## Hill, Carol

From:Andre Vanterpool <AVanterpool@krmc.org>Sent:Thursday, March 20, 2014 1:23 PMTo:Hill, CarolCc:Murnahan, ColleenSubject:Amendment to License 25-15463-01Attachments:NRC License Change 6- Breast Seed 2014 Dr. Friedman Benedetto Pomerantz - wade<br/>off.pdf

Dear Mrs. Hill,

Please accept the attached document to amend the License 25-15463-01. Please send the receipt acknowledgement to <u>avanterpool@krmc.org</u>

Thank you for your time.

Andre Vanterpool BS, RT (N) (R) Lead Nuclear Medicine/PET CT/Mobile Technologist Nuclear Medicine Department Kalispell Regional Healthcare (406)752-1770 F (406)756-4715 C (406)-212-6642 avanterpool@krmc.org

> PUBLIC Immediate Release Normal Release

NON-PUBLIC

A.3 Sensitive-Security Related
A.7 Sensitive Internal
Other:

17 Date: 4-1-2014 Reviewer:



March 20, 2014

Nuclear Materials Licensing Branch U.S Nuclear Regulatory Commission, Region IV 612 Lamar Boulevard, Suite 400 Arlington, TX 76011-4125

RE: Kalispell Regional Medical Center (License number 25-15463-01) Amendment request to:

- 1. Request current Authorized User to be upgraded to 35.300, Oral administration of sodium iodide I-131, in quantities less than or equal to 33 millicuries.
- Request current Authorized Users to be upgraded to 35.1000 use of Iodine-125 low dose rate brachytherapy seeds used for localization of non-palpable lesions.
- 3. Remove Authorized User No longer employed at license facility

## Dear Carol Hill:

Please accept the attached NRC FORM 313 A (AUI) attestation of clinical case experience for the authorization of currently listed Authorized User Benjamin J. Pomerantz, MD for 35.300, Oral administration of sodium iodide I-131, in quantities less than or equal to 33 millicuries. Please accept the attached NRC FORM 313(AUD) and letter of attestations for current Authorized User William R Benedetto, MD and Richard Friedman, MD for 35.1000 usage material. Finally, please remove Authorized User Debra L. Wade, MD from the license as she is no longer employed by the licensing facility.

If you require additional information or have questions concerning this amendment request please contact one of the following:

Andre Vanterpool, Lead Nuclear Medicine Technician Office phone (406)752-1770 cell (406) 212-6642 Email: <u>AVanterpool@krmc.org</u>

Lisa Bosworth, medical Health Physicist, MPC Inc. Office phone: (208)-860-6260 Email: LNBosworth@msn.com

Thank you for your cooperation and attention in this matter.

Sincerely,

Andre Vanterpool BS, RT (N, R), ARSO Lead Nuclear Medicine /PET CT/ Mobile Technologist Nuclear Medicine Department Kalispell regional Medical Center (406)752-1770 F (406)756-4715 C (406)212-6642

NRC FORM 313A (		AR REGULATORY COMMISSION	1
(05-2012)	APPROVED BY OMB: NO. 3150-0120 EXPIRES: (05/31/2015)		
Name of Propose	d Authorized User	State or Territory Where Licens	ed
Benjamin Pomer	antz, MD	Montana	
Requested Auth	norization(s) (check all that apply):		
35.300	Use of unsealed byproduct material for which	ch a written directive is require	ed
OR			
✓ 35.300	Oral administration of sodium iodide I-131 m 1.22 gigabecquerels (33 millicuries)	equiring a written directive in	quantities less than or equal to
35.300	Oral administration of sodium iodide I-131 m gigabecquerels (33 millicuries)	equiring a written directive in	quantities greater than 1.22
35.300	Parenteral administration of any beta-emittee than 150 keV for which a written directive is		clide with a photon energy less
35.300	Parenteral administration of any other radio	nuclide for which a written dir	ective is required
		NING AND EXPERIENCE he three methods below)	
date of app training and	d Experience, including board certification, n lication or the individual must have related or l experience was completed. Provide dates, related to the uses checked above.	ontinuing education and expe	rience since the required
1. Board C	Certification		
a. Provide	a copy of the board certification.		
	90, provide documentation on supervised cli document this experience.	nical case experience. The t	able in section 3.c. may
and superv	96, provide documentation on classroom and ised clinical case experience. The tables in his experience.	d laboratory training, supervis sections 3.a., 3.b., and 3.c. n	ed work experience, nay be used to
d. Skip to a	nd complete Part II Preceptor Attestation.		
2. Current	35.300, 35.400, or 35.600 Authorized Use	r Seeking Additional Autho	rization
a. Authoriz	ed User on Materials License	under	the requirements below or
equivale	ent Agreement State requirements (check all	that apply):	
35.3	90 35.392 35.394	35.490 35.69	0
required sup	ly authorized for a subset of clinical uses un pervised case experience. The table in secti Also provide completed Part II Preceptor A	ion 3.c. may be used to docu	
documenta case exper	ly authorized under 35.490 or 35.690 and re tion on classroom and laboratory training, su ience. The tables in sections 3.a., 3.b., and e completed Part II Preceptor Attestation.	pervised work experience, and	nd supervised clinical

