MERIDIAN HEALTH SYSTEM



OCEAN MEDICAL CENTER RADIATION ONCOLOGY DEPT 732-836-4109 (phone) 732-836-4036 (fax)

Q-8

Dr. Nathan Kaufman

Dr. Jonathan Briggs

Dr. Hasmik Diratzouian

Dr. Adnan Danish

29-20690-01

Fax

To: Sh	ir bey (control # 140	-142) Fax: 610-	337-5269
From:	Keunchul Lee	Date: 9/5	-/2007
Re: NRC	2 License	Pages:	
cc: 54			
Urgent	☐ For Review	☐ Please Comment	☐ Please Reply
Comments:	prease yeview	his preceptor ? the items, they and if there is	any thing missing
	Please all me Thank you	at (132) 450-	-2630. heldee

140742 NMSS/RGN1 MATERIALS-002



June 22, 2007

United States Nuclear Regulatory Commission 475 Allendale Road King of Prussia, PA 19406-1415

Ref. N.R.C. material license #29-20690-01 AMENDMENT REQUEST

Gentlemen/Women:

Please amend our Nuclear Material License #29-20690-01 to include

- 1. Add Adnan F. Danish, M.D. as Authorized User for the material and use issued in 35.300; 35.400, and Iridium-192 for uses in a High Dose Rate Afterloader Unit. 35. 6 00
- 2. Add Sharad K. Saraf, Ph.D. as Authorized Medical Physicist for Iridium-192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training.
- 3. Remove Kapil P. Shukla, M.S. from the list of Authorized Medical Physicists.

A copy of letter from the American Board of Radiology which mentioned that Dr. Danish is certified in Radiation Oncology and a copy of Dr. Saraf's Certificate of American Board of Radiology are attached.

Please do not hesitate to call Dr. Keunchul Lec, Medical Physicist at 732-450-2630 or e-mail him (kclee@meridianhealth.com) should you need any additional information.

Sincerely,

C. Mlanaco, M.D Robert Monaco, M.D.

Radiation Safety Officer

President

Meridian Health Line 1.800.560.9990 - www.meridianhealth.com 425 Jack Martin Blvd. • Brick, NJ 08724

NRC FORM 313A (AUT) U.S. NUCLEAR REGULATORY COMMISSION AUTHORIZED USER TRAINING AND EXPERIENCE APPROVED BY OMB: NO. 3150-0120 AND PRECEPTOR ATTESTATION EXPIRES: 10/31/2008 (for uses defined under 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396] Name of Proposed Authorized User State or Territory Where Licensed Danish, M.O. Requested Authorization(s) (check all that apply): Use of unsealed byproduct material for which a written directive is required OR Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 35.300 1.22 gigabecquerels (33 millicuries) Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 35,300 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. **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. 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): 35.394 35.490 35.690 35.390 35.392 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.

3. Training and Experience for	Proposed Authorized	l User			
a. Classroom and Laboratory Tra		35.392	35.39	4 🔲	35.396
Description of Training	Locatio	on of Training		Clock Hours	Dates of Training*
Radiation physics and instrumentation					
Radiation protection					
Mathernatics pertaining to the use and measurement of radioactivity					
Chemistry of byproduct material for medical use					
Radiation biology	Montefor Total Hours of Train	e Met Gr			6/2002
	Total Hours of Train	ing: Browx	,NY		
b. Supervised Work Experience	35.390	35.392	35.39	4 🗍	35.396
If more than one supervising i of this page.					-
Supervised Work Experience		Total He Experie			
Description of Experience Must Include:		perience/License Imber of Facility	or	Confirm	Dates of Experience
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys				Yes No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters				Yes No	
Calculating, measuring, and safely preparing patient or human research subject dosages				Yes No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material				Yes No	
Using procedures to contain spilled byproduct material safely and using proper				Yes No	

FORM 313A (AUT) U.S. NUCLEAR REGULATORY COMMISSION					
	IING AND EXPERIE	NCE AND PRECEPTOR ATTESTATION (cor	ntinued)		
Training and Experience for Pr	oposed Authorized	User (continued)			
b. Supervised Work Experience	(continued)				
Supervising Individual		License/Permit Number listing supervising individual	vidual as an		
		Main of England			
Supervising individual meets the	requirements below.	or equivalent Agreement State requirements (check all that		
apply)**:			11		
35.390 With experience a	dministering dosages	s of:			
35.392	requiring a written dire	ective in quantities less than or equal to 1.22			
35.394 : Oral Nal-131 i	•	nan 1.22 gigabecquerels (33 millicuries)			
☐ 35.396 ☐ Parenteral add	ministration of beta-er	mitter, or photon-emitting radionuclide with a p	hoton		
		a written directive is required ner radionuclide requiring a written directive			
L	. 	ering dosages in the same dosage category or categories	s as the individual		
requesting authorized user status.	ave expendings in administ	ering dusages in the same dusage category or coregories			
 Supervised Clinical Case Exp If more than one supervising multiple copies of this page. 	individual is necessar	ry to document supervised work experience, p	rovide		
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)					
Oral administration of sodium		11. tobia a Nal Ctr	C/7005-		
iodide I-131 requiring a written directive in quantities greater	3	promelore may	4/		
than 1.22 gigabecquerels (33 millicuries)		Montefiore Med Ctr Bronx : NY	19 200b		
Parenteral administration of any beta-emitter, or		pavern as Med ctr	6/2006-		
photon-emitting radionuclide with a photon energy less than	3	Memorial Sloan	6/2006-		
150 keV for which a written directive is required		pavernew Med Ctr Memorial Sloan Kettering	6/ 2007		
Parenteral adminstration of any other radionuclide for which a written directive is required					
(List radionuclides)					
, ,			L		

