Physicians Imaging Center New Jersey

April 21, 2009

Materials Licensing Branch

Ų.S. Nuclear Regulatory Commission, Region 1

J-6

475 Allendale Rd.

King of Prussia, PA 19406-1415

Ph: 610.337.5000

03030030

Re: License No. 29-28041-01

Dear Sir or Madam,

This is a request for an amendment to our NRC license to add Dr. Bala Nandigam as an Authorized User for cardiac procedures.

Copies of documents verifying the training and experience of Dr. Nandigam are enclosed.

Please feel free to contact us if you need any additional information.

Sincerely,

Charles H. Rose, MA, MDSPH, D(ABSNM)

Administrator

Physicians Imaging Center 180 Avenue at the Common

Shrewsbury, NJ 07702

dc: file

Enclosures

2009 APR 27 PM 12: 3

143641 NMSS/RGN1 MATERIALS-002 NRC FORM 313A (AUD) (10-2007)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION

APPROVED BY OMB: NO. 3150-0120

YPIRES: 10/31/2008

(for uses defined und	der 35.100, 35.20 90, 35.290, and 3		EXPIRES. 10/3	172000
ame of Proposed Authorized User	· · · · · · · · · · · · · · · · · · ·	State or Territory Where Licens	sed	
Bala Nandigam, M.D.		Florida		
equested Authorization(s) (check all to	that apply)	1		
35.100 Uptake, dilution, and excreti	tion studies			
35.200 Imaging and localization stu	udies	•		
35.500 Sealed sources for diagnosi	is (specify device)	
		G AND EXPERIENCE three methods below)		
Training and Experience, including be the date of application or the individual the required training and experience education and experience related to	board certification, mu ual must have obtaine was completed. Pro	ust have been obtained within ed related continuing education ovide dates, duration, and des	on and experier	nce since
1. Board Certification	1			
a. Provide a copy of the board cer	rtification.			
b. If using only 35.500 materials, s Preceptor Attestation.	stop here. If using 35	5.100 and 35.200 materials, s	ikip to and com	plete Part II
2. Current 35.390 Authorized Use	er Seeking Additior	al 35.290 Authorization		
a. Authorized user on Materials Li	;	meeting 10 CFR 35.	.390 or equival	ent Agreement
State requirements seeking aut			•	•
b. Supervised Work Experience. (If more than one supervising in copies of this section.)	ndividual is necessary	/ to document supervised wo	rk experience,	provide multiple
Description of Experience		f Experience/License or t 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	d 1820 Boy Fort Mye	Triad of Isotopes 1829 Boyscout Rd. Fort Myers, FL		4/20/09
	Total Hours	of Experience:		
Supervising Individual		License/Permit Number listing authorized user	supervising indi	vidual as an
Dr. Thomas Fabian		# 3301-1		
Supervisor meets the requirements 35.290 35.390 + g	s below, or equivalent generator experience	-	nts (check all th	nat apply).

FORM \$13A (AUD) DT) AUTHORIZED USER TRAINING	AND EXPERIENCE AND PRECEPTOR	U.S. NUCLEAR REGUL R ATTESTATION (c	
3. Training and Experience for Pro	·		-
a. Classroom and Laboratory Trainir	g.		
Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	INME, Orlando, FL Institute for Nuclear Medi Education; HQ in Boulder,		Mar. 21- 2009
			and 1999- 2000
Radiation protection	Same as Above	15	Mar. 21-2 2009 and 1999-
			2000_
Mathematics pertaining to the use and measurement of radioactivity	Same as Above	10	Mar. 21-2 2009
			and '99-2
Chemistry of byproduct material for medical use (not required for 35.590)	Same as Above	15	Mar. 21-2 2009
	1		and '99-0
Radiation biology	Same as Above	10	Mar. 21-2 2009
			and '99-00
	Total Hours of Training: 100 hr	's. (200 hr	rs in 199-2
b. Supervised Work Experience (cor (If more than one supervising indi provide multiple copies of this sec	apletion of this table is not required for 3 idual is necessary to document supervision.)	5.590).	
Supervised Work Experience	Total Hours Experience:	of>750 hrs exp	erience
Description of Experience Must Include:	Location of Experience/License of Permit Number of Facility	Or Confirm	Dates of Experience
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation	Harbor Cardiology& Vascula Port Charlotte, FL	ar Ctr. XX Yes	11/2001 to 04/2008