1

3. <u>Training and Experience fo</u> a. Classroom and Laboratory Tr		<u>d User</u> 35.392	35.	394	35.396
Description of Training	Locatio	n of Training		Clock Hours	Dates of Training*
Radiation physics and instrumentation					
Radiation protection					
Mathematics pertaining to the use and measurement of radioactivity					
Chemistry of byproduct material for medical use					
Radiation biology					
	Total Hours of Train	ing:			
<ul> <li>b. Supervised Work Experience If more than one supervising of this page.</li> </ul>		35.392 to document supe		394 🗌 ning, provide	] 35.396 multiple copies
	individual is necessary	to document supe		ning, provide	<ul> <li>Conclusion escarationero</li> </ul>
If more than one supervising of this page.	individual is necessary rk Experience Location of Ex	to document supe	ervised trai	ning, provide	<ul> <li>Conclusion escarationero</li> </ul>
If more than one supervising of this page. Supervised Wo Description of Experience	individual is necessary rk Experience Location of Ex	Total Houperience/License of	ervised trai	ning, provide rience:	multiple copies
If more than one supervising of this page. Supervised Wo Description of Experience Must Include: Ordering, receiving, and unpacking radioactive materials safely and performing the	individual is necessary rk Experience Location of Ex	Total Houperience/License of	ervised trai	ning, provide erience: Confirm	multiple copies
If more than one supervising of this page. Supervised Wo Description of Experience Must Include: Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of	individual is necessary rk Experience Location of Ex	Total Houperience/License of	ervised trai	ning, provide erience: Confirm Yes No	multiple copies
If more than one supervising of this page. Supervised Wo Description of Experience Must Include: Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters Calculating, measuring, and safely preparing patient or human research subject	individual is necessary rk Experience Location of Ex	Total Houperience/License of	ervised trai	ning, provide rience: Confirm Yes No Yes No Yes Yes	multiple copies

C FORM 313A (AUT) 2012)		U.S. NUCLEAR REGULA	
AUTHORIZED USER TR	AINING AND EXPERIE	INCE AND PRECEPTOR ATTESTATION (co	ontinued)
. Training and Experience for		I User (continued)	
b. Supervised Work Experier	ice (continued)		
Supervising Individual		License/Permit Number listing supervising ind authorized user	lividual as an
Supervising individual meets apply)**:	the requirements below	, or equivalent Agreement State requirements	check all that
35.390 With experience	e administering dosage	s of:	
	31 requiring a written dir arels (33 millicuries)	rective in quantities less than or equal to 1.22	
Oral Nal-13	31 in quantities greater f	than 1.22 gigabecquerels (33 millicuries)	
energy less	than 150 keV requiring	mitter, or photon-emitting radionuclide with a g a written directive is required	photon
	administration of any ot	her radionuclide requiring a written directive	
** Supervising Authorized User mu requesting authorized user statu		tering dosages in the same dosage category or categori	es as the individual
multiple copies of this pag	e. 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 that or equal to 1.22 gigabecquere (33 millicuries)	n	Kalispell Regional Medical Center	1/18/2013 4/1/2013 (2)
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 tha 150 keV for which a written directive is required	n		
Parenteral administration of a other radionuclide for which a written directive is required	יער ק		
(List radionuclides)			

NRC FORM 313A (AUT) (05-2012)