NRC FORM 313A (AUT) (3-2007)	U.S. NUCLEAR REGULATORY COMMISSION
	ND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)
3. Training and Experience for Propose	d Authorized User (continued)
c. Supervised Clinical Case Experience	e (continued)
Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Supervising individual meets the require apply)**:	ements below, or equivalent Agreement State requirements (check all that
35.390 With experience adminis	tering dosages of:
35.392 Oral Nal-131 requiring gigabecquerels (33 r	ng a written directive in quantities less than or equal to 1.22 millicuries)
Oral Nal-131 in quan	ntities greater than 1.22 gigabecquerels (33 millicuries)
: Parenteral administra	ation of beta-emitter, or photon-emitting radionuclide with a photon keV requiring a written directive is required
: _ ''	ation of any other radionuclide requiring a written directive
 Supervising Authorized User must have expereduesting authorized user status. 	erlence In administering dosages in the same dosage category or categories as the Individual
d. Provide completed Part II Preceptor	Attestation.
PAI	RT II – PRECEPTOR ATTESTATION
individual as long as the preceptor p	individual's preceptor. The preceptor does not have to be the supervising provides, directs, or verifies training and experience required. If more than ment experience, obtain a separate preceptor statement from each.
First Section Check one of the following for each requ	ested authorization:
For 35.390:	
Board Certification	
l attest that Name of Propose	has satisfactorily completed the training and experience
requirements in 35.390(a)(1).	·
	OR
<u>Training and Experience</u>	
I attest that	has satisfactorily completed the 700 hours of training
,	imum of 200 hours of classroom and laboratory training, as required by

NRC FORM 313A (AUT)	U.S. NUCLEAR REGULATORY COMMISSION
(3-2007) AUTHORIZED L	JSER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)
Preceptor Attestation (continued)
First Section (contin	ued)
For 35.392 (Identica	Attestation Statement Regardless of Training and Experience Pathway):
I attest that	Name of Proposed Authorized User has satisfactorily completed the 80 hours of classroom
	training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case uired in 35.392(c)(2).
For 35.394 (Identica	I Attestation Statement Regardless of Training and Experience Pathway):
l attest that	has satisfactorily completed the 80 hours of classroom
	training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case uired in 35.394(c)(2).
Second Section	
I attest that	Advan Danish has satisfactorily completed the required clinical case
experience req	uired in 35.390(b)(1)(ii)G listed below:
	of requiring a written directive in quantities less than or equal to 1.22 perels (33 millicuries)
Oral Nal-13	1 in quantities greater than 1.22 gigabecquerels (33 millicuries)
	administration of beta-emitter, or photon-emitting radionuclide with a photon than 150 keV requiring a written directive is required
Parenteral a	administration of any other radionuclide requiring a written directive
Third Section	
l attest that	has satisfactorily achieved a level of competency to
e	Name of Proposed Authorized User
	endently as an authorized user for:
	11 requiring a written directive in quantities less than or equal to 1.22 orels (33 millicuries)
Oral Nal-13	1 in quantities greater than 1.22 gigabecquerels (33 millicuries)
	administration of beta-emitter, or photon-emitting radionuclide with a photon than 150 keV requiring a written directive is required
Parenteral a	administration of any other radionuclide requiring a written directive

