

2800 Tenth Avenue North P.O. Box 37000 Billings, Montana 59107-7000

February 23, 2009

Roberto J. Torres, Senior Health Physicist U.S. Nuclear Regulatory Commission, Region IV 612 E. Lamar Blvd. Suite 400 Arlington, TX 76011 817-860-8188

Christopher K. Fitz, Medical Physicist/Radiation Safety Officer Billings Clinic Health System Department Of Nuclear Medicine 2800 10th Ave. North P.O. Box 37000 Billings, MT 59107 RECEIVED

MAR - 9 2009

DNMS

Re: Amendment Request for Billings Clinic License Number 25-01051-01

Mr. Torres, we request to add two new authorized users to our license. Please accept this letter and the supporting material to add John M. Schallenkamp, MD, as an authorized user for 10 CFR 35.300 (radioactive material requiring a written directive) use. We also wish to add Christian F. Gaissmaier, MD, as an authorized user for 10 CFR 35.200 (imaging and localization) uses. NRC 313a (AU) have been completed for each user.

We also wish to have the following authorized users deleted from our license: James Kelly Vincent, MD, and Gordon L. Cox. MD.

If you require addition information please call me at 406-672-6756.

Sincerely,

Christopher K. Fitz, JD, MS

Medical Physicist/Radiation Safety Officer

Peggy Wharton

VP for Clinic Operations

NRC FORM 313A (AUD) (10-2007)

U.S. NUCLEAR REGULATORY COMMISSION

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

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION

	35.100, 35.200, and 35.500) 35.290, and 35.590]		
Name of Proposed Authorized User	State or Territory Whe	re Licensed	
Christian F. Gaissmaier, MD	МТ	חביים יים	-
Requested Authorization(s) (check all that a	apply)	RECEIVE)
35.100 Uptake, dilution, and excretion s	studies	MAR - 9 2009	
√ 35.200 Imaging and localization studies	3	MAN 9 2009	
35.500 Sealed sources for diagnosis (sp	pecify device	DNMS	
	RT I TRAINING AND EXPERIENCE		
* Training and Experience, including board the date of application or the individual me the required training and experience was education and experience related to the	nust have obtained related continuing scompleted. Provide dates, duration,	education and experience sin	ice
✓ 1. <u>Board Certification</u>			
a. Provide a copy of the board certification	ation.		
 If using only 35.500 materials, stop Preceptor Attestation. 	here. If using 35.100 and 35.200 ma	terials, skip to and complete F	Part II
2. Current 35.390 Authorized User S	seeking Additional 35.290 Authoriza	<u>ition</u>	
 a. Authorized user on Materials Licens State requirements seeking authori b. Supervised Work Experience. (If more than one supervising indivice copies of this section.) 		CFR 35.390 or equivalent Ag	
Description of Experience	Location of Experience/License Permit Number of Facility		ates of perience*
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 Num authorized user	ber listing supervising individual	as an
Supervisor meets the requirements be 35.290 35.390 + gen	elow, or equivalent Agreement State researchers experience in 32.290(c)(1)(ii)(G		ply).

NRC FO (10-2007)	RM 313A (AUD) AUTHORIZED I	USER TRAININ	G AND EXPERIE	NCE AND PRECEPTO	U.S. NUCLEAR REGULATO R ATTESTATION (con	
					<u></u>	,
Note:	PART II – PRECEPTOR ATTESTATION 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)					
1				esting that the individua s "general clinical comp	l has knowledge to fulfill etency."	the duties of the
First S Check	ection one of the follow	wing for each u	se requested:			
For	<u>35.190</u>					
	Board Certificati	<u>on</u>				
	attest that			has satisfactorily cor	npleted the requirements	s in
		·	sed 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.					ntly as an
				OR		
1	Training and Exp	<u>perience</u>				
	I attest that	Name of Propo	sed Authorized User	has satisfactorily cor	mpleted the 60 hours of t	raining and
	35.190(c)(1),	, and has achiev	ved a level of comp	classroom and laborate betency sufficient to fund d under 10 CFR 35.100	ory training, required by action independently as a D.	10 CFR in
For	35.290					
	Board Certificati	on				
	✓ I attest that	Christian F.	Gaissmaier	has satisfactorily cor	mpleted the requirements	s in
		.90(a)(1) and ha	s achieved a level	of competency sufficie d under 10 CFR 35.100	ent to function independe 0 and 35.200.	ntly as an
				OR		
	Training and Ex	<u>perience</u>				
	I attest that			has satisfactorily cor	mpleted the 700 hours of	training
	CFR 35.290	nce, including a (c)(1), and has a	achieved a level of		boratory training, require to function independently and 35.200.	
	d Section			:t		
Compi			attestation and so ow, or equivalent A	_	ements, as an authorized	d user for:
	35.190	√ 35.290	35.390	35.390 + genera	tor experience	
Name o	of Preceptor		Signatur		Telephone Number	Date
Scott A	N. Sample, MB		Scott A.	Tali to	238-2000	8-1AN9
License	/Permit Number/Fa	icility Name				