AUTUODIZED	U.S. NUCLEAR REGULATORY CO	MMISS
AUTHORIZED	D USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued	I)
Training and Expe	erience for Proposed Authorized User (continued)	
c. Supervised Clin	nical Case Experience (continued)	
Supervising Individua	al License/Permit Number listing supervising individual as authorized user	an
Supervising individ apply)**:	dual meets the requirements below, or equivalent Agreement State requirements (check a	all tha
35.390 With	h experience administering dosages of:	
	Oral Nal-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	
35.394	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	
	Parenteral administration of any other radionuclide requiring a written directive	
** Supervising Authorize requesting authorize	rized User must have experience in administering dosages in the same dosage category or categories as the in zed user status.	ndividua
d. Provide complet	eted Part II Preceptor Attestation.	
	PART II – PRECEPTOR ATTESTATION	
individual as lon	be completed by the individual's preceptor. The preceptor does not have to be the super ng as the preceptor provides, directs, or verifies training and experience required. If more is necessary to document experience, obtain a separate preceptor statement from each.	
	e boxes below, the preceptor is attesting that the individual has knowledge to fulfill the dur ught and not attesting to the individual's "general clinical competency."	ties of
st Section		
eck one of the follow	owing for each requested authorization:	
For 35.390:		
<b>Board Certifica</b>	ation	
Doard Octanica		
	Benjamin Pomerantz MD has satisfactorily completed the training and evo	eriena
	Benjamin Pomerantz, MD has satisfactorily completed the training and exp Name of Proposed Authorized User	erienc
✓ I attest that	Name of Proposed Authorized User	erienc
✓ I attest that		erienc
✓ I attest that	Name of Proposed Authorized User	erienc
✓ I attest that	Name of Proposed Authorized User ts in 35.390(a)(1).	erienc
✓ I attest that requirements Training and Example.	Name of Proposed Authorized User ts in 35.390(a)(1). OR Experience	
✓ I attest that requirements	Name of Proposed Authorized User ts in 35.390(a)(1). OR Experience	

NRC FORM 313A (AUT)		U.S. NUCLEAR REGULATORY COMMISSION
(05-2012) AUTHORIZE	D USER TRAINING AND EXPERIEN	CE AND PRECEPTOR ATTESTATION (continued)
Preceptor Attestation	and the second	
First Section (con	tinued)	
For 35.392 (Identi	ical Attestation Statement Regardle	ess of Training and Experience Pathway):
I attest that		has satisfactorily completed the 80 hours of classroom
	Name of Proposed Authorized User	
	ory training, as required by 10 CFR 35 required in 35.392(c)(2).	.392(c)(1), and the supervised work and clinical case
For 35.394 (Identi	ical Attestation Statement Regardle	ess of Training and Experience Pathway):
I attest that	Name of Proposed Authorized User	has satisfactorily completed the 80 hours of classroom
and laborato experience	ory training, as required by 10 CFR 35 required in 35.394(c)(2).	.394 (c)(1), and the supervised work and clinical case
Second Section		
✓ I attest that	Benjamin Pomerantz, MD Name of Proposed Authorized User	has satisfactorily completed the required clinical case
experience i	required in 35.390(b)(1)(ii)G listed belo	ow:
	-131 requiring a written directive in qu querels (33 millicuries)	antities less than or equal to 1.22
Oral Nal-	-131 in quantities greater than 1.22 gi	gabecquerels (33 millicuries)
	al administration of beta-emitter, or ph ass than 150 keV requiring a written d	noton-emitting radionuclide with a photon irective is required
Parenter	al administration of any other radionu	clide requiring a written directive
Third Section		
✓ I attest that	Benjamin Pomerantz, MD Name of Proposed Authorized User	has satisfactorily achieved a level of competency to
function inde	ependently as an authorized user for:	
	-131 requiring a written directive in qu querels (33 millicuries)	antities less than or equal to 1.22
Oral Nal-	-131 in quantities greater than 1.22 gi	gabecquerels (33 millicuries)
	al administration of beta-emitter, or ph ess than 150 keV requiring a written di	noton-emitting radionuclide with a photon irective is required
Parenter	al administration of any other radionuc	clide requiring a written directive