NRC FORM 313A (AUT) (3-2007)	U.S. NUCLEAR REGULATORY COMMISSION				
1.	USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)				
Fourth Section					
For 35.396:					
Current 35.490	or 35.690 authorized user:				
l attest that	is an authorized user under 10 CFR 35.490 or 35.690				
laboratory tra experience re	Name of Proposed Authorized User Agreement State requirements, has satisfactorily completed the 80 hours of classroom and ining, as required by 10 CFR 35.396 (d)(1), and the supervised work and clinical case equired by 35.396(d)(2), and has achieved a level of competency sufficient to function y as an authorized user for:				
Parentera than 150	al administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less keV for which a written directive is required				
Parentera	al adminstration of any other radionuclide for which a written directive is required				
	OR				
Board Certifica	tion:				
l aftest that	has satisfactorily completed the board certification				
required by 1 35.396(d)(2), authorized us Parenters than 150 Parenters Fifth Section Complete the following	s of 35.396(c), has satisfactorily completed the 80 hours of classroom and laboratory training 0 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by and has achieved a level of competency sufficient to function independently as an ser for: all administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less keV for which a written directive is required all administration of any other radionuclide for which a written directive is required all administration and signature: rements 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 Nal-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) Oral Nal-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					
	dministration of any other radionuclide requiring a written directive				
Name of Preceptor Nathan Taut	Man M.D Tulker Lafre (732836-4109 8/17/07				
License/Permit Number/F					
License a	# Ly - L0010 V 1				

NRC FORM 313A (3-2007)	(AUS)	U.S. NUCLE	AR REGULATORY CO	MMISSION		
A	(for uses define	TRAINING AND EPTOR ATTESTA d under 35.400 ar 190, 35.491, and 3	TION nd 35.600)		APPROVED BY (EXPIRES: 10/31/	OMB: NO. 3150-0120 2008
Name of Propos	sed Authorized User		State or Territory Wr	nere License	ed	
つた.	Adnan F. D	Panish, mo	New ,	Jers-	eg	
Requested	35.400 M	anual brachytherapy s	ources 35.600	Telethera	py unit(s)	
Authorization	(s) 35.400 O	phthalmic use of stron	tium-90 🔲 35.600) Gamma s	stereotactic radi	osurgery unit(s)
(check all tha	t apply) 35.600 R	emote afterloader unit	(s)			
		PART I TRAINING				
date of a required	and Experience, including polication or the individuration and experience rience related to the us	ıal must have obtained was completed. Prov	l related continuing	education	and experience	since the
Z 1. Board	Certification					
a. Provid	le a copy of the board o	ertification.				
	5.600, go to the table in authorization is sought		ning provider and da	ates of train	ning for each ty	pe of use for
c. Skipt	o and complete Part II F	Preceptor Attestation.				
2 CURRAN	: 35.600 Authorized Us	ear Ranuestina Addit	ional Authorizatio	n for 35.60	00 Use(s) Chec	ked Above
	the table in section 3.e.	_	ior new device.			
_	o and complete Part II F					
3. <u>Traini</u>	ng and Experience for	Proposed Authorize	<u>d User</u>			
a. Class	room and Laboratory Tr	aining 35.490	35.491	35.0	690	
Des	cription of Training	Local	tion of Training		Clock Hours	Dates of Training*
Radiation instrume	n physics and ntation					
Radiation	protection					
Mathema use and radioacti	atics pertaining to the measurement of vity					
Radiation	n biology					
	•	Total Hours	of Training:		l	L

Training and Experience for Propo	sed Authorized User (continued)		
Supervised Work and Clinical Expe	erience for 10 CFR 35.490 (If more than one ork experience, provide multiple copies of the	supervising indiv is page.)	vidual īs
Supervised Work Experience	Total Hours of Experience:		
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		Yes No	
Checking survey meters for proper operation		Yes No	
Preparing, implanting, and safely removing brachytherapy sources		☐ Yes ☐ No	
Maintaining running inventories of material on hand		Yes No	
Using administrative controls to prevent a medical event involving the use of byproduct material		Yes No	
Using emergency procedures to control byproduct material		Yes No	
Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License Permit Number of Facility	э ог	Dates of Experience
Approved by: Residency Review Committee for Radiation Oncology of the ACGME			
Royal College of Physicians and Surgeons of Canada Committee on Postdoctoral Training of the American Osteopathic Association			

FORM 313A (AUS) 7) AUTHORIZED USER TRAINING	U.S. NU AND EXPERIENCE AND PRECEPTOR ATTE		TORY COMMISSION ontinued)
Training and Experience for Propos			
c. Supervised Clinical Experience for	10 CFR 35.491		
Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history			
Supervising Individual	License/Permit Number listing Authorized User	supervising indi	ividual as an
d. Supervised Work and Clinical Expe	erience for 10 CFR 35.690		
Remote afterloader unit(s)		stereotactic ra	adiosurgery unit(s)
Supervised Work Experience	Total Hours of Experience:		
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Reviewing full calibration measurements and periodic spot-checks	·	Yes No	
Preparing treatment plans and calculating treatment doses and times		Yes No	
Using administrative controls to prevent a medical event involving the use of byproduct material		Yes No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		☐ Yes ☐ No	
Checking and using survey meters		Yes No	
Selecting the proper dose and how it is to be administered		☐ Yes ☐ No	

