

Date: 11/24/09

Br 2

To: NRC
Region 1, 475 Allendale Road
King of Prussia, PA 19406-1415

From: Ultimate Health Services
License # 47-25408-01
5170 US Route 60 East
Huntington, WV 25705

03034556

Re: Adding and deleting authorized users, change in contact information

Please amend license # 47-25408-01 with the following:

- Add Cardiologist Daniel Decker Snavely, MD, FACC as an authorized user; the preceptor attestation is enclosed.
- Add Radiologist Roger Blake, MD as an authorized user for ultimate health services. Enclosed is license # 47-09576-01 of which he is included.
- Delete Raed Jitan, MD as an authorized user as he is no longer with this practice.
- Change contact information from Michael Sundall CEO (resigned from corporation) to Mark Morgan CFO.

Thank you very much for your attention to this matter.



Sincerely yours,
George Linsenmeyer MD, FACC, RSO

RECEIVED
REGION 1
2009 NOV 27 PM 12: 22

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MISSOURI MATERIALS-001

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.190, 35.290, and 35.590]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized User: Daniel Decker Snaveley MD State or Territory Where Licensed: WV

Requested Authorization(s) (check all that apply)

- 35.100 Uptake, dilution, and excretion studies
- 35.200 Imaging and localization studies
- 35.500 Sealed sources for diagnosis (specify device _____)

PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

1. Board Certification

- a. Provide a copy of the board certification.
- b. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.

2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization

- a. Authorized user on Materials License _____ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.
- b. Supervised Work Experience.
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the 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			

Total Hours of Experience:

Supervising Individual _____ License/Permit Number listing supervising individual as an authorized user _____

Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).

- 35.290
- 35.390 + generator experience in 32.290(c)(1)(ii)(G)

NRC FORM 313A (AUD)
(6-2007)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	University of Cincinnati	112 hrs.	4/98-6/98 1/99, 4/99 11/99, 5/00
Radiation protection	University of Cincinnati	112 hrs.	4/98-6/98 1/99, 4/99 11/99, 5/00
Mathematics pertaining to the use and measurement of radioactivity	University of Cincinnati	112 hrs.	4/98-6/98 1/99, 4/99 11/99, 5/00
Chemistry of byproduct material for medical use (not required for 35.590)	University of Cincinnati	112 hrs.	4/98-6/98 1/99, 4/99 11/99, 5/00
Radiation biology	University of Cincinnati	112 hrs.	4/98-6/98 1/99, 4/99 11/99, 5/00
Total Hours of Training:			

**b. Supervised Work Experience (completion of this table is not required for 35.590).
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)**

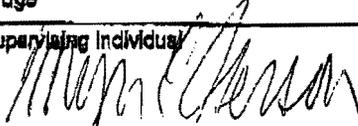
Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	OH # 02110310001 University of Cincinnati	<input type="checkbox"/> Yes <input type="checkbox"/> No	4/98-6/98 1/99, 4/99 11/99, 5/00
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	"	<input type="checkbox"/> Yes <input type="checkbox"/> No	"

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AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience. (continued)

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages	DH# 02110310001 University of Cincinnati	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	4/98-6/98 11/99-4/00 11/99-5/00
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	"	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	"
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	"	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	"
Administering dosages of radioactive drugs to patients or human research subjects	"	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	"
Eluting generator systems appropriate for the 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	"	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	"

Supervising Individual:  License/Permit Number listing supervising individual as an authorized user: **DH #02110310001**

Supervisor meets the requirements below, or equivalent Agreement State requirements (check one).
 35.190 35.290 35.390 35.390 + generator experience in 35.290(c)(1)(ii)(G)

c. For 35.690 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

NRC FORM 313A (AUD)
(3-2007)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II - PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in 35.580)

First Section

Check one of the following for each use requested:

For 35.190

Board Certification

I attest that _____ has satisfactorily completed the requirements in

Name of Proposed Authorized User

10 CFR 35.190(a)(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.

OR

Training and Experience

I attest that Daniel Decker Snowden MD has satisfactorily completed the 80 hours of training and

Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(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.

For 35.290

Board Certification

I attest that _____ has satisfactorily completed the requirements in

Name of Proposed Authorized User

10 CFR 35.290(a)(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.

OR

Training and Experience

I attest that Daniel Decker Snowden MD has satisfactorily completed the 700 hours of training

Name of Proposed Authorized User

and experience, including a minimum of 80 hours of classroom and laboratory training, required by 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.

Second Section

Complete the following for preceptor attestation and signature:

I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

- 35.190
- 35.290
- 35.390
- 35.390 + generator experience

Name of Preceptor <u>MYRON C. GIBSON MD</u>	Signature <u>[Signature]</u>	Telephone Number <u>513 558 3074</u>	Date <u>11/20/09</u>
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License/Permit Number/Facility Name
UNIVERSITY HOSPITAL CINCINNATI OHIO # 02110310001

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U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 59

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.

<p style="text-align: center;">Licensee</p> <p>1. St. Mary's Medical Center</p> <p>2. 2900 First Avenue Huntington, West Virginia 25702-1241</p>	<p>In accordance with the letters dated June 9 and June 15, 2009,</p> <p>3. License number 47-09576-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date February 28, 2013</p> <hr/> <p>5. Docket No. 03008388 Reference No.</p>
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- | | | |
|--|---|--|
| <p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p> <p>C. Any byproduct material permitted by 10 CFR 35.300</p> <p>D. Any byproduct material permitted by 10 CFR 35.400</p> | <p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Sealed Sources (Amersham Health or Medi-Physics, Inc. Models 6711 and 6733; Bard Brachytherapy, Inc. Model STM 1251; BEBIG or Theragenics Corp. Model 125.S06; Best Medical International Models 81-01 and 2301; Implant Sciences Corporation Model 3500; International Brachytherapy SA Model 1251L; IsoAid, L.L.C. Model IAI-125A; Mills Biopharmaceuticals, LLC Models I-125 SL and I-125 SH; North American Scientific, Inc. Model MED3631; Nucletron B.V. Model 130.002)</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. 1.5 curies</p> <p>D. 800 millicuries</p> |
|--|---|--|

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|---|--|--|
| 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 |
| E. Iridium 192 permitted by 10 CFR 35.600 | E. Sealed Sources (Nucletron Model 105.002 [manufactured by Mallinckrodt Medical BV or AEA Technology, Inc.]) | E. 2 sources, not to exceed 20 curies total |
| F. Strontium 90 | F. Sealed Sources (Bebig Model Sr0.S03; AEA Technology Model SICW series [SICW.1 and SICW.2]) | F. 5 millicuries per source and 800 millicuries total |
| G. Nickel 63 | G. Plated Foils (Perkin-Elmer Model 330-0119) | G. 5 sources, not to exceed 15 millicuries each and 75 millicuries total |
| H. Strontium 90 | H. Sealed Sources (Tracerlab Model RA-1) | H. 100 millicuries |
| I. Yttrium 90 | I. Resin microspheres (Sirtex Medical Limited Model SIR-Spheres® [manufactured by Sirtex Wilmington LLC, Sirtex Medical Limited, or ANSTO radiopharmaceuticals and industrials]) | I. 100 millicuries per vial and 540 millicuries total |

9. Authorized use:

- A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
- B. Any imaging and localization study permitted by 10 CFR 35.200.
- C. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300.
- D. Any manual brachytherapy procedure permitted by 10 CFR 35.400.
- E. One source for medical use permitted by 10 CFR 35.600, in a Nucletron Model 105.999 remote afterloader unit. The source activity may not exceed 10 curies at the time of medical use. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.
- F. For use in Best Vascular, Inc. A1000 series models for intravascular brachytherapy.
- G. To be used for sample analysis in compatible gas chromatography devices that have been registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.
- H. Strontium 90 in an ophthalmic radiotherapy source for storage only.
- I. For permanent brachytherapy in the Sirtex Medical Limited SIR-Spheres® delivery system.

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CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 2900 First Avenue, Huntington, West Virginia.
11. The Radiation Safety Officer for this license is James T. Norweck, M.S., DABR.
12. Licensed material is only authorized for use by, or under the supervision of:
 - A. Individuals permitted to work as an authorized user and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.
 - B. Physicians permitted to work as authorized users for Yttrium 90 SIR-Spheres® use in accordance with the notification commitments in the letter dated August 25, 2008.
 - C. The following individuals are authorized users for medical use as indicated:

Authorized Users

Material and Use

Paul D. Akers, M.D.

35.100; 35.200; oral administration of sodium iodide I-131 for imaging and localization studies

Paul V. Akers, M.D.

35.100; 35.200; oral administration of sodium iodide I-131 for imaging and localization studies

Marsha S. Anderson, M.D.

35.100; 35.200; oral administration of sodium iodide I-131 for imaging and localization studies

Rodger A. Blake, M.D.

35.100; 35.200; 35.300

Paul Henry Blom, M.D.

35.100; 35.200

Silvestre P. Cansino, M.D.

35.100; 35.200

Bruce S. Chertow, M.D.

35.100; 35.200; 35.300

Peter A. Chirico, M.D.

35.100; 35.200; 35.300

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Authorized UsersMaterial and Use

James Allen Cochrane, M.D.

35.100; 35.200

Ricky Jack Compton, M.D.

35.100; 35.200; oral administration of sodium iodide I-131 for imaging and localization studies

Robert J. Cure, M.D.

35.100; 35.200; oral administration of sodium iodide I-131

Hans G. Dransfeld, M.D.

35.100; 35.200; 35.300

Joseph Dransfeld, M.D.

35.100; 35.200; oral administration of sodium iodide I-131 for imaging and localization studies

Lee Corey Haikal, M.D.

35.100; 35.200; oral administration of sodium iodide I-131 for imaging and localization studies

David M. Keadle, M.D.

35.100; 35.200; oral administration of sodium iodide I-131

Michael V. Korona, Jr., M.D.

35.100; 35.200

Eric Lawrence Leonard, M.D.

35.100; 35.200; oral administration of sodium iodide I-131 for imaging and localization studies

Phillip P. Lepanto, M.D.

35.300; 35.400; Iridium-192 for uses in a High Dose Rate Remote Afterloader Unit; Strontium-90 for intravascular brachytherapy procedures; Yttrium-90 SIR-Spheres

Donald Lewis, M.D.

35.100; 35.200; 35.300

George J. Linsenmeyer, III, M.D.

35.100; 35.200

Richard E. McWhorter, M.D.

35.100; 35.200; 35.300

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<u>Authorized Users</u>	<u>Material and Use</u>
Grant Douglas Petty, M.D.	35.100; 35.200
James Milton Reynolds, M.D.	35.100; 35.200
Charles Seigler, M.D.	35.100; 35.200
Sanjeev Sharma, M.D.	35.300; 35.400; Iridium-192 for uses in a High Dose Rate Remote Afterloader Unit; Strontium-90 for intravascular brachytherapy procedures; Yttrium- 90 SIR-Spheres
William S. Shells, M.D.	35.100; 35.200; oral administration of sodium iodide I-131 for imaging and localization studies
Tina M. Sias, M.D.	35.100; 35.200
Ralph A. Stevens, M.D.	35.100; 35.200
Torin P. Walters, M.D.	35.100; 35.200; oral administration of sodium iodide I-131 for imaging and localization studies
James Keith Watson, M.D.	35.100; 35.200
Abid Yaqub, M.D.	Oral administration of sodium iodide iodine-131
Nadia Yaqub, M.D.	Oral administration of sodium iodide iodine-131
Abdolreza (Ray) Agahtehrani, M.D.	35.100; 35.200
Tipu Saleem, M.D.	Oral administration of sodium iodide iodine-131

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D. The following individuals are authorized medical physicists as indicated:

Authorized Medical Physicists

Material and Use

M. Douglass Allan, M.S., DABR

Iridium-192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training; Strontium-90 in an Intravascular Brachytherapy Device for calibrations, spot-checks, and training; Strontium-90 ophthalmic sources for storage only

C. Thomas Brannan, M.S., DABR

Iridium-192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training; Strontium-90 in an Intravascular Brachytherapy Device for calibrations, spot-checks, and training; Strontium-90 ophthalmic sources for storage only

Joseph Britt Colenda, M.S., DABR

Iridium-192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training; Strontium-90 in an Intravascular Brachytherapy Device for calibrations, spot-checks, and training; Strontium-90 ophthalmic sources for storage only

E. The following individuals are authorized users for non-medical uses as indicated:

Users

Material and Use

Paul V. Akers, M.D.

Nickel-63

James Allen Cochrane, M.D.

Nickel-63

Phillip P. Lepanto, M.D.

Nickel-63

Richard E. McWhorter, M.D.

Nickel-63

- F. Intravascular brachytherapy procedures shall be conducted under the supervision of the authorized user, who will consult with the interventional cardiologist/physician and authorized medical physicist prior to initiating treatment. The procedures shall be conducted in the physical presence of the authorized user or the authorized medical physicist.

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13. The intravascular brachytherapy afterloader device shall be inspected and serviced at intervals recommended by the manufacturer, and maintenance and repair shall be performed by the manufacturer or persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services
14. 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.
15. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:
- A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
 - B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
 - C. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.
 - D. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
 - E. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.
 - F. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

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- G. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.
16. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.
17. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
18. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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19. 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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26 and the letter dated August 25, 2008. 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 August 29, 2002	[ML022460072]
B.	Application and letter dated January 30, 2003	[ML030350061]
C.	Letter dated June 4, 2004	[ML041740737]
D.	Letter dated March 3, 2006	[ML060820563]
E.	Letter dated April 5, 2006	[ML061020163]
F.	Letter dated September 15, 2006	[ML062700557]
G.	Letter dated September 18, 2006	[ML062700563]
H.	Letter dated September 29, 2006	[ML062760170]
I.	Letter dated October 25, 2006	[ML063100400]
J.	Letter dated January 8, 2007	[ML070080383]
K.	Letter dated February 12, 2007	[ML070430488]
L.	Letter dated August 25, 2008	[ML082470501]
M.	Letter dated September 26, 2008	[ML082820265]
N.	Letter dated June 9, 2009	[ML091630311]

For the U.S. Nuclear Regulatory Commission

Date July 8, 2009

By Original signed by Sandra Gabriel

Sandra Gabriel
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406
Wednesday, July 8, 2009 16:38:12

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

11/2/02, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (47-25408-01)
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** 144311.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.