RC FORM 313A (AUT)				U.S. NUCLEAR REGULA	TORY COMMISSIO
AUTHORIZE	D USER TRAINI	NG AND EXPERI	ENCE AND PREC	EPTOR ATTESTATION (co	ontinued)
ourth Section					
For 35.396:					
Current 35.490	or 35.690 autho	orized user:			
I attest that	Name of Pro	posed Authorized User	is an authoriz	ed user under 10 CFR 35.4	90 or 35.690
laboratory ti experience	t Agreement Sta aining, as require	te requirements, h ed by 10 CFR 35.3 96(d)(2), and has a	96 (d)(1), and the	mpleted the 80 hours of cla supervised work and clinica competency sufficient to fur	l case
		of any beta-emitte written directive is		ng radionuclide with a photo	on energy less
Parenter	al administration	of any other radio	nuclide for which a	written directive is required	I
			OR		
<b>Board Certific</b>	ation:				
I attest that			has satisfacto	orily completed the board ce	ertification
required by 35.396(d)(2 authorized t	10 CFR 35.396 ( ), and has achiev iser for:	d)(1) and the supe red a level of comp	rvised work and cli etency sufficient to	urs of classroom and labora inical case experience requi o function independently as	ired by an
		of any beta-emitte written directive is		ng radionuclide with a photo	on energy less
	al administration	of any other radio	nuclide for which a	written directive is required	
Fifth Section Complete the follow	ng for precepto	r attestation and	signature:		
✓ I meet the requ	irements below,	or equivalent Agre	ement State requir	ements, as an authorized u	ser for:
✓ 35.390	√ 35.392	✓ 35.394	₹ 35.396		
✓ I have experier requesting aut		dosages in the fol	lowing categories	for which the proposed Auth	norized User is
✓ Oral Nal-13 millicuries)	1 requiring a writ	ten directive in qua	intities less than or	equal to 1.22 gigabecquer	els (33
✓ Oral Nal-13	1 in quantities gro	eater than 1.22 gig	abecquerels (33 m	illicuries)	
Parenteral a 150 keV rec	administration of l juiring a written d	beta-emitter, or pho irective is required	oton-emitting radio	nuclide with a photon energ	ly less than
✓ Parenteral a	dministration of	any other radionac	lide requiring a wri	tten directive	
lame of Preceptor		Signature	/	Telephone Number	Date
Richard Friedman		1/1/		(406) 752-1770	03/19/2014
icense/Permit Number/	Facility Name				
25-15463-01 Kalispell I	Regional Medical C	Center			
RC FORM 313A (AUT) (05-2012)		and the second	and the second secon		PAG

merican Society for Therapeutic Radiology and Oncology, the Association of riversity Hadiologists, and American Association of Physicists in Medicine American College of Radiology, the American Roentgen Day Society, American Radium Society, the Radiological Society of North America, merican Soard of Wadin the Section on Radiology of the American Medical Association, and clinical work, has met certain standards and qualifications and has passed the examinations conducted under the authority of Benjamin Iohn Pomerantz, MI Thereby demonstrating to the satisfaction of the Board Has pursued an accepted course of graduate study that he is qualified to practice the speciality of Organized through the cooperation of the The American Board of Hadiology On this third day of June, 2008 Hendry certifies that Ser les AMERICAN BOARD

			an and the state of the state o		14.6-Tan. Inc 14.0
NRC FORM 313A (AUD) (05-2012)	U.S. NUCLE	AR REGULATO	RY COMMISSION		
AUTHORIZED USER TR AND PRECEPT (for uses defined under [10 CFR 35.190,	OR ATTESTA 35.100, 35.20	TION 0, and 35.5		APPROVED BY EXPIRES: (05/3	OMB: NO. 3150-0120 31/2015)
Name of Proposed Authorized User		State or Territ	ory Where License	ed	
Richard Friedman, MD		Montana			
Requested Authorization(s) (check all that	apply)	1 25 1000	(RSL) RADIOA	CTIVE SEED L	DEALIZATION
35.100 Uptake, dilution, and excretion	studies	Shine			E-125
35.200 Imaging and localization studie	s	2	,s ,		
35.500 Sealed sources for diagnosis (s	specify device)				
	RT I TRAINING				
	elect one of the t			4	
* Training and Experience, including boar the date of application or the individual r the required training and experience wa education and experience related to the	must have obtaine s completed. Pro	ed related cor vide dates, d	ntinuing education	n and experie	nce since
✓ 1. Board Certification					
a. Provide a copy of the board certific	ation.				
<ul> <li>b. If using only 35.500 materials, stop Preceptor Attestation.</li> </ul>	here. If using 35.	.100 and 35.2	200 materials, sk	kip to and com	plete Part II
2. Current 35.390 Authorized User	Seeking Addition	al 35.290 Au	thorization		
a. Authorized user on Materials Licer	ise	mee	ting 10 CFR 35.3	390 or equival	ent Agreement
State requirements seeking author	rization for 35.290				
<ul> <li>b. Supervised Work Experience. (If more than one supervising indiv copies of this section.)</li> </ul>	idual is necessary	/ to documen	t supervised wo	rk experience,	provide multiple
Description of Experience		f Experience/ Number of F		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 Experienc	;e:		
Supervising Individual		License/Perr authorized u	nit Number listing ser	supervising ind	ividual as an
Supervisor meets the requirements be	elow, or equivalen nerator experience			nts (check all	that apply).