AUTHORIZE	D USER TRAINING	3 AND EXPERIE	ENCE AND PRECEPTOR	R ATTESTATION (co	ontinued)
Training and Exp	perience for Propo	osed Authorized	User (continued)	<u> </u>	
d. Supervised Wo	rk and Clinical Exp	erience for 10 C	FR 35.690 (continued)		
Clinical experien oncology as part formal training	of an approved	Loc	cation of Experience/Lice Permit Number of Facili		Dates of Experience
Approved by:					
Residency Re Committee for Oncology of the	r Radiation he ACGME of Physicians				
and Surgeons Committee on Training of the Osteopathic A	Postdoctoral American				
Supervising Individu	ıai		License/Permit Number Authorized User	er listing supervising ind	dividual as an
e. For 35.600, describe training provider and dates of training for each type of use for which authorization is sought. Description of Training Training Provider and Dates					
	Remote Aft	terloader	Teletherapy	II.	Stereotactic losurgery
Device operation	He Hout Med Ct Brang Montes	efford tv			
Safety procedures for the device use	Montes Med Gt Bron, Monte	hore' x Ny			
Clinical use of the device	Med Co	~, NX			
individual (il mora (na	idual. If training provid an one supervising Indiv ed work experience, pro	vidual is necessary 🚼	License/Permit Number listi Authorized User	ing supervising individu	ial as an
Authorized for the	e following types of	use:			

NRC FORM 313A (AUS)	U.S. NUCLEAR REGULATORY COMMISSION
(3-2007) AUTHORIZED USER TRA	AINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)
	PART II - PRECEPTOR ATTESTATION
individual as long as the pro	ed by the individual's preceptor. The preceptor does not have to be the supervising eceptor provides, directs, or verifies training and experience required. If more than to document experience, obtain a separate preceptor statement from each.
First Section Check one of the following for ea	ich requested authorization:
<u>For 35.490:</u>	
Board Certification	
I attest that	has satisfactorily completed the requirements in
35.490(a)(1) and has a	to of Proposed Authorized User children children independently as an children by a children independently as an children by a children independently as an an children independently as an
	OR
Training and Experience	
I attest that	has satisfactorily completed the 200 hours of
	ne of Proposod Authorized User
clinical experience in ra level of competency sul	ory training, 500 hours of supervised work experience, and 3 years of supervised idiation oncology, as required by 10 CFR 35.490(b)(1) and (b)(2), and has achieved a efficient to function independently as an authorized user of manual brachytherapy uses authorized under 10 CFR 35.400.
For 35.491:	
I attest that	has satisfactorily completed the 24 hours of
	nd of Proposed Authorized User
has used strontium-90 t	by training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, for ophthalmic treatment of 5 individuals, as required by 10 CFR 35.491(b), and has appetency sufficient to function independently as an authorized user of strontium-90 for
Second Section	1
<u>For 35.690:</u>	
Board Certification	
I attest that	has satisfactorily completed the requirements in
35.690(a)(1).	e of Proposed Authorized user
<u>Training</u> and Experience	OR
Training and experience	
I attest that	has satisfactorily completed 200 hours of classroom
and laboratory training	g, 500 hours of supervised work experience, and 3 years of supervised clinical n therapy, as required by 10 CFR 35.690(b)(1) and (b)(2).
	AND

NRC FORM 313A (AUS)		U.S. NUCLEAR REGULATO	ORY COMMISSION
AUTHORIZED USER TRAINING	AND EXPERIENCE AND PRECEPT	OR ATTESTATION (conf	tinued)
Preceptor Attestation (continued)			
Third Section			
For 35.690: (continued)			
I attest that		aining required in 35.690(c) for device
	osod Authorized User and clinical use for the type(s) of use f	for which authorization is s	ought, as
Remote afterioader unit(s)	Teletherapy unit(s) Gamr	ma stereotactic radiosurge	ery unit(s)
	AND		
Fourth Section			
I attest that Admi		level of competency suffic	ient to
•	paed Authorized User sufficient to function independently as	s an authorized user for:	
Remote afterloader unit(s)		ma stereotactic radiosurge	erv unit(s)
Fifth Section			
Complete the following for preceptor	attestation and signature:		!
I meet the requirements in 10 an authorized user for:	CFR 35.490, 35.491, 35.690, or equiv	ralent Agreement State rec	quirements, as
35.400 Manual brachythera	apy sources 35.600 Teletherapy	unit(s)	
35,400 Ophthalmic use of s	strontium-90 🔲 35.600 Gamma ster	eotactic radiosurgery unit((s)
35.600 Remote afterloader	unit(s)		
Name of Preceptor // / S	signature, 150	Telephone Number	Date/ /
Nathan Kautman MD	Hatis Jack	739 936-4109	8/17/07
License/Permit Number/Facility Name		(1)	
Liceuse # 29-2	20690 -01		
			•