

12-4-2007

U.S. NRC Region I 475 Allendale Road King of Prussia, PA 19406

03019530

Re:

License Amendment to change Radiation Safety Officer for

NRC Radioactive Materials License # 47-19919-01

(Logan Regional Medical Center, locate in Logan, West Virginia)

Change takes effect on January 1, 2008

Dear Sandra Gabriel,

- 1. We wish to change Radiation Safety Officer from Sharon Long to James T. Norweck, MS as Radiation Safety Officer responsible for ensuring the safe use of radiation under our radioactive materials license. Change takes effect on January 1, 2008. Mr. Norweck is certified in Diagnostic Radiologic Physics by the American Board of Radiology, is currently listed on an Agreement State Radioactive Materials License as RSO for all licensed activities, and has appropriate training and experience. Supporting documentation is enclosed.
- 2. Please remove Sharon Long from our Registration. Takes effect on January 1, 2008.

Mr. Norweck agrees to implement the radiation protection program. Please find attached the Radiation Safety Officer Agreement, and Delegation of Authority.

We appreciate your consideration of this amendment request. If you have any questions regarding this request or should you need any further information, please do not hesitate to contact me.

Sincerely yours

Kevin Fowler CEO Hospital Administrator

141415

Georgia Department of Natural Resources 4220 International Parkway, Suite 100, Atlanta, Georgia 30354

20 International Parkway, Suite 100, Atlanta, Georgia 30354 Noel Holcomb, Commissioner Carol A. Couch, Ph.D., Director Environmental Protection Division 404/362-2675

RADIOACTIVE MATERIALS PROGRAM GEORGIA RADIOACTIVE MATERIALS LICENSE

Pursuant to the Georgia Radiation Control Act O.C.G.A. 31-13 (H.B. 947) 1990 and the Georgia Department of Natural Resources Rules and Regulations, designated Chapter 391-3-17, and in reliance on statements and representations heretofore made by the 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 and regulations of the Georgia Department of Natural Resources and orders issued by the Department, now or hereafter in effect, and to any condition specified below.

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Lic	ense	(1. Name and	2. Ad	ddress)	3.		cordance with letter dated March 28, License Number GA 328-1 is
	WellStar Kennestone Hospital 677 Church Street						nded in its entirety to read as follows:
	rietta, Geo				4.	Expiration Date: March 31, 2009	
					5.	Telep	phone Number: (770) 793-5000
6.		CTIVE AL (ELEMENT SS NUMBER)	7.	CHEMICAL AND/O PHYSICAL FORM	OR	8.	. MAXIMUM QUANTITY LICENSEE MAY POSSESS AT ANY ONE TIME
A.		active material in (6)(g) of -3-1702	A.	In vitro test kits per (6)(g) of Rule 391-3			As needed
B.		active material by (41) of Rule 05	B.	Any radiopharmace permitted by (41) o 391-3-1705		В.	. As needed
C.	permitted 391-3-17-	active material by (44) of Rule .05 (including generators and 1)	C.	Any radiopharmace permitted by (44) or 391-3-1705 (incluaerosols, generator iodine-131)	f Rule ding	C.	. As needed
D.		active material by (48) of Rule .05	D.	Any radiopharmace permitted by (48) or 391-3-1705		D.	. 900 millicuries
E.		active material in (55) of Rule 05	E.	Any therapeutic sea source permitted in Rule 391-3-1705		E.	. As needed
F.	Germaniu 68	ım 68/Gallium	F.	Germanium 68/Gal Generator (DuPont		F.	100 millicuries

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6.	RADIOACTIVE MATERIAL (ELEMENT AND MASS NUMBER)	7.	CHEMICAL AND/OR PHYSICAL FORM	8.	MAXIMUM QUANTITY LICENSEE MAY POSSESS AT ANY ONE TIME
			IGG-100)		
G.	Strontium 82/Rubidium 82	G.	Strontium 82/Rubidium 82 Generator (Rubidium Chloride)	G.	300 millicuries
Н.	Germanium 68	H.	Germanium Chloride (GeCl ₄)	Н.	100 millicuries
I.	Fluorine 18	1.	Fluorodeoxyglucose (FDG)	1.	As needed (unit doses with a nominal activity of 20 mCi each)
J.	Iridium 192	J.	Sealed Sources (Models which are registered in accordance with Rule 391-3-17.02(11)(I) or equivalent regulations of the US NRC or another Agreement State)	J.	2 sources, 24 Curies maximum activity with no source to exceed 13 Curies
K.	Any radioactive material, except alpha emitters	K.	See item 9.K. below	K.	See item 9.K. below
L.	Any radioactive material, except alpha emitters	L.	Sealed Source	L.	As needed

