	Total Clock Hours of Course	BREAKDOWN OF COURSE CONTENT IN CLOCK HOURS*				
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radio-activity	Radiation Biology	Radiopharmaceutical Chemistry
CARDINAL HEALTH DUBLIN, OH	9/14/2015 to 10/26/2015	CARDINAL HEALTH AUTHORIZED USER EDUCATION PROGRAM	200	85	58	25	32	0
*Note: Show a breakdown of hours by institution, dates, and subjects. List each hour only once (i.e., under the most applicable subject category)		<b>TOTAL HOURS</b>	200	85	58	25	32	0

Signature:



Scott Claunch, Corporate Radiation Safety Officer

Date: 11/3/2015

Cardinal Health  
Nuclear Pharmacy Services  
Quality & Regulatory  
7000 Cardinal Place  
Dublin, OH 43017  
tel 614.757.5000  
fax 614.652.4598

www.cardinal.com



## PET Manufacturing Services Training Authorization

August 20, 2015

I have reviewed the education and training documents listed below and they meet the training requirements outlined in the PET Manufacturing Services Radiation Safety Manual, Section 9.

PETtrace Cyclotron Training (30-60-90 Day Training Documentation)

Basic Radioisotope Handling Techniques Worksheet

Didactic Training Certificate

Therefore, I authorize **John Taylor Vernon** to act as a AU/Cyclotron operator on any PET Manufacturing License that grants self-approval for Authorized Users/Cyclotron Operators. A copy of this approval letter must be kept on file at all locations where the above named individual has worked for 5 years after the last date of employment.

A handwritten signature in black ink, appearing to read "Glenn Sullivan".

---

Glenn Sullivan  
Manager, Health Physics  
Quality and Regulatory  
Nuclear Pharmacy Services

## RADIOISOTOPE HANDLING EXPERIENCE

Name: Taylor Vernon

Date 21 Aug 2015

Document the actual use/handling of radioactive material under the supervision of an Authorized User.

ISOTOPE	MAXIMUM ACTIVITY HANDLED	USE See key below: 1,2,3,4,5,6,7	EXPERIENCE Actual clock hours (Include date range of experience)	WHERE EXPERIENCE GAINED
<u>F18</u>	<u>12 Ci</u>	<u>1,2,3,4,5,6,7</u>	<u>14 Feb 2005</u> <u>through</u> <u>21 Aug 2015</u>  <u>2000 hours/</u> <u>year</u>	<u>Cardinal Health</u> <u>PET sites</u> <u>-Pittsburgh</u> <u>-Philadelphia</u> <u>-Beltsville</u>
<u>Co57</u>	<u>5 mCi</u>	<u>1,2,5,6</u>		
<u>Na22</u>	<u>200 mCi</u>	<u>1,2,5,6</u>		

Key for "Use": the number, or numbers, entered under "Use" should correspond to the handling experience for each isotope.

1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys
2. Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides
3. Calculating, assaying and safely preparing dosages for patients or human research subjects
4. Using appropriate internal controls to avoid mistakes in the labeling and/or administration of by product or accelerator material
5. Using procedures to prevent or minimize contamination and using proper decontamination procedures
6. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests
7. Production of radioactive materials via bombardment in a nuclear reaction.

## Cardinal Health Manufacturing Training Summary

John Vernon has completed the following Cardinal Health Manufacturing training at the Sharon Hill cyclotron site on June 9, 2005. This training was performed on a GE PETrace cyclotron by an authorized user and cyclotron operator who received manufacturer or equivalent training on the GE PETrace cyclotron.

### PET Trace Cyclotron Training

1. Health, General and Radiation Safety
2. Cyclotron Theory and Physics
3. Controls and Displays
4. Operating Instructions
5. Preventive Maintenance
6. Cyclotron Software
7. Cyclotron Shielding
8. Cyclotron Documentation

**100 hours**

### FDG Chemical Synthesis

1. Chemical Syntheses Theory
2. Materials Preparation
3. Chemical Preparation
4. Coincidence Synthesis Box Preparation
5. Coincidence Synthesis Box Operation
6. Handling up to 3 Ci of FDG
7. GMP Practices
8. Production Abnormalities

**60 hours**

### Quality Control

1. Radionuclidic Identification: Half-life test
2. Ph Testing
3. Chemical Purity of Fludeoxyglucose F-18 Injections: Gas Chromatography
4. Radiochemical Identity and Purity of Fludeoxyglucose F-18 Injection: Radio-TLC
5. Chemical Purity of Fludeoxyglucose F-18 Injection: Kryptofix TLC
6. Bacterial Endotoxin Testing: LAL
7. Membrane Filter Integrity Test
8. Radionuclidic Purity of Fludeoxyglucose F-18 injection: MCA Analysis
9. Sterility Testing

**80 hours**

### Radiation Testing and Equipment

1. Radiation Safety Training for Individuals Working in or Frequenting Restricted Areas
2. Portable Survey Meters and Wipe Tests
3. Transport and Receipt of Radioactive Materials
4. Dose Calibrator and Fume Hood

**25 hours**

### Component Materials Management

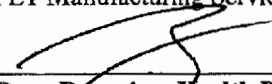
1. Receiving
2. Tracking
3. Batch Record Compliance
4. Record Retention
5. Inventory

**15 hours**

**TOTAL: 280 hours**

**Certification of Review of Training**

I certify that I have reviewed the training and experience documentation of the above named individual and have determined that the individual has satisfactorily completed the training and experience requirements set forth in the PET Manufacturing Services Radiation Safety Training Manual.

  
\_\_\_\_\_  
**Dave Breuning, Health Physicist**  
**Quality and Regulatory**

6/9/05  
\_\_\_\_\_  
**Date**



**University of Arkansas for Medical Sciences  
and  
The University of New Mexico Health Sciences Center**

Nuclear Education

**John Vernon**

Nuclear Pharmacy Courses & Training	Nuclear Physics	Instrumentation	Radiation Safety	Radiation Biology	Radiopharmacy	Total
	004-039-01-201-H-01	004-039-01-200-H-01	004-039-01-203-H-01	004-039-01-202-H-01	004-039-01-204-H-01	
Radiation Physics & Instrumentation	75	25				100
Radiation Protection			30			30
Math & Measure of Radioactivity	5	5			10	20
Radiation Biology				20		20
PET Radiochemistry					30	30
TOTALS	80	30	30	20	40	200

Course dates: March 14- May 30, 2005

*Nicki Hilliard*

Nicki L. Hilliard, Pharm.D., BCNP  
Associate Professor of Nuclear Pharmacy

*Jeffrey Norenberg*  
Jeffrey Norenberg, Pharm.D., M.S., BCNP  
Associate Professor of Nuclear Pharmacy

# Certificate of Completion

The University of Arkansas for Medical Sciences  
and the  
University of New Mexico Health Science Center  
certify that

*John Vernon*

has completed the didactic education requirements for  
Authorized User of Radioactivity education  
as specified by the Nuclear Regulatory Commission.



## Authorized User of Radioactivity Education and Training

*John A. Ryan, PharmD*  
Dean, UNM College of Pharmacy

*Nicki Hilliard*  
Executive Committee, Professor

*Stephanie Fisher*  
Dean, UAMS College of Pharmacy

*[Signature]*  
Executive Committee, Associate Professor

May 30, 2005

This is to acknowledge the receipt of your letter application dated

December 9, 2015, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (34-32780-02)  
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** 589751.  
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