FORM 313A (AUD) <sup>2)</sup> AUTHORIZED USER TRAINING A	ND EXPERIENCE AND PRECEPTOR ATT	UCLEAR REGULA	
. Training and Experience for Propo	sed Authorized User		
a. Classroom and Laboratory Training			
Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use ( <i>not required for</i> 35.590)			
Radiation biology			
	Total Hours of Training:		1
	bletion of this table is not required for 35.590) dual is necessary to document supervised wo on.)		
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	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		Yes	

NRC FORM 313A (AUD) (05-2012)

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Training and Experience for Proposed b. Supervised Work Experience. (contin			
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience
Calculating, measuring, and safely preparing patient or human research subject dosages		Yes	
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 decontamination procedures		Yes No	-
Administering dosages of radioactive drugs to patients or human research subjects		Yes No	
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs		Yes No	
Supervising Individual	License/Permit Number Ilsting authorized user	supervising indi	vidual as an

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

Device	Type of Training	Location and Dates

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

NRC FORM 313A (AUD) (05-2012)

NRC FORM 313A (AUD)	U.S. NUCLEAR REGULATORY COMMISSION
AUTHORIZED USER TRAINING AND EXPER	RIENCE AND PRECEPTOR ATTESTATION (continued)
PART II – PRE	ECEPTOR ATTESTATION
individual as long as the preceptor provides, dir	preceptor. The preceptor does not have to be the supervising rects, or verifies training and experience required. If more than ience, obtain a separate preceptor statement from each. (Not 90)
By checking the boxes below, the preceptor is a of the position sought and not attesting to the in	attesting that the individual has knowledge to fulfill the duties ndividual's "general clinical competency."
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	
authorized user for the medical uses authorized user for the medical user authorized user authorized user for the medical user authorized user authorized user for the medical user authorized user authorized user for the medical user authorized user for the medical user authorized user for the medical user authorized user authorized user for the medical user authorized user authorized user for the medical user authorized user authorized user authorized user for the medical user authorized user for the medical user authorized user authorized user for the medical user authorized user authorized user for the medical user authorized user aut	evel of competency sufficient to function independently as an rized under 10 CFR 35.100.
	OR
Training and Experience	
I attest that     Name of Proposed Authorized User	has satisfactorily completed the 60 hours of training and
experience, including a minimum of 8 hours	s of classroom and laboratory training, required by 10 CFR ompetency sufficient to function independently as an rized under 10 CFR 35.100.
For 35.290	
Board Certification	12 No. 10 No.
✓ I attest that Richard Friedman, MD	has satisfactorily completed the requirements in
Name of Proposed Authorized User	
	evel of competency sufficient to function independently as an rized under 10 CFR 35.100 and 35.200, wi) 35, 100
Table and Free days	OR
Training and Experience	
Name of Proposed Authorized User	has satisfactorily completed the 700 hours of training
and experience, including a minimum of 80	hours of classroom and laboratory training, required by 10 I of competency sufficient to function independently as an rized under 10 CFR 35.100 and 35.200.
Second Section	
Complete the following for preceptor attestation and	d signature:
✓ I meet the requirements below, or equivalent	nt Agreement State requirements, as an authorized user for:
35.190 35.290 35.390	35.390 + generator experience 2 35.1000
Name of Preceptor Signature	Telephone Number Date
Gordon Stillie, MD	(406) 756-1790 03/20/2014
License/Permit Number/Facility Name	
25-15463-01/Kalispell Regional Medical Center	

NRC FORM 313A (AUD) (05-2012)



March 10, 2014

To Whom It May Concern:

This letter should serve as documentation of supervised clinical case experience for Richard Friedman, MD performing radioactive seed localization (RSL) of non-palpable breast lesions with I-125 seeds. Dr. Friedman is a board certified radiologist and an authorized used listed on Kalispell Regional Medical Center's license, number 25-15463-01. I observed Dr. Friedman perform 3 implants of breast lesions. I witnessed patients L.N. on 1/9/14, R.G. on 1/9/14, and W.K. on 3/10/14. I instructed Dr. Friedman in the proper techniques for safe handling of the seeds, appropriate preparation, as well as seed deployment. We reviewed radiation safety relative to the use of I-125 seeds for localization including but not limited to:

- Performing the related surveys using appropriate instrumentation;
- Preparing, implanting and safely removing RSL sources safely, to include the use of remote handling tools to manipulate seeds and the proper use of shields;
- Performing routine monitoring before, during, and after all uses of the seeds to ensure rapid identification and remediation of a leaking or broken source;
- Emergency procedures, such as regarding broken or leaking seeds;
- Reviewing and understanding the administrative controls in place to prevent a medical event; and
- Maintaining running inventories of radioactive material on hand.