9. AUTHORIZED USE

- A. In vitro testing procedures as listed in (6)(g) of Rule 391-3-17-.02.
- B. Uptake, dilution, or excretion studies as permitted by (41) of Rule 391-3-17-.05.
- C. Imaging and localization studies as permitted by (44) of Rule 391-3-17-.05.
- D. Therapeutic procedures as permitted by (48) of Rule 391-3-17-.05.
- E. Brachytherapy procedures as permitted by (55) of Rule 391-3-17-.05.
- F. For elution of Gallium 68 for use in imaging and localization studies.
- G. For elution of Rubidium 82 for use in imaging and localization studies.
- H. For instrument performance tests.

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Authorized Use (continued)

- For imaging of glucose metabolism.
- J. One source for medical use described in 391-3-17-.05(67) in a Varian Systems VariSource HDR remote afterloader brachytherapy unit. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.
- K. For possession, storage, use and transportation incidental to the performance of tests for leakage and/or contamination on sealed sources, and on devices containing sealed sources, which contain radionuclides.
- L. Sealed sources incidental to the performance of tests for leakage and proper operation of devices on/off mechanism and indicators.

CONDITIONS

- 10. Radioactive material shall be used at the licensee's address stated in item 2 above, WellStar Kennestone Regional Oncology Center, 55 South Medical Drive, Suite 100, Marietta, Georgia 30060, WellStar Kennestone Imaging @ 210 Building, 60 Lacy Street, Marietta, Georgia 30060, WellStar Kennestone Medical Imaging Towne Lake @ South Cherokee, 120 Stonebridge Parkway, Woodstock, Georgia 30189, WellStar Kennestone Imaging @ 700 Building, 700 Church Street, Marietta, Georgia 30060, and WellStar Kennestone Imaging, Suite #LL10, 91 Tower Road, Marietta, Georgia 30060.
- 11. The licensee shall comply with the provisions of Georgia Department of Natural Resources Rule 391-3-17-.03, "Standards for Protection Against Radiation. Amended.", Rule 391-3-17-.05, "Use of Radionuclides in the Healing Arts. Amended.", Rule 391-3-17-.06, "Transportation of Radioactive Material. Amended.", and Rule 391-3-17-.07, "Notice, Instructions and Reports to Workers: Inspections. Amended."
- 12. In accordance with DNR Board Policy adopted May 28, 2003 the fees associated with this license, fee category A.2 are:

Application fee \$710.00 Annual fee \$2400.00 Amendment fee \$430.00 Non-routine Inspection fee \$1500.00

Checks for the fees should be made payable to the <u>Department of Natural Resources</u>, <u>Radioactive Materials Program</u>, and mailed to the following address:

Radioactive Materials Fees P.O. Box 101161 Atlanta, GA 30392

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Condition 12 (continued)

Mail license applications and amendment requests to the following address:

Radioactive Materials Program 4220 International Parkway, Suite 100 Atlanta, GA 30354

All license applications, amendments and fee payments should be mailed the same day.

Annual fees are billed by the Department at the beginning of each fiscal year.

- 13. A. The Radiation Safety Officer in this program shall be James T. Norweck, MS, DABR.
 - B. The Assistant Radiation Safety Officer in this program shall be Thomas G. Ruckdeschel, MS. DABR.
- 14. Radioactive material shall be used by or under the supervision (as defined in (18) of Rule 391-3-17-.05) of the following individuals as indicated:
 - A. Individuals permitted to work as an authorized user, and/or authorized medical physicist in accordance with Rule 391-3-17-.05(10) and (11).
 - B. The following individuals are authorized users for medical use:

James B. Burns, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG
Michael H. Wolff, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG
Joseph Armistead, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG
Augustus G. Vaughn, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG
Alan Zuckerman, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG
Thomas W. Hinz, M.D.	391-3-1705(41), (44), (48), <i>in vitro</i> studies, and F-18 FDG