25-01051-01, Billings Clinic, Billings, MT

Incorporated 1996

CERTIFICATION BOARD OF NUCLEAR CARDIOLOGY

CERTIFIES THAT

Christian F. Gaissmaier, MD

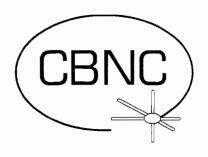
HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD FOR PHYSICIANS RESIDING IN THE UNITED STATES AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION, IS HEREBY DESIGNATED

A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF

NUCLEAR CARDIOLOGY

FOR THE PERIOD 2004 THROUGH 2014

CERTIFICATE # 3317



OCTOBER 24, 2004

NRC FORM 313A (AUT) (10-2007)

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

		00.000]			
Name of Propos	sed Authorized User	State or Territory Where License	ed		
John M. Scha	illenkamp, M.D.	MT, WY, MN, WI			
Requested Au	thorization(s) (check all that apply):		RECEIVED		
3 5.300	Use of unsealed byproduct material for whi	ch a written directive is require	MAR - 9 2009		
OR			DNMS		
35.300	Oral administration of sodium iodide I-131 r 1.22 gigabecquerels (33 millicuries)	requiring a written directive in o			
35.300	Oral administration of sodium iodide I-131 r gigabecquerels (33 millicuries)	requiring a written directive in o	quantities greater than 1.22		
35.300 Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy than 150 keV for which a written directive is required			lide with a photon energy less		
35.300	Parenteral administration of any other radio	onuclide for which a written dire	ective is required ,		
		G AND EXPERIENCE three methods below)			
of applicate experience	* 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. Provid	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. 				
and su	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	o and complete Part II Preceptor Attestation.				
2. Currer	nt 35.300, 35.400, or 35.600 Authorized Use	er Seeking Additional Author	rization		
a. Author	ized User on Materials License	unde	er the requirements below or		
equiva	alent Agreement State requirements (check a				
35	35.392 35.394	35.490 35.69	0		
require	ently authorized for a subset of clinical uses u ed supervised case experience. The table in ience. Also provide completed Part II Precep	section 3.c. may be used to do			
docun case e	ently authorized under 35.490 or 35.690 and inentation on classroom and laboratory training experience. The tables in sections 3.a., 3.b., arovide completed Part II Preceptor Attestation	g, supervised work experience and 3.c. may be used to docur	e, and supervised clinical		

- Classessesses and Laboration T	r Proposed Authorized User		05.000
a. Classroom and Laboratory T	raining ✓ 35.390	5.394	35.396
Description of Training	Training Location of Training Clock Hours		Dates of Training*
Radiation physics and instrumentation	Mayo Clinic, Div. Radiation Oncology Rochester, MN	140	07/01/01 to 07/01/05
Radiation protection	Mayo Clinic, Div. Radiation Oncology Rochester, MN	130	07/01/01-07/0 /05
Mathematics pertaining to the use and measurement of radioactivity	Mayo Clinic, Div Radiation Oncology Rochester, MN	130	07/01/01-07/0 /05
Chemistry of byproduct material for medical use	Mayo Clinic, Div Radiation Oncology Rochester, MN	10	07/01/01-07/0 /05
Radiation biology	Mayo Clinic, Div Radiation Oncology Rochester, MN	120	07/01/01-07/0 1/05
Total Hours of Training:			
If more than one supervising of this page. Supervised Work Experience	individual is necessary to