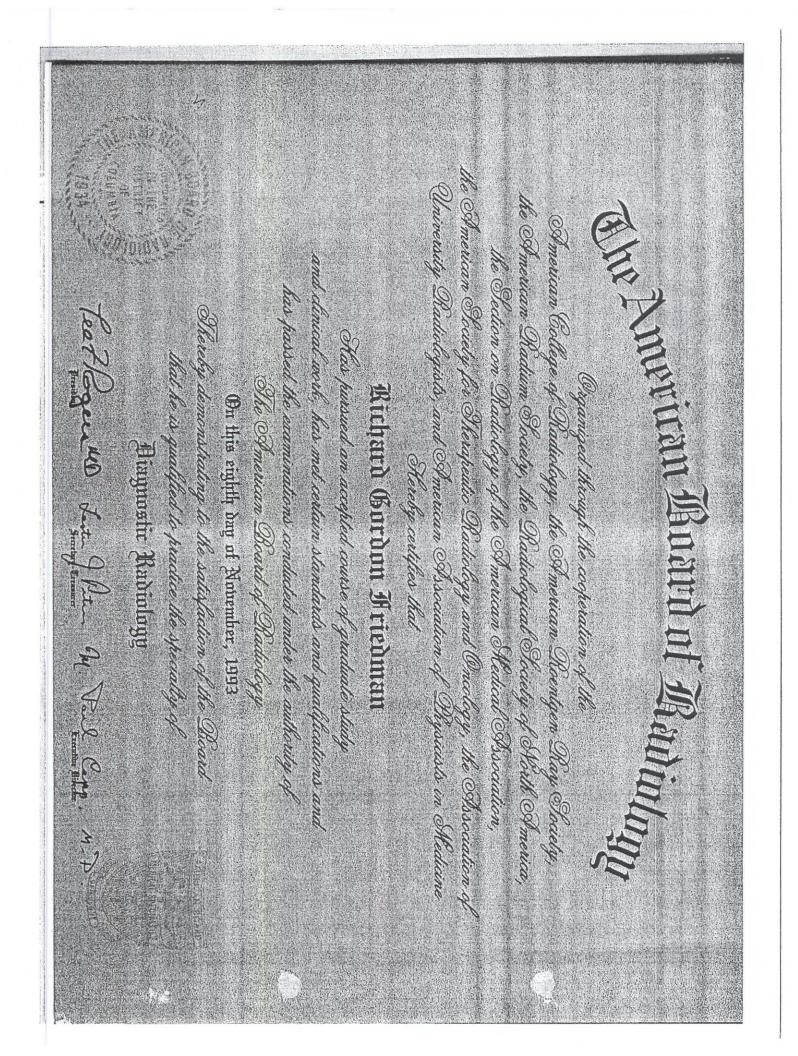
Dr. Friedman has gained the competency to perform these procedures independently.

Sincerely

Gordon Donald Stillie, DO, MS, MBA, FACRO

I

343 Sunnyview Lane, Kalispell, MT 59901 (406)752-1790 Phone \* (406)756-3529 Fax



NRC FORM 313A (AUD) (05-2012)	U.S. NUCLEA	R REGULATORY COMMISSIO	N	
AUTHORIZED USER TF AND PRECEPT (for uses defined under [10 CFR 35.190,	OR ATTESTA 35.100, 35.200	ΓΙΟΝ ), and 35.500)	APPROVED BY EXPIRES: (05/	OMB: NO. 3150-0120 31/2015)
Name of Proposed Authorized User	1	State or Territory Where Lice	nsed	· · · · · · · · · · · · · · · · · · ·
William R Benedetto, MD		Montana		
Requested Authorization(s) (check all that	apply)	[] 35,1000 (RSL)	RADINA DUILIE S	minacipan 1 (20
35.100 Uptake, dilution, and excretion	studies			I-125
35.200 Imaging and localization studie	s			
35.500 Sealed sources for diagnosis (	specify device)			
PA	ART I TRAINING	AND EXPERIENCE	ana ana internetata	
		hree methods below)		
* Training and Experience, including boar the date of application or the individual the required training and experience war education and experience related to the	must have obtaine as completed. Prov	d related continuing educa vide dates, duration, and d	ation and experie	nce since
✓ 1. Board Certification				
a. Provide a copy of the board certific	ation.			
<ul> <li>b. If using only 35.500 materials, stop Preceptor Attestation.</li> </ul>	here. If using 35.	100 and 35.200 materials,	skip to and com	plete Part II
2. Current 35.390 Authorized User	Seeking Addition	al 35.290 Authorization		
a. Authorized user on Materials Licer	nse	meeting 10 CFR 3	5.390 or equival	ent Agreement
State requirements seeking author	rization for 35.290.			
<ul> <li>b. Supervised Work Experience. (If more than one supervising individual copies of this section.)</li> </ul>	vidual is necessary	to document supervised v	vork experience,	provide multiple
Description of Experience		Experience/License or 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	of Experience:		k
Supervising Individual		License/Permit Number listi authorized user	ng supervising ind	vidual as an
Supervisor meets the requirements be		Agreement State requiren	nents <i>(check all i</i>	ihat apply).