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Condition 14 (continued)

	Material and Goo
Robert Stephenson, M.D.	391-3-1705(41), (44), (48), <i>in vitro</i> studies, and F-18 FDG
James M. Tallman, M.D.	391-3-1705(41), (44), (48), <i>in vitro</i> studies, and F-18 FDG
Joseph H. Moyers, M.D.	391-3-1705(41), (44), (48), <i>in vitro</i> studies, and F-18 FDG
Jaydip Datta, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG
George M. McCord, M.D.	391-3-1705(41), (44), (48), <i>in vitro</i> studies, and F-18 FDG
M. Terry Ward, M.D.	391-3-1705(41), (44), (48), <i>in vitro</i> studies, and F-18 FDG
Dennis Incorvati, M.D.	391-3-1705(44), and F-18 FDG limited to cardiovascular clinical procedures
Paul Simonoff, M.D.	391-3-1705(44), and F-18 FDG limited to cardiovascular clinical procedures
William Charles Chocallo, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG
Robert E. Chandlee, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG
Walter Louis Meier, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG
Steven Brantley, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG
Raul Paraliticci, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG

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Condition 14 (continued)

	Material and Use
Donald A. Page, M.D.	Any Radioactive Material identified in (44) of Rule 391-3-1705; instrument performance tests; recharging of Ga-68/Ge-68 generator system; and F-18 FDG for uses incident to the diagnosis of cardiac disease
John Williams, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F- 18 FDG
Linda Brown, M.D.	391-3-1705(41), (44), (48), <i>in vitro</i> studies, and F-18 FDG
Martin Silbiger, M.D.	391-3-1705(41), (44), (48), <i>in vitro</i> studies, and F-18 FDG
Howard J. Snapper, M.D.	391-3-1705(44), and F-18 FDG limited to cardiovascular clinical procedures
Lorie Hughes, M.D.	391-3-1705 (48), (55), and Iridium 192 for uses in a high dose rate afterloader brachytherapy unit
Clark M. Pollitt, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F- 18 FDG
Kenneth L. Haile, M.D.	391-3-1705 (55), and Iridium 192 for uses in a high dose rate afterloader brachytherapy unit
Seymour J. Rosenbloom, M.D.	391-3-1705(48) and <i>in vitro</i> studies
William Thoms, M.D.	391-3-1705 (55), and Iridium 192 for uses in a high dose rate afterloader brachytherapy unit
David Alan Zimmerman, M.D.	391-3-1705(44), and F-18 FDG limited to cardiovascular clinical procedures
J. Edward Robertson, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG

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Condition 14 (continued)

	Material and Use
Brian Mark Gordon, M.D.	391-3-1705(41), (44), (48), <i>in vitro</i> studies, and F-18 FDG
Mark McLaughlin, M. D.	391-3-1705 (55), and Iridium 192 for uses in a high dose rate afterloader brachytherapy unit
Daniel J. Klienman, M. D.	Any Radioactive Material identified in (44) of Rule 391-3-1705; instrument performance tests; recharging of Ga-68/Ge-68 generator system; and F-18 FDG for uses incident to the diagnosis of cardiac disease
Nydia Bladuell, M. D.	391-3-1705(44), and F-18 FDG limited to cardiovascular clinical procedures
David Caras, M. D.	391-3-1705(44), and F-18 FDG limited to cardiovascular clinical procedures
Brian S. Vincent, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG
Sarah B. Webb, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG
Pauline R. Sleder, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG
Martha H. Garrison, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG
Mark L. Wetherly, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG
Mark J. Silverstein, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG
Jay Cinnamon, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG

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Condition 14 (continued)

Ashutosh Vaddadi Rao, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG
Bruce E. Alayof, M.D.	391-3-1705(44), and F-18 FDG limited to cardiovascular clinical procedures
Julian T. Isakow, M.D.	391-3-1705(44), and F-18 FDG limited to cardiovascular clinical procedures
Randall Grimes, M.D.	391-3-1705(44), and F-18 FDG limited to cardiovascular clinical procedures
Dhaval G. Patel, M.D.	391-3-1705(44), and F-18 FDG limited to cardiovascular clinical procedures
Reed Seligman, M.D.	391-3-1705(44), and F-18 FDG limited to cardiovascular clinical procedures
Nitin Mayur, M.D.	Oral administration of sodium iodide I-131 and <i>in vitro</i> studies
Kevin Early, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG
John Gira, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG
Scott Wottrich, M.D.	391-3-1705(41), (44), <i>in vitro</i> studies, and F-18 FDG
Sarito Kansal, M.D.	391-3-1705(44), and F-18 FDG limited to cardiovascular clinical procedures
Diosdado Irlandez, M.D.	391-3-1705(44), and F-18 FDG limited to cardiovascular clinical procedures
Antonio Baute, M.D.	391-3-1705(44), and F-18 FDG limited to cardiovascular clinical procedures

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Condition 14 (continued)

C. The following individuals are authorized medical physicists:

Material and Use

Dwight T. Still, MMS, DABR

Iridium 192 in a High Dose Rate Remote

Afterloader Unit for calibrations, and spot

checks

Jyotsna Vanapalli, MS

Iridium 192 in a High Dose Rate Remote Afterloader Unit for calibrations, and spot

checks

- 15. The licensee may receive, possess and use radioactive material for check, calibration, transmission, and reference sources as authorized by (32) of Rule 391-3-17-.05.
- 16. A. The licensee shall perform required tests for leakage or contamination at intervals not to exceed six (6) months in accordance with Rule 391-3-17-.03(6). Analysis of the tests shall be performed by persons specifically authorized by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform such services.
 - B. Notwithstanding the requirements of Rule 391-3-17-.03(6), Cesium 137 sealed sources (3M Company Models 6H6A, 6H6B, and 6C6D) shall be tested for leakage and/or contamination at intervals not to exceed 3 years. Any source received from another person, which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer, shall not be put into use until tested.
- 17. Sealed sources containing radioactive material shall not be opened by the licensee.
- 18. The licensee shall not transfer possession and/or control of materials or products containing radioactive material as a contaminant except:
 - A. By transfer of waste to an authorized recipient;
 - B. By transfer to a specifically licensed recipient; or
 - C. As provided otherwise by a specific condition of this license pursuant to the requirements of (13) of Rule 391-3-17-.03.

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Conditions (continued)

- 19. Procedures for the afterloader devices (including intravascular brachytherapy devices) shall be conducted in the physical presence of the authorized medical physicist and the authorized user as required by Rule 391-3-17-.05(71)(f).
- 20. Documentation of training for Nuclear Medicine Technologists and Radiation Therapists outlined in Rule 391-3-17-.05(25) shall be maintained for Department inspection as required by Rule 391-3-17-.05(100).
- 21. All records or copies of records pertaining to Radioactive Material License GA 328-1shall be maintained by the Radiation Safety Office at the licensee's address stated in item 2 above.
- 22. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material with a half-life greater than 120 days to quantities less than those specified in Rule 391-3-17-.02(8)(g)4. Exceeding quantities in .02(8)(g)4. requires the submittal of a financial assurance mechanism or a decommissioning funding plan.
- 23. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material at a single location to quantities below the limits specified in Rule 391-3-17-.02(21)(e) Schedule E, which requires consideration of the need for an emergency plan (.02)(7)(h)) for responding to a release of licensed material.
- 24. Patients who have been administered therapeutic quantities of radiopharmaceuticals shall be furnished with a patient information sheet supplied by the manufacturer (if applicable) or equivalent information on a hospital-generated information sheet. The "Instructions for Family of Released Patient" form, Appendix IV of NCRP Report 37, or equivalent shall be provided to patients. Records of these instructions shall be kept on file for inspection by the Department.
- 25. The licensee shall conduct a physical inventory every six months of sealed sources in accordance with Rule 391-3-17-.05(33)(d).
- 26. The licensee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash in accordance with Rule 391-3-17-.05(40).
- 27. The specified possession limit includes all licensed material possessed by the licensee under this license whether in storage, implanted in patients, or otherwise in use.

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Conditions (continued)

- 28. A. Radionuclides separated from a generator either by elution of a generator or by an extraction process shall be tested to detect and quantify contaminant activity in accordance with Rule 391-3-17-.05(45)(b).
 - B. Prior to first use of a generator, the licensee shall establish written procedures for personnel performing tests to detect and quantify contaminants. These procedures shall include all necessary calculations and steps to be taken if activities of contaminants in excess of the limits specified in 391-3-17-.05(45)(a) are detected.
 - C. Personnel performing tests to detect and quantify contaminants shall be given specific training in performing these tests prior to conducting such tests.
 - D. 1. The licensee shall maintain for inspection by the Department records of the results of each test performed to detect and quantify contaminants and records of training given to personnel performing these tests.
 - 2. Records described in Subitem D.1. above shall be maintained for three (3) years following the performance of the tests and the training of personnel.
- 29. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with statements, representations, and procedures contained in the documents, including any enclosures, listed below:
 - A. Application received March 4, 2004, signed by Robert Lipson, M.D., President and CEO
 - B. Letter with attachments dated March 28, 2005 and signed by James T. Norweck, M.S., Certified Medical Physicist, Radiation Safety Officer

This license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in Rule 391-3-17-.05(16). The Georgia Department of Natural Resources' regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the Regulations.

FOR THE DEPARTMENT OF NATURAL RESOURCES

Date:	April 11, 2005	BY	- Su Sale
			.)

Liz Seale

· · LOGAN GENERAL HOSPITAL NUCLEAR MEDICINE DEPARTMENT LOGAN, WEST VIRGINIA NRC # 47-19919-01

Patient Record # 65373

12-05-2007 08:30

Name : Birth Dt:

Dept ID_: 120064/

Status_: OP Doctor__: KITI

Tech___: MM

Exam Dt.: 12-05-2007 at 08:29 Inj:08:29

Exams : THYROID I-123 UPTAKE

Rad.Phar: I-123 Syncor Inv/Lot#: 91495/701836

Expires: 12/5/2007 11:59:00 PM Dose Act: 228.000uCi Var:----Dose Vol: 1.000Caps RxAct: 0.000uCi Inject : Oral AdvRct:N DsRt:Oral

Estimated Absorbed Dosimetry Report :

TOTAL BODY

0.0205 rads 7.7520 rads

THYROID

RSO Agreement to Implement Licensee's Radiation Protection Program

A licensee's management shall appoint a Radiation Safety Officer, who agrees in writing to be responsible for implementing the Radiation Protection Program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. This requirement applies to any individual who assumed the duties of RSO after October 24, 2002 for NRC licenses (the effective date of the Final Rule for NRC Licensee's).

The established duties and responsibilities of the Radiation Safety Officer are:

- Each licensee shall develop, document, and implement a Radiation Protection Program sufficient to ensure compliance with the provisions of the Regulations. The RSO shall be responsible for implementing the Radiation Protection Program.
- 2. As part of the Radiation Protection Program, the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA);
- 3. The licensee shall, at least annually, review the Radiation Protection Program content and implementation
- 4. Review and approve revisions to the Radiation Protection Program

The licensee agrees to provide the Radiation Safety Officer with sufficient authority, organizational freedom, time, resources, and management prerogative, to:

- 1. Identify radiation safety problems;
- 2. Initiate, recommend, or provide corrective actions;
- 3. Stop unsafe operations; and,
- 4. Verify implementation of corrective actions.

Facility Name & Location:	Logan Regional Medical Center Logan, West Virginia	License No.	
	Management Representative Name:		Date
	Management Representative Signature:	Timber _	12/5/
Agreed	Radiation Safety Officer Name:	James T. Norweck, MS	Date
to by:	Radiation Safety Officer Signature:	Rend Jorech	-
	Alternate Radiation Safety Officer Name:		Date
	Alternate Radiation Safety Officer Signature:		

Important: Maintain a copy of this documentation with the Radiation Protection Program

Radiation Safety Officer – Delegation of Authority

Facility:

Logan Regional Medical Center

Logan, West Virginia

Memo To:

All Employees

From:

Kevin Fowler, Chief Executive Officer

Subject

Delegation of Authority

James T. Norweck, MS, has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radiation. The Radiation Safety Officer 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 Radiation Safety Officer shall ensure that the license activities are performed using approved procedures and meeting the regulatory requirements in the daily operations of the Radiation Safety Program. Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities.

finntral

This is to acknowledge the receipt of the second of the se	nd to inform you that the initial processing which				
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 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				