Same as Above

Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters

Same as above

XXYes

☐ No

A.

raining and Experience for Propo . Supervised Work Experience. (CO				
Description of Experience Must Include:	Location of Experience/Lica Permit Number of Faci	erse or Sity	contirm .	Dates of Experience
Calculating, measuring, and safely preparing patient or human research subject desages	Same as Above	1 1	Yes No	04/06 To 04/09
Using administrative controls to prevent a medical event involving the use of unscaled byproduct material	Same as Above	∤	Yes No	04/08 To 04/09
Using procedures to contain apilled byproduct material safety and using proper decontamination procedures	Same as Above	i -	Yes No	04/08
Administering dosages of radioactive drugs to patients or human research subjects	Same as Above	- 1 ⁻	Yes No	04/08
Eluring generator systems appropriately in the preparation of radioactive drugs for imaging and localization studies, measuring and teating the studies, reasonuction purity, and processing the cluste with reagent luts to prepare labeled radioactive crugs	TRIAD OF ISO1 1820 Boyscout FT. Myers, FLORIDA.		Yes No	oHsolo
DR. Thomas Pabia	authorized user	tumber listing supe 32	origing ind	
Supervisor meets the requirements to	35.390 35.360 + genera	itor experience in	•	
For 35.590 only, provide docume	Type of Training	<u> </u>	on and O	Etes
	-N/A-			
		<u> </u>		

CME CREDIT STATEMENT

Physician Form

The Assertem Coilege of Cardiology Foundation (ACCF) is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The American College of Cardiology Foundation (ACCF) certifies that

BALA: K. NANDIGATO MO PACC.
Registrato Name - Republish

has participated in the educational activity titled "The 28th Annual Recent Advances in Clinical Nuclear Cardiology & Cardiac CT: Featuring Case Review with the Experts"

at Washington, DC on May 4-6, 2006

and is awarded up to 23.5 AMA PRA Category 1 Credit(s) TM, Physicians should only claim credit commensurate with the extent of their participation in the activity.

Karen N. Thompson, CMP. Chief Education Specialist

(Maximum Hours Allowable) # 23.50

Indicate hours claimed and return yellow page to the registration counter immediately following this configurate. This is your official record of Indicate hours claimed and return yellow page to the registration counter immediately following this configurate. This is your official record of Indicate hours claimed and return yellow page to the registration counter immediately following this configurate. This is your official record of Indicate hours claimed and return yellow page to the registration counter immediately following this configurate. This is your official record of Indicate hours claimed and return yellow page to the registration counter immediately following this configurate. This is your official record of Indicate hours claimed and return yellow page to the registration counter immediately following this configurate. This is your official record of Indicate hours claimed and return yellow page to the registration counter immediately following this configurate.

In the unlikely event this form is not returned at the program, please mail within two weeks to ACC, ATTN: Resource Contact 2006-1853, 9111 Old Georgetown Rd. Bethesda, MD 20814. Please note: if the ACC does not receive your claim form within two weeks, no CME credit will be applied to your activity record.

APLETE INFORMATIO	N HELOW: Indicate Total Bours Chimed	(v) Seculopsi Attended	CME Credits
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15 a.m.			1.00
30 a.m 12-15 a.m.	Lunch Presentation: Update on Advocacy and Imaging	 /	0.75
18 p.m. 1:15 p.m.		≅ ∕	0.75
5 p.m 2:00 p.m.	1	.	
9 p.m 2:45 p.m.	Breek	-	0.75
15 p.m.		<u> </u>	1.25
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90 p.m.	Adjoorn	Maximum cre	GIES SHOWED ION THE PROPERTY.
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00 a.m 10:00 a.m.	Manage 1	4 .	1.25
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aturday, May 6, 2006	•	~	1.00
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2:00 p.m 1:00 p.m.		· 🗷	0.75
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45 p.m 3:30 p.m.	ļ .	∵⁄	0.50
30 p.m 4:00 p.m.	Adjourn - CME credit statements and evaluations will	De collected at this time.	
:00 p.m.		Maximum or BER OF CME CREDITS AWARDED	edits allowed for Saturday = 7

OB	vised Work Experience. (con scription of Experience Alust Include:	Loc	ation of Experience/License or Permit Number of Facility	Confirm	Experience*
anpiect c	ng, measuring, and safely g patent or human research lossiges	Sam	e as Abeve	√ tes	11/01
	Iministrative controls to a medical exert involving the resealed byproduct material	Sam	e as Above	☐ No	04/08
Using P	recordures to contain spilled ict material safety and using decontamination procedures	1	e as Above	XX Yes	04/06
	pering dosages of radioactive patients or human research	B 534	me as Aboye	XX Yes	11/01
etuate studios	preparation of radioactive or maging and localization in measuring and testing the for radionuclidic purby, and using the etuate with reagent	}	Fr. Myers, FLORIDA		
fects to	propare labeled radioactive	}			
Crugs Super	raing insvidual 2. It PATEL		License/Permit Number authorized user	3301-	
Crugs Super	raing insvidual 2. It PATEL		authorized user	3301 -	one).
Super	rising individual 2. H. PATEL Next meets the requirement 36.190 X 35.290	is below, or	authorized user	3301 -	enack J XIII (G)

MIN ZI ZOOS TOE III ZO MI MALBOL GALIOTOĞY

THA NO. 341 023 1001

r. 00/00

NRC FOR	M 3	13A (AUD)				U.S. NUCLEAR REGULAT	ORY COMMISSION
(10-2007)	ΑŲ	THORIZED U	SER TRAINING	AND EXPERIE	ENCE AND PRECEP	TOR ATTESTATION (cor	ntinued)
	j		Р	ART II – PREC	EPTOR ATTESTATI	ON	
	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 that one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in 35.590)						
	By pos	checking the batterial characteristics the characteristics and the characteristics are characteristics and the characteristics are characteristics and the characteristics are characteristics.	ooxes below, the nd not attesting	preceptor is att to the individual	testing that the individual to the state of	dual has knowledge to fulfil mpetency."	I the duties of the
First Se Check			ing for each us	e requested:	:		
For 3	35.1	90		(
	Во	ard Certificatio	<u>n</u>	!			
		I attest that		· !	has satisfactorily	completed the requirement	ts in
	1	10 CFR 35.19 authorized us	0(a)(1) and has	d Authorized User achieved a leve al uses authoriz	el of competency suffi ed under 10 CFR 35.	icient to function independe 100.	ently as an
				· I	OR	·	
	Tra	ining and Exp	<u>erience</u>	1			
		I attest that		1	has satisfactorily	completed the 60 hours of	training and
		35.190(c)(1).	ncluding a minim	d a level of con	of classroom and labor retency sufficient to ed under 10 CFR 35.	ratory training, required by function independently as 100.	10 CFR an
For 3	<u>35.2</u>	<u> 290</u>		i !			
	Во	ard Certificatio	<u>n</u>	ļ [
		I attest that			has satisfactorily	completed the requiremen	ts in
		10 CFR 35.29 authorized us	90(a)(1) and has	d Authorized User achieved a leve al uses authoriz	el of competency suff ed under 10 CFR 35.	icient to function independent 100 and 35.200.	ently as an
	1				OR		
	Tra	ining and Exp	<u>erience</u>				of training
	XX	I attest that	Bala Nandig	am M.D.	has satisfactorily	completed the 700 hours of	n daming
		CFR 35 290(c	c)(1), and has ac	hieved a level o	ours of classroom and of competency sufficient and ed under 10 CFR 35.	d laboratory training, requirent to function independent 100 and 35.200.	red by 10 as an
Second	i Se	ction			e ju s c z i s ja e u 4 e u 4 e u 4 e u		
Comple	ete		for preceptor a				. d
		I meet the red	quirements belov	v, or equivalent	Agreement State req	quirements, as an authorize	ea user for:
		35.190	∑x35.290	35.390	35.390 + gen	erator experience	
Name of	Pre	eceptor		Signature	2 771	Telephone Number	Date
L TA	l o	mas VM F	ab I AN MD	Gr	1 this	941. 235. 4646	4-21-09
License/	- 1	mit Number/Fac		· ·	of PORT C	122/11	
	1	5646-11	Advance D	-MAGING	of luci C	nn rclotte	PAGE 4

FUNDAMENTALS

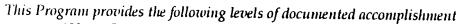
.(1)...(1)...(2)...

Radioisotope Handling Attestation and Certification Completion and Competency

This document is an affidavit that, as evidenced by written examination,

Bala K, Nandigam, M.D.

has successfully completed this program of education and has achieved the objectives of this program.



100 Continuing Education Units (CEU)

100 Didactic Instructional Hours (DIH)

Certifying Official

In compliance with 10CFR35/AEA 73-689

100 Board Accepted Hours NUSPEX, NMTCB

ABMRSO, ABR, ABNM, CBNC

March 29th, 2009

Date Completed

204092

Certification

Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the American Council on Education (ACE), recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.



This is to certify that

Bala K, Nandigam, M.D.

Has completed up to

100 Hours

Of Category 1 CME credit through participation in the course(s)/activities conducted by the Institute for Nuclear Education (INME), March 2009, in Orlando, FL.

This CME activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) thru the Joint Sponsorship of the Institute for Medical Studies (IMS) and INME.

IMS is accredited by the ACCME to provide continuing medical education for physicians.

IMS designates this educational activity for a maximum of 100 credit hours AMA PRA Category 1 Credits™.

Participants should claim only those hours of credit that he/she actually spent in the activity as established by registration and attendance.

Please retain this Certificate for your records.

The Institute for Medical Studies 14 Monarch Bay Plaza, Suite 202 Monarch Bay, CA 92629

NUCLEAR MEDICAL EDUCATION PROGRAM

Affidavit of Academic Completion and Competency

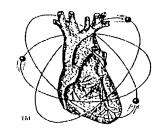
This document is to attest that Bala K. Nandigam, MD

has successfully completed the didactic program

MEDICAL RADIATION INSTRUMENTATION

and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.

This program provides the following levels of accomplishment:



5 Continuing Education Units (CEU)

50 Technical/Professional Credit specified by the American Pharmaceutical Association and the American Association of Health Physicists*

*additional documentation will be provided to Regulatory Agencies upon participant request

20 October 1999

Date Class Commenced

Charles A. Rose

Authorized Signature

197784

Affidavit of Competency

Institute for Nuclear Medical Education

5660 Airport Blvd., Suite 101, Boulder, Colorado 80301 — 800-548-402

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education.

NUCLEAR MEDICAL EDUCATION PROGRAM

Affidavit of Academic Completion & Competency

This document is to attest that

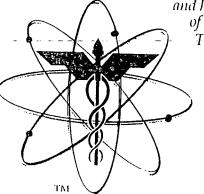
Bala K. Nandigam, MD

has successfully completed the didactic program

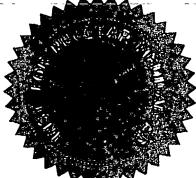
MEDICAL RADIATION PROTECTION

and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.

This program provides the following levels of accomplishment:



- 5.0 Continuing Education Units (CEU)
- 50 Board Accepted Hours NUSPEX, NMTCB III b, ABMRSO, CBNC, MRLB
- 3.0 Semester Hours American Council on Education (ACE), American Association for Collegiate Registrars



Certifying Official

19 January 2000

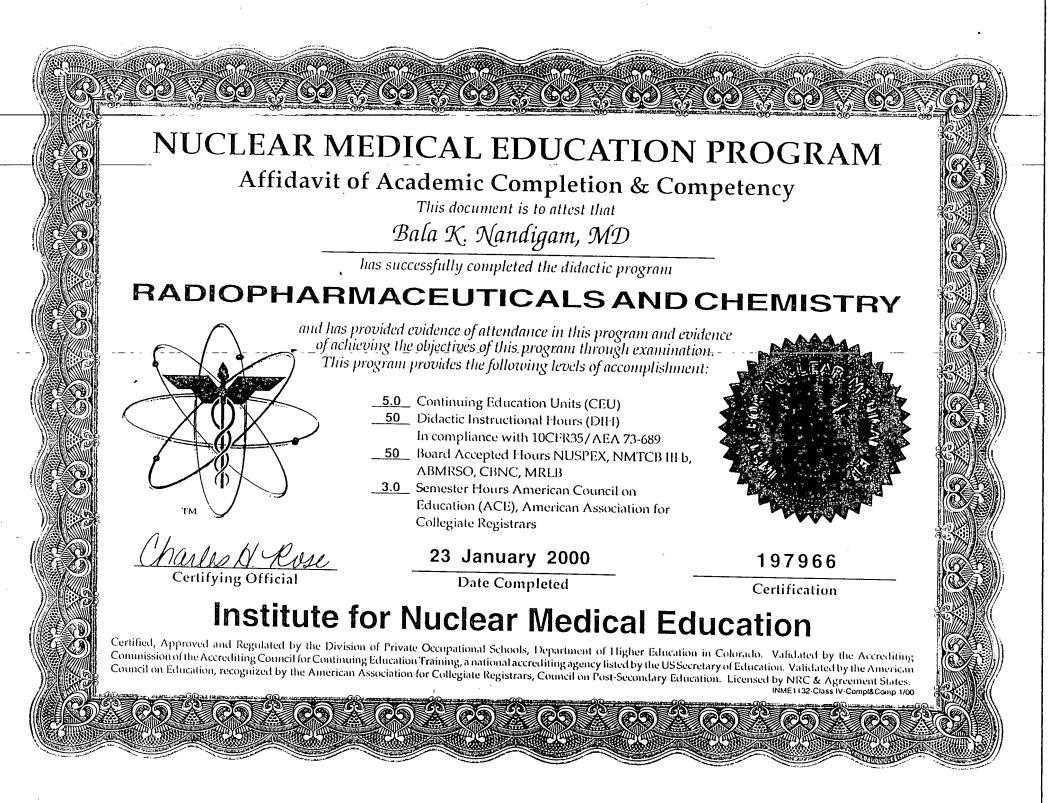
Date Completed

197940

Certification

Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.



NUCLEAR MEDICAL EDUCATION PROGRAM

CAN CANDIDAY

Affidavit of Academic Completion

This document is to attest that

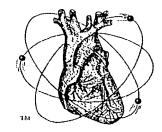
Bala K. Nandigam, MD

has successfully completed the didactic program

PRINCIPLES OF RADIATION PHYSICS

and has provided evidence of attendance in this program and evidence of achieving the objectives of program hours.

-This program-provides the following-levels of-accomplishment:



- 5 Continuing Education Units (CEU)
- 50 Technical/Professional Credit specified by the American Pharmaceutical Association and the American Association of Health Physicists*

16 October 1999

Date Class Commenc

*additional documentation will be provided to Regulatory Agencies upon participant request

Charles J. Rose

Authorized Signature

197708

Affidavit of Competency

Institute for Nuclear Medical Education

5660 Airport Blvd., Suite 101, Boulder, Colorado 80301 - 800-548-4024

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education.

To Whom It May Concern:

This letter is to affirm that Dr. Bala Nandigam, M.D., has received training and experience in Nuclear Cardiology at Harbor Cardiology and Vascular Center between 11/2001 to the present, and successfully completed this training program on 4/20/2009.

During this training program, Dr. Nandigam received not less than 500 hours of supervised work experience. The experience of Dr. Nandigam was gained under the supervision of an Authorized User.

The supervised work experience included participation/supervision of: ordering, receiving, and unpacking of radioactive materials safely, and performing the related radiation surveys; calibrating instruments used to determine the activity of dosages and performing checks for the proper operation of survey meters; calculating, measuring and safely preparing patient or human research subject dosages; using administrative controls to prevent medical events; using procedures to safely contain spills and using proper decontamination procedures; administration of dosages of radioactive drugs to patients or human research subjects.

I certify that Dr. Nandigam has satisfactorily completed the requirements in 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 35.100 and 35.200.

Should you require any additional information, please feel free to contact me at: Ph: 941.235.4646.

Sincerely,

Dr. Thomas Fabian

License No. 3646-1 (Advanced Imaging of Port Charlotte, FL)

Cc: file

STATE OF FLORIDA DEPARTMENT OF HEALTH BUREAU OF RADIATION CONTROL

RADIOACTIVE MATERIALS LICENSE SUPPLEMENTAL SHEET

HARBOR CARDIOLOGY & VASCULAR CENTER, PA 1600 Tamiami Trail 3rd Floor of City Center Building Port Charlotte, FL 33948

With reference to correspondence dated April 24, 2008, State of Florida Radioactive Materials License Number 3301-1 is hereby amended.

TO CHANGE CONDITION 12 TO READ.

CONDITIONS

12. A. The following individuals are authorized for the materials and uses as indicated:

Authorized	l Material an	d Uses as	ij
Described	in Items 6, 7	, 8, and 9	1
,	The Contract of		: 1

Names

64E-5.627

Thomas Fabian, M.D.

64E-5.627

(except generators and reagent kits)

Hiren Patel, M.D.

B. The radiation safety officer is Thomas Fabian, M.D.

License Number:

3301-1

Amendment No.: 6 Control Number: 20080428-0718 LICENSEE COPY

Corrected Copy
Page 1 of 2 Page(s)

Category:

[5C]

Expiration Date: 10/31/2011a

STATE OF FLORIDA DEPARTMENT OF HEALTH BUREAU OF RADIATION CONTROL

RADIOACTIVE MATERIALS LICENSE SUPPLEMENTAL SHEET

12. 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.

For the Bureau of Radiation Control:

MAY 2 3 2008

Issuance Date:

Bryan S. Tatem

Environmental Specialist II 4052 Bald Cypress Way – Bin C21 Tallahassee, FL 32399-1741

A party whose substantial Interest is affected by this order may petition for an administrative hearing pursuant to sections 120,589 and 120,57, Fiorida Statutes. Such proceedings are governed by Rule 28-108, Florida Administrative Code. A petition for administrative hearing must be in writing and must be received by the Agency Clark for the Department, within twenty-care (21) days from the receipt of this order. The address of the Agency Clark is: Agency Clark, 4052 Bold Cypress Way, BIN # A02, Talianassee, Florida 32399-1703. The Agency Clark is: Agency Clark is: Agency Clark is addressed and in the second of the petition is not all all as earn to: Bureau of Radiation Control, 4052 Beld Cypress Way, BIN # C21, Talianassee, FL 32399-1741. The Bureau Chlof's facsimile number is 850-487-0435. Mediation is not available as an alternative remedy. Your failure to submit a patition 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 pacement in final order, a party who is adversely affected by it is entitled to judicial review pursuant to Section 120.68, Florida-Statutos. 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 Clark 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

License Number:

3301-1

LICENSEE COPY

Category:

[5C]

Amendment No.:

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Corrected Copy

Expiration Date:10/31/2011a

Control Number: 20080428-0718

Page 2 of 2 Page(s)