. Training and Experience for Propos	ND EXPERIENCE AND PRECEPTOR AT		
a. Classroom and Laboratory Training.			
Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use <i>(not required for</i> 35.590)			
Radiation biology			
	Total Hours of Training:		
	etion of this table is not required for 35.590 ual is necessary to document supervised v n.)		
Supervised Work Experience	Total Hours of Experience:	No (Second a) for a grant of the second and	
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	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper		Yes No	

NRC FORM 313A (AUD) (05-2012)

Training and Ex	perience for P	roposed Auth	orized User (continued	1)		
b. Supervised W	Vork Experience	. (continued)				
	n of Experience t Include:	Le	Location of Experience/License or Permit Number of Facility		Confirm	Dates of Experience
Calculating, mea preparing patient subject dosages	t or human rese				Yes	
Using administra prevent a medica use of unsealed	al event involvin				Yes	
Using procedure byproduct materi proper decontam	ial safely and us	sing			Yes	
Administering do drugs to patients subjects				1	Yes	
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		en he id ent			Yes	
Supervising Individ	lual		License/Permit authorized user	Number listing supe	ervising indi	vidual as an
Supervisor meet	s the requireme	nts below, or e	equivalent Agreement Sta	ate requirements	(check one	»).
35.190	35.290	35.390	35.390 + gener	rator experience i	n 35.290(c	)(1)(ii)(G)
c. For 35.590 on	ly, provide docu	mentation of tr	raining on use of the devi	ice.		
Device		Туре	Type of Training Loc		cation and Dates	

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

RC FO 5-2012)	RM 313A (AUD) AUTHORIZED	USER TRAININ	G AND EXPERIE	ENCE AND PRECEPT	U.S. NUCLEAR REGULA	
	And a second second		PART II – PREC	EPTOR ATTESTATIO	N	****
lote:	individual as long one preceptor is	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)				
				testing that the individu ividual's "general clinica	al has knowledge to ful al competency."	fill the duties
	Section					
	one of the follow	ving for each u	se requested:			
For	35.190					
	Board Certification	on				
	I attest that			has satisfactorily co	mpleted the requirement	nts in
		90(a)(1) and ha		el of competency suffici ed under 10 CFR 35.10	ent to function independ	dently as an
				OR		
	Training and Exp	perience				
	I attest that			has satisfactorily co	mpleted the 60 hours o	f training and
	_	Name of Propo	sed Authorized User	_		
	35.190(c)(1),	and has achiev	red a level of com		tory training, required b nction independently as 00.	
For	35.290					
	Board Certification	on				
	✓ I attest that	William R Bend	edetto, MD	has satisfactorily co	mpleted the requirement	nts in
		Name of Propo	sed Authorized User	_		
					ent to function independ 00 and 35.200. <i>AvD</i> 35.10	
	Training and Eve	orianaa		OR		
	Training and Exp	benence		h	1.4.14. 700 1	
	I attest that	Name of Prane	sed Authorized User	nas satisfactorily co	mpleted the 700 hours	of training
	CFR 35.290(	ce, including a c)(1), and has a	minimum of 80 ho achieved a level o		aboratory training, requ to function independer 0 and 35.200.	
	d Section lete the following	for preceptor	attestation and s	signature:		و و و و او او و و و و و و و و و
	✓ I meet the re	quirements belo	w, or equivalent	Agreement State requir	rements, as an authoriz	ed user for:
	35.190	35.290	35.390	35.390 + genera	tor experience 235	,1000
ame o	of Preceptor		Signature	111 hox	Telephone Number	Date
ordon	D Stillie, MD				(406) 756-1790	03/19/2014
cense	/Permit Number/Fac	cility Name		HIV	1	
		*				
	63-01/Kalispell reg	ional Medical Ce	enter			



March 12, 2014

To Whom It May Concern:

This letter should serve as documentation of supervised clinical case experience for William Benedetto, MD performing radioactive seed localization (RSL) of non-palpable breast lesions with I-125 seeds. Dr. Benedetto is a board certified radiologist and an authorized used listed on Kalispell Regional Medical Center's license, number 25-15463-01. I observed Dr. Benedetto perform 3 implants of breast lesions. I witnessed patients P.N. on 1/21/14, A.W. on 3/12/14, and R.B. on 3/12/14. I instructed Dr. Benedetto in the proper techniques for safe handling of the seeds, appropriate preparation, as well as seed deployment. We reviewed radiation safety relative to the use of I-125 seeds for localization including but not limited to:

- Performing the related surveys using appropriate instrumentation;
- Preparing, implanting and safely removing RSL sources safely, to include the use of remote handling tools to manipulate seeds and the proper use of shields;
- Performing routine monitoring before, during, and after all uses of the seeds to ensure rapid identification and remediation of a leaking or broken source;
- Emergency procedures, such as regarding broken or leaking seeds;
- Reviewing and understanding the administrative controls in place to prevent a medical event; and
- Maintaining running inventories of radioactive material on hand.

Dr. Benedetto has gained the competency to perform these procedures independently.

Sincerely,

Gordon Donald Stillie, DO, MS, MBA, FACRO

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343 Sunnyview Lane, Kalispell, MT 59901 (406)752-1790 Phone \* (406)756-3529 Fax

COLUMBIA DISTRIC the American Sciety for Therapeutic Radiology and Oncology, the Association of The American Moard of Rad University Pladiologists, and American Association of Physicists in Medicine American College of Dadiology, the American Roentgen Day Society, the American Dadium Society, the Dadiological Society of North America, the Section on Diadiology of the American Medical Association, and clinical work, has met certain standards and qualifications and has passed the examinations conducted under the authority of Thereby demonstrating to the satisfaction of the Board an Maynard my Willia Has pursued an accepted course of graduate study milliam Kalph Tenedetta, M. D. hat he is qualified to practice the specialty of Organized through the cooperation of the The American Doard of Dadiology On this settenth day of November, 1995 ちいうち ちょうちょうちょうちょう しょうしょう しゅうちょう **Hingmustic Radiology** Hereby certifies that thary-Treasurer Loude NO M. Vail Capp. M. D Frecutive Birect 3 5 0 3 5 8

NRC FORM 532	U. S. NUCLEAR REGULATORY COMMISSION				
(1-2012)					
E BEI S	DATE DATE				
03/28/20	14				
~******	E				
NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE					
Kalispell Regional Medical Center Radiology Department	25-15463-01				
ATTN: Michael T. Henson, M.D.	MAIL CONTROL NUMBER				
Radiation Safety Officer	583503				
310 Sunnyview Lane Kalispell, Montana 59901	LICENSING AND/OR TECHNICAL REVIEWER				
	ch				
This is to acknowledge the receipt of your:					
✓ LETTER and/or APPLICATION	DATED: 03/20/2014				
The initial processing, which included an administrative	review, has been performed.				
✓ AMENDMENT					
There were no administrative omissions identified during	ng our initial review.				
This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.					
Your application for a new NRC license did not include your taxpayer identification number. Please fill out NRC Form 531, located at the following link:					
http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf					
Send the completed NRC Form 531, by facsimile, to the following number: (301) 415-5387					
A copy of your action has been emailed to our License Fee and Accounts Receivable Branch, in our Headquarters office in Rockville, MD. You will be contacted separately if there is a fee issue involved.					
Your application has been assigned the above listed <b>MAIL CONTROL NUMBER.</b> When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:					
Region IV U. S. Nuclear Regulatory Commiss DNMS/NMSB - B 1600 E. Lamar Boulevard Arlington, TX 76011-4511 (817) 200-1103 or (817) 200-1140	sion				

13/28/14

#### BETWEEN:

Accounts Receivable/Payable and Regional Licensing Branches

## [ FOR ARPB USE ] INFORMATION FROM WBL

Program Code: 02120 Status Code: Pending Amendment Fee Category: 7C Exp. Date: 03/31/2015 Fee Comments: CODE 23 Decom Fin Assur Reqd: N

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# License Fee Worksheet - License Fee Transmittal

#### A. REGION

1. APPLICATION ATTAC	HED
Applicant/Licensee:	KALISPELL REGIONAL MEDICAL CENTER
Received Date:	03/20/2014
Docket Number:	3009152
Mail Control Number:	583503
License Number:	25-15463-01
Action Type:	Amendment

2. FEE ATTACHED

Amount:

3. COMMENTS

Signed: Date:

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / /

1. Fee Category and Amount:

2. Correct Fee Paid. Application may be processed for: