BON SECOURS
DEPAUL MEDICAL CENTER
Bon Secours Health System

August 7, 2007

NMSB1

U.S. Nuclear Regulatory Commission
Region 1 Office
475 Allendale Road
King of Prussia, PA 19406-1415

03003302

Subject: Bon Secours DePaul Medical Center
License Amendment (License 45-00986-01)

To Whom It May Concern:

We are writing to request the following changes be made to our the materials license for DePaul Medical Center (license 45-00986-01):

- Please add Jonathan C. White, M.D.
- Please add Andrew P. Loiacono, M.D.
- Please add Yasmeen Knowles, M.D.
- Please add Kevin Halista, M.D.

We are requesting each of these physicians be added to the license for 35.100 and 35.200 uses. Enclosed are forms for documentation of their training and experience or of their inclusion on another NRC license. These requests have been approved by our Radiation Safety Committee.

Thank you for your assistance. If you have questions regarding this inquiry, please contact me at 757-889-5945.

Sincerely,

Kristi Sink
Director Oncology

Copy to: Daniel Duggan, EVP/Administrator
Robert Mariano, M.D., Radiation Safety Officer

141089

NMSS/RGN1 MATERIALS-002

150 Kingsley Lane Norfolk, Virginia 23505 Telephone 757/889-5000 Fax 757/423-3148

Jonathan C. White, M.D.

STATE OF MAINE
MATERIALS LICENSE

License No. 05611
Amendment 10 (corr.)

Pursuant to the Maine Radiation Statutes (22 MRSA 677) and Maine Department of Human Services regulations on radiation (10-144A CMR 220), 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 radioactive material as designated below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the Maine Department of Human Services now or hereafter in effect and to any conditions specified below.

1. Name Maine Medical Center	This license is issued in accordance with correspondence dated: November 21, 2005	
2. Address 22 Bramhall Street Portland, Maine 04102	3. License Number **05611**	Amendment Number 10 (corrected)
	4. Expiration Date January 31, 2010	

5. Radionuclide	6. Form of Material	7. Maximum Activity
A. Any radioactive material with atomic number 1 through 83	A. Any	A. 400 millicuries (14.8 GBq) per radionuclide, not to exceed 15 curies (555 GBq) total
B. Any radioactive material with atomic number 1 through 83	B. Sealed sources	B. 4 curies (148 GBq) per radionuclide , not to exceed 15 curies (555 GBq) total
C. Technetium-99m (^{99}Tc)	C. Any	C. 5 curies (185 GBq) total
D. Cesium-137 (^{137}Cs)	D. Sealed Sources	D. 250 curies (9.25 TBq) per source, not to exceed 500 curies (1.85 TBq) total
E. Iridium-192 (^{192}Ir)	E. Sealed Sources	E. 13 Curies (481 GBq) per source and **21.9 Curies** (810.3 GBq) total

8. Authorized use
   A. through C. Possession and use in medical diagnosis, therapy and research in humans; instrument calibration, and in-vitro studies.
   D. Possession and use in whole body irradiation of mice, mitotic inactivation of tissue culture cells, and other animal and in-vitro laboratory research.
   E. One source for possession and medical use described in G.600 in a Nucletron Model 105.999 remote afterloading brachytherapy unit. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.

CONDITIONS

9. A. Licensed material may be used at the licensee's facilities located at Maine Medical Center, 22 Bramhall Street, Portland, Maine; Maine Medical Center Research Institute, 81 Research Drive, Scarborough, Maine, Maine Medical Center Campus, 98 Campus Drive, Scarborough, Maine, Coastal Cancer Treatment Center, 205 Congress Avenue, Bath, Maine, and at the Maine Medical Center Brighton Campus, 335 Brighton Avenue, Portland, Maine.

   B. Licensed material may also be received and stored at the offsite warehouse located at 78 Scott Drive, Westbrook, Maine.

STATE OF MAINE
MATERIALS LICENSE

Supplementary Sheet

10. A. Licensed material shall be used by, or under the supervision of, individuals designated in writing by the Radiation Safety Committee, **Michael Quinn, M.D., Chairperson**.

B. The use of licensed material in or on humans shall be by a physician, dentist, or podiatrist as defined in Part A of the State of Maine Rules Relating to Radiation Protection (SMRRRP).

C. Individuals designated in writing to work as authorized users shall meet the training and experience criteria established in Part G of the SMRRRP and outlined in the application dated September 29, 1999.

D. The Radiation Safety Officer for this license is Elizabeth G. Quate, M.S.

11. In addition to the possession limits in Item 7, the licensee shall further restrict the possession of licensed material so that at no time is a quantity of radioactive material possessed in excess of a quantity which requires decommissioning funding in accordance with C.8.F.

12. The sealed sources or detector cells containing the licensed material, shall not be opened or sources removed from the source holders or detector cells by the licensee.

13. A. Sealed sources and detector cells shall be tested for leakage and/or contamination as specified in Part D of the SMRRRP unless specifically provided otherwise in this license.

B. The licensee is authorized to collect leak samples for analysis by the licensee, or persons specifically licensed by the Agency, the Nuclear Regulatory Commission, or an Agreement State to perform such services may perform tests for leakage and/or contamination.

14. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the Unites States Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.

15. The licensee shall conduct a physical inventory of all sealed sources and devices as specified in Part G of the SMRRRP.

16. The licensee is authorized to transport licensed material in accordance with the provisions of Part L of the SMRRRP, "Transportation of Radioactive Material," 10 CFR Part 71, and the regulations of the Federal and State Departments of Transportation.

17. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided:

A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

C. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

STATE OF MAINE
MATERIALS LICENSE

Supplementary Sheet

18. A. 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 Agency's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

1. Renewal application dated December 29, 2004
2. Letter dated March 2, 2005

B. The licensee shall comply with the requirements described in the Agency letter dated November 21, 2005 and attached document entitled "Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern." The licensee shall complete implementation of said requirements within 6 months from the issuance of the license amendment or the first day that radionuclides in quantities of concern are possessed at or above the limits specified in Table 1 of the attachment, whichever is later. Within 25 days after the implementation of the requirements of this condition, the licensee shall notify the Maine Radiation Control Program in writing that it has completed the requirements of this condition.

Date: March 27, 2006

Shawn W. Seeley
Inspector / License Reviewer
Radiation Control Program
Division of Environmental Health

MAINE MEDICAL CENTER
PORTLAND, MAINE

PERMIT FOR USE OF RADIOACTIVE MATERIALS

PERMIT NUMBER: 002

EFFECTIVE DATE: January 25, 2004 EXPIRATION DATE: January 25, 2006

The Radiation Safety Committee of the Maine Medical Center, Portland, Maine hereby authorizes:

JONATHAN C. WHITE, M.D., PH.D.

To possess and use the following radioactive materials:

ISOTOPE	FORM	AMOUNT (mCi)	PURPOSE
Any radioactive material identified in G.100	Any radiopharmaceutical identified in G.100	As needed	Any uptake, dilution and excretion procedure approved in G.100
Any radioactive material identified in G.200	Any radiopharmaceutical identified in G.200	As needed	Any imaging and localization procedure approved in G.200
Any radioactive material identified in G.300	Any radiopharmaceutical identified in G.300	As needed	Any radiopharmaceutical therapy procedure approved in G.300
Gadolinium-153	Sealed Sources	800 mCi	For possession and use for non-uniform attenuation corrections in nuclear medicine camera
Any radioactive material identified in C.6.F	Prepackaged kits	As needed	In-vitro studies
Uranium depleted in Uranium-235	Cadmium plated metal	400 kg	Shielding in a linear accelerator
Strontium-90	Sealed Sources	10 mCi	For instrument calibration
Cesium-137	Sealed Sources	200 mCi	For use in J.S. Shepherd Model 28-5 calibrator for calibrating instruments
Xenon-133 gas	Gas	As needed	For use in blood flow in solution or pulmonary function studies
Any radioactive material with atomic numbers 1-83	Any	200 mCi each radionuclide and 5 Ci total	For use in in-vitro studies. Laboratory research, and research on human Subjects

MAINE MEDICAL CENTER
PORTLAND, MAINE

PERMIT FOR USE OF RADIOACTIVE MATERIALS

PERMIT NUMBER: 002

EFFECTIVE DATE: January 25, 2004 EXPIRATION DATE: January 25, 2006

Radioactive materials are authorized only for possession and use at:

Maine Medical Center, 22 Bramhall Street, Portland, Maine
Maine Medical Center Brighton Campus, 335 Brighton Avenue, Portland, Maine
Maine Medical Center Research Institute, 81 Research Drive, Scarborough, Maine
Maine Medical Center's offsite warehouse, 78 Scott Drive, Westbrook, Maine
Maine Medical Center, 100 U.S. Route 1, Scarborough, Maine

Possession and use of radioactive materials is subject to the conditions described on the following page:

Elizabeth G. Quate, M.S.
Radiation Safety Officer

Jonathan C. White, M.D., Ph.D., Chair
Radiation Safety Committee

STATE OF MAINE
MATERIALS LICENSE

Pursuant to the Maine Radiation Statutes (22 MRSA 677) and Maine Department of Human Services regulations on radiation (10-144A CMR 220), 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 radioactive material as designated below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the Maine Department of Human Services now or hereafter in effect and to any conditions specified below.

1. Name Maine Molecular Imaging, LLC	This license is issued in accordance with correspondence dated: October 22, 2001	
2. Address 33 Gorham Road Scarborough, Maine 04074	3. License Number 05623	Amendment Number
	4. Expiration Date January 31, 2007	

5. Radionuclide	6. Form of Material	7. Maximum Activity
A. Any Positron Emission Tomography (PET) isotope identified in G.100	A. Any Positron Emission Tomography (PET) radiopharmaceutical identified in G.100	A. 120 millicuries (4440 MBq)
B. Cobalt-57	B. Sealed Sources	B. Not to exceed 15 millicuries (555 MBq)
C. Cesium-137	C. Sealed Sources	C. Not to exceed 500 microcuries (18.5 MBq)
D. Germanium-68	D. Sealed Sources	D. Not to exceed 35 millicuries (1295 MBq)

8. Authorized use
   - A. Any Positron Emission Tomography (PET) procedure approved in G.100
   - B. Calibration and/or reference sources
   - C. Calibration and/or reference sources
   - D. Calibration and/or reference sources

9. Licensed material may only be delivered to the licensee's mobile unit, the primary storage location, and used while at:

   (1) 33 Gorham Road, Scarborough, Maine.
   (2) Maine Medical Center – Brighton Campus, 335 Brighton Avenue, Portland, Maine.
   (3) MaineGeneral Medical Center, 6 East Chestnut Street, Augusta, Maine.
   (4) St. Mary's Regional Medical Center, Campus Ave, Lewiston, Maine.
   (5) Mid-Coast Hospital, 123 Medical Center Drive, Brunswick, Maine.
   (6) Southern Maine Medical Center, One Medical Center Drive, Biddeford, Maine

10. Radiation Safety Officer: Michael Quinn, M.D.

DEPARTMENT OF HUMAN SERVICES
DIRECTOR
CONDITIONS

STATE OF MAINE
MATERIALS LICENSE

Supplementary Sheet

11.	Authorized Users:	Material and Use:
	Michael Quinn, M.D.	Items 5.A. through 5.D.
	Roger T. Pezzuti, M.D.	Items 5.A. through 5.D.
	Jonathan C. White, M.D.	Items 5.A. through 5.D.

12. All radioactive material shall be delivered directly to the mobil unit. No material shall be delivered to client facilities.

13. A letter of agreement with each client facility will be obtained authorizing Maine Molecular Imaging to place the mobile unit on the client's property and to receive and use radioactive material only in the mobile unit.

14. The licensee may transport licensed material in accordance with the provisions of Part L of the Maine Rules Relating to Radiation Protection, U. S. Nuclear Regulatory Commission rules 10 CFR 71, and the regulations of Federal and State Departments of Transportation.

15. 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 Agency's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated October 22, 2001
B. Letter dated December 11, 2001

Date December 27, 2001

Wayne D. Malloch, Inspector
Radiation Control Program
Division of Health Engineering

Andrew P. Loiacono, M.D.

D

NRC FORM 313A (AUD) (10-2006) U.S. NUCLEAR REGULATORY COMMISSION

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: Andrew P. Loiacono

State or Territory Where Licensed: VA

Requested Authorization(s) *(check all that apply)*

- [x] 35.100 Uptake, dilution, and excretion studies
- [x] 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)*.

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

NRC FORM 313A (AUD) (10-2006) 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	Eastern Va. Med. School Sentara Norfolk Gen. Hosp Norfolk VA NRC Lic # 45-00131-02	20	2001-2005
Radiation protection	"	20	"
Mathematics pertaining to the use and measurement of radioactivity	"	20	"
Chemistry of byproduct material for medical use *(not required for 35.590)*	"	20	"
Radiation biology	"	20	"
	Total Hours of Training:	100	

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.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	as above EVMS - SNORT NRC Lic # 45-00131-02	50	2001-2005
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	"	50	"
Calculating, measuring, and safely preparing patient or human research subject dosages	"	200	"

NRC FORM 313A (AUD) U.S. NUCLEAR REGULATORY COMMISSION
(10-2006)

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	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	EVMS - SNGH as above	200	2001-2005
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	"	50	"
Administering dosages of radioactive drugs to patients or human research subjects	"	100	"
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	"	50	"
	Total Hours of Experience:	700	

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Lester S. Johnson, MD, PhD	45-00131-02

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check one)*.

☑ 35.100 ☑ 35.290 ☐ 35.390 ☐ 35.390 + generator experience in 35.290(c)(1)(ii)(G)

c. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates
	NA	

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) U.S. NUCLEAR REGULATORY COMMISSION
(10-2006)

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 seperate preceptor statement from each. (Not required to meet training requirements in 35.590)

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 A. P. Loiacono has satisfactorily completed the 60 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 A. P. Loiacono 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	Signature	Telephone Number	Date
Lester S. Johnson		757-388-5902	3-2-07

License/Permit Number/Facility Name: Sentara Norfolk General Hospital 45-00131-02

NRC FORM 313A (AUT) (10-2000) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396]

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

Name of Proposed Authorized User: Andrew P. Loiacono

State or Territory Where Licensed: VA

Requested Authorization(s) *(check all that apply)*:

- ☐ 35.300 Use of unsealed byproduct material for which a written directive is required

OR

- ☑ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ☐ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)
- ☐ 35.300 Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required
- ☐ 35.300 Parenteral administration of any other radionuclide for which a written directive is required

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 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. For 35.390, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience.

c. For 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience.

d. Skip to and complete Part II Preceptor Attestation.

☐ 2. **Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization**

a. Authorized User on Materials License _____ under the requirements below or equivalent Agreement State requirements *(check all that apply)*:

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.490 ☐ 35.690

b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

NRC FORM 313A (AUT) (10-2006) 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 ☐ 35.390 ☑ 35.392 ☐ 35.394 ☐ 35.396

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	EVMS SNGH 45-00131-02	20	2001-2005
Radiation protection	"	20	"
Mathematics pertaining to the use and measurement of radioactivity	"	20	"
Chemistry of byproduct material for medical use	"	20	"
Radiation biology	"	20	"
Total Hours of Training:		100	

b. Supervised Work Experience ☐ 35.390 ☑ 35.392 ☐ 35.394 ☐ 35.396

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	as above	50	2001-2005
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	"	50	"
Calculating, measuring, and safely preparing patient or human research subject dosages	"	200	"
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	"	200	"
Using procedures to contain spilled byproduct material safely and using proper deocontamination procedures	"	50	"
Total Hours of Supervised Work Experience:		550	

NRC FORM 313A (AUT) (10-2006) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

b. Supervised Work Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Patsy J. Loiacono	45-00131-02

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

- ☐ 35.390
- ☑ 35.392
- ☐ 35.394
- ☐ 35.396

With experience administering dosages of:

- ☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- ☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- ☐ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

c. Supervised Clinical Case Experience

If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	10	EVMS SN 6H 45-00131-02	2001-2005
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)			
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required			
Parenteral adminstration of any other radionuclide for which a written directive is required (List radionuclides)			

NRC FORM 313A (AUT) U.S. NUCLEAR REGULATORY COMMISSION
(10-2006)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

c. Supervised Clinical Case Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
P. J. Loiacono MD	45-00131-02

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

- ☐ 35.390 With experience administering dosages of:
- ☑ 35.392
  - ☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ☐ 35.394
  - ☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- ☐ 35.396
  - ☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
  - ☐ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

d. Provide completed Part II Preceptor Attestation.

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.

First Section
Check one of the following for each requested authorization:

For 35.390:

Board Certification

☐ I attest that _____ has satisfactorily completed the training and experience
Name of Proposed Authorized User

requirements in 35.390(a)(1).

OR

Training and Experience

☐ I attest that _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

NRC FORM 313A (AUT) U.S. NUCLEAR REGULATORY COMMISSION
(10-2006)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☑ I attest that Andrew P. Loiacono (Name of Proposed Authorized User) has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case experience required in 35.392(c)(2).

For 35.394 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case experience required in 35.394(c)(2).

Second Section

☑ I attest that Andrew P. Loiacono (Name of Proposed Authorized User) has satisfactorily completed the required clinical case experience required in 35.390(b)(1)(ii)G listed below:

☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

Third Section

☑ I attest that Andrew P. Loiacono (Name of Proposed Authorized User) has satisfactorily achieved a level of competency to function independently as an authorized user for:

☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

NRC FORM 313A (AUT) (10-2006) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For 35.396:

Current 35.490 or 35.690 authorized user:

☐ I attest that _____ (Name of Proposed Authorized User) is an authorized user under 10 CFR 35.490 or 35.690 or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral adminstration of any other radionuclide for which a written directive is required

OR

Board Certification:

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily completed the board certification requirements of 35.396(a), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral adminstration of any other radionuclide for which a written directive is required

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Fifth Section

Complete the following for preceptor attestation and signature:

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

☐ 35.390 ☑ 35.392 ☐ 35.394 ☐ 35.396

☑ I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor	Signature	Telephone Number	Date
Patsy J. Loiacono			

License/Permit Number/Facility Name

(EVMS) SNGH 45-00131-02

NRC FORM 313A (4MT) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For 35.396:

Current 35.490 or 35.690 authorized user:

I attest that _____ (Name of Proposed Authorized User) is an authorized user under 10 CFR 35.490 or 35.690 or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral administration of any other radionuclide for which a written directive is required

OR

Board Certification:

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily completed the board certification requirements of 35.396(a), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral administration of any other radionuclide for which a written directive is required

Fifth Section

Complete the following for preceptor attestation and signature:

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

☐ 35.390 ☑ 35.392 ☐ 35.394 ☐ 35.396

☑ I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

☑ Oral NaI 131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor: Patsy J. Loiacono Signature: Patsy J. Loiacono MD Telephone Number: 757 594 5203 Date: 3/8/07

License, Permit, or Facility Number: (EVMS) 5J06H Facility Name: 45-00131-02

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Yasmeen Knowles, M.D.

NRC FORM 313A (AUD)
(10-2006)

U.S. NUCLEAR REGULATORY COMMISSION

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: Yasmeen Knowles

State or Territory Where Licensed: VA

Requested Authorization(s) *(check all that apply)*

- [x] 35.100 Uptake, dilution, and excretion studies
- [x] 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)

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	Eastern Va. med. School Sentara Norfolk Gen. Hosp Norfolk VA NRC Lic. #45-00131-02	20	2000-2004
Radiation protection	"	20	"
Mathematics pertaining to the use and measurement of radioactivity	"	20	"
Chemistry of byproduct material for medical use *(not required for 35.590)*	"	20	"
Radiation biology	"	20	"
	Total Hours of Training:	100	

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.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	Same as above	50	2000-2004
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	"	50	"
Calculating, measuring, and safely preparing patient or human research subject dosages	"	200	"

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	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Same as previous	200	2000 - 2004
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	"	50	"
Administering dosages of radioactive drugs to patients or human research subjects	"	100	"
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	"	50	"
	Total Hours of Experience:	700	

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Lester S. Johnson, MD, PhD	45-00131-02

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 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates
	NA	

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

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 35.590)

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 Yasmeen Knowles has satisfactorily completed the 60 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 Yasmeen Knowles 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	Signature	Telephone Number	Date
Lester S. Johnson	Lester S. Johnson MD,PhD	757 388 5902	3-2-07

License/Permit Number/Facility Name
Sentara Norfolk General Hospital 45-00131-02

Kevin Halista, M.D.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

RADIOACTIVE MATERIALS LICENSE

Pursuant to Chapter 404, Florida Statutes, and Chapter 64E-5, Florida Administrative Code (F.A.C.), and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to receive, acquire, possess and transfer the radioactive material(s) designated below and to use such radioactive material(s) for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the state of Florida, Department of Health now or hereafter in effect and to any conditions specified below.

Licensee	
1. Name: **LAKELAND REGIONAL MEDICAL CENTER, INC.**	3. License Number: **189-1** is hereby amended in its entirety with reference to correspondence dated(2) August 31, 2006, September 4, 2006, and September 5, 2006
2. Address: **Department of Nuclear Medicine 1324 Lakeland Hills Boulevard Lakeland, FL 33804-5448**	4. Expiration Date: **3/31/2011** 5. Category: **5B**

6. Radioactive Material (element and mass number)	7. Chemical And/Or Physical Form	8. Maximum Quantity That Licensee May Possess At Any One Time
A. Any radioactive material described in section 64E-5.626, F.A.C.	A. Any radiopharmaceutical for diagnostic use involving measurements of uptake, dilution or excretion as described in section 64E-5.626, F.A.C.	A. As necessary
B. Any radioactive material described in section 64E-5.627, F.A.C.	B. Any radiopharmaceutical for diagnostic use involving imaging and localization as described in section 64E-5.627, F.A.C., except gases, aerosols and generators	B. As necessary
C. Any radioactive material described in section 64E-5.630, F.A.C.	C. Any radiopharmaceutical for therapeutic use as described in section 64E-5.630, F.A.C.	C. As necessary

STATE OF FLORIDA
DEPARTMENT OF HEALTH
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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
D.	Any radioactive material described in section 64E-5.632, F.A.C.	D.	Any sealed source for brachytherapy as described in section 64E-5.632, F.A.C.	D.	2 curies
E.	Technetium 99m	E.	Aerosol	E.	As necessary
F.	Molybdenum 99/Technetium 99m	F.	Solid and liquid (Molybdenum/ Technetium 99m generators)	F.	5 curies
G.	Gadolinium 153	G.	Sealed sources (E.I. DuPont Corp. Models NER-430, NER-431, Gulf Nuclear, Inc. Model GD-1, Amersham Corp. Model GDC-CY1, Lunar Corp. Model GD series and Biosources, Ltd. Model OS-213A)	G.	2 sources; not to exceed 1500 millicuries each
H.	Uranium 238	H.	Depleted metal	H.	400 pounds
I.	Iodine 125	I.	Sealed Source (Amersham/Medi-Physics, Model 6702; IsoAid, L.L.C., Model IAI-125A(Advantage I-125); Implant Sciences Corporation, Model 3500; Shanghai Syncor Pharmaceuticals Co., LTD, Model BGT-125-1; Bard Brachytherapy, Inc., Model STM 1251; North American Scientific, Inc., Model MED 3631; IsoStar Texas, Inc., Model IS-125 Series; and Medi-Physics, Inc. Model 6733(EchoSeed) 6735, and 6711(OncSeed)	I.	10 millicuries, no individual source to exceed 0.7 millicuries each
J.	Palladium 103	J.	Sealed Source (North American Scientific, Inc. Model MED 3633, Theragenics Corp Model 200, MDS Nordion Model ATI-103Pd)	J.	10 millicuries, no individual source to exceed 0.7 millicuries each
K.	Gadolinium 153	K.	Sealed Source (Isotope Products Laboratories Model NES8429)	K.	4 sources: not to exceed 600 millicuries each

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BUREAU OF RADIATION CONTROL

9. Authorized Use

A. Any medical use described in section 64E-5.626, F.A.C.

B. Any medical use described in section 64E-5.627, F.A.C., except gases, aerosols and generators.

C. Any medical use described in section 64E-5.630, F.A.C.

D. Any medical use described in section 64E-5.632, F.A.C.

E. To be used for pulmonary function studies as described in section 64E-5.627, F.A.C.

F. Production of technetium 99m pertechnetate for processing with reagent kits in preparing radiopharmaceuticals in accordance with section 64E-5.628, F.A.C., or calibration standards in accordance with sections 64E-5.617, F.A.C. This use does not include distribution.

G. One source to be used in a Novo Diagnostic Systems Model BMC-LAB22a bone mineral analyzer as described in section 64E-5.631, F.A.C., and one source for exchanges.

H. To be used as shielding in a Varian Clinac 6/100 linear accelerator.

I. and J. To be used for localization of breast lesions for biopsies as approved by the FDA or Institutional Review Board.

K. To be used as transmission sources for attenuation correction of SPECT studies.

CONDITIONS

10. The authorized place of use is the licensee's facility located at the address in Item 2.

11. Failure to comply with the provisions of this license is a felony of the third degree pursuant to section 404.161, Florida Statutes. Also, violations may warrant an administrative fine of up to $1,000.00 per violation per day, pursuant to section 404.162, Florida Statutes.

12. A. The following individuals or persons under their supervision are authorized for the materials and uses as indicated:

Authorized Material and Uses as Described in Items 6, 7, 8, and 9	Names
64E-5.626, 64E-5.627, 64E-5.630, and 64E-5.631(3)	James L. Holiman, M.D. Francis D. Drake, M.D. Wilton M. Reavis, M.D. Jorge L. Gonzalez, M.D. Robert K. Ramsey, M.D.

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DEPARTMENT OF HEALTH
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12. A. Continued:

Authorized Material and Uses as Described in Items 6, 7, 8, and 9	Names
64E-5.626, 64E-5.627, and 64E-5.630	Ronald Stillerman, D.O. Jerome Scavone, M.D. Charles A. Sutton, M.D. Christian T. Schmitt, M.D.
64E-5.626, 64E-5.630, and 64E-5.631(3)	Thomas W. Oates, M.D.
64E-5.626, 64E-5.627, and 64E-5.630 (except gold 198 and colloidal phosphorus 32)	Joseph M. McDowell, M.D. Katherine Reed, M.D.
64E-5.630, 64E-5.631(3), 64E-5.632 and strontium 90/yttrium 90 for intravascular coronary brachytherapy as described in FDA PMA number P000018/S18 and P000018/S15	Randy V. Heysek, M.D.
64E-5.630 (except gold 198 and iodine 131 for thyroid carcinoma)	Eugene T. Davidson, M.D.
64E-5.630 and 64E-5.632	Andrea Trotti, III, M.D. Leslie Lubich, M.D. Sandra J. Sha, M.D. Victor C. Archie, M.D. Douglas P. Calvin, M.D. H. Brian Balfour, M.D.
64E-5.626, 64E-5.627, 64E-5.630 (except gold 198, samarium 153, yttrium 90, strontium 89, phosphorus 32 and iodine 131 for the treatment of thyroid carcinoma)	Sameet Rao, M.D.
64E-5.626 and 64E-5.627	Kevin Halista, M.D. Carole J. Ebersole, M.D. Bradley P. Barnes, M.D. Michael B. Esposito, M.D. Robert R. Harriage, II, M.D. Howard Gorell, M.D. Kenneth G.S. Ferguson, II, M.D. Merlyn Eckelberg, M.D.

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12. A. Continued:

Authorized Material and Uses as Described in Items 6, 7, 8, and 9	Names
64E-5.626 and 64E-5.627	John Bradshaw, M.D. Larry M. Dietrich, M.D. Thomas M. Goodnight, M.D. Bret D. Henricks, M.D. Evan Chambers, M.D. Chat Virapongse, M.D. Andrew Martin Schneider, M.D. Bruce Miller, D.O. Ali Shariati, M.D. C. Christopher Pittman, M.D. Martha I. Lima-Charron, M.D. David L. Weaver, M.D. Thelma L. Chisholm, M.D. Charley Myrick, III, M.D. Amir Salmanzadeh, M.D. Tomas D. Korensky, M.D. Scott A. Fargher, M.D. Mehdi Poustchi-Amin, M.D. Dario M. Topolcic, M.D. Fakhir Elmasri, M.D. Husuam K. Habboub, M.D. Avinash Khanna, M.D.
64E-5.626, 64E-5.627 and Iodine 125 and Palladium 103 sealed sources for localization studies	Mary S. Gardner, M.D.
64E-5.626 and 64E-5.627 (except generators and reagent kits)	Helena Mahias-Navarte, M.D. Joseph P. Massaro, M.D.
64E-5.627 for cardiac studies only	Patrick J. Reddy, M.D. Christopher L. Simek, M.D. Philip Owen, M.D. Douglas Ebersole, M.D. Luis Carrillo, M.D. John G. Canto, M.D. Sean O'Rourke, M.D.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

12. A. Continued:

Authorized Material and Uses as Described in Items 6, 7, 8, and 9	Names
64E-5.627 for cardiac studies only (except generators and reagent kits)	Sami K. Baddoura, M.D. Mircea Basaraba, M.D. Vladimir Curkovic, M.D. Vineel Sompalli, M.D. Z. Jacob Litwinczuk, M.D.

B. The radiation safety officer is Alan Bako, M.S., DABR.

C. Radiologic technologists who use and administer radioactive materials or perform brachytherapy or teletherapy procedures under the general supervision of an authorized user shall hold a valid certificate as required by Chapter 468, F.S.

D. The authorized medical physicist for medical physics support is:

Authorized Material and Uses as Described in Items 6, 7, 8, and 9	Names
64E-5.632	Alan Bako, M.S.DABR

13. Radioactive material transported on public thoroughfares shall be packaged, prepared for shipment, and transported in accordance with Title 49, Code of Federal Regulations and Chapter 64E-5, F.A.C.

14. Sealed sources containing licensed material shall not be opened.

15. The licensee shall not authorize release from confinement for medical care any patient administered a radiopharmaceutical until:

A. The dose rate is less than 5 millirem (50 microsieverts) per hour at a distance of 1 meter; or

B. The amount of radioactive material in the patient is less than 30 millicuries.

16. Any therapeutic dose of iodine 131 shall be received in capsule form only.

STATE OF FLORIDA
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BUREAU OF RADIATION CONTROL

22. B. The licensee shall comply with all applicable requirements of Chapter 64E-5, Florida Administrative Code, and these regulations shall supersede the licensee's statements in applications or correspondence, unless the statements are more restrictive than the regulations.

For the Bureau of Radiation Control:

ORIGINAL SIGNED BY:
LEE THOMAS

Issuance Date: SEP 15 2006

Lee Thomas
Environmental Specialist II
4052 Bald Cypress Way – Bin C21
Tallahassee, FL 32399-1741
(850) 245-4545

A party whose substantial interest is affected by this order may petition for an administrative hearing pursuant to sections 120.569 and 120.57, Florida Statutes. Such proceedings are governed by Rule 28-106, Florida Administrative Code. A petition for administrative hearing must be in writing and must be received by the Agency Clerk for the Department within twenty-one (21) days from the receipt of this order. The address of the Agency Clerk is: Agency Clerk, 4052 Bald Cypress Way, BIN # A02, Tallahassee, Florida 32399-1703. The Agency Clerk's facsimile number is 850-410-1448. A copy of the petition should also be sent to: Bureau Chief, Bureau of Radiation Control, 4052 Bald Cypress Way, BIN # C21, Tallahassee, FL 32399-1741. The Bureau Chief's facsimile number is 850-487-0455. Mediation is not available as an alternative remedy. Your failure to submit a petition for hearing within 21 days from receipt of this order will constitute a waiver of your right to an administrative hearing, and this order shall become a "final order." Should this order become a final order, a party who is adversely affected by it is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings may be commenced by filing one copy of a Notice of Appeal with the Agency Clerk of the Department of Health and a second copy, accompanied by the filing fees required by law, with the Court of Appeal in the appropriate District Court. The notice must be filed within 30 days of rendition of the final order.

This is to acknowledge the receipt of your letter/application dated 8/7/2007 (RECEIVED 9/24/2007) and to inform you that the initial processing which includes an administrative review has been performed.

☑ AMEND. 45-00986-01
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

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 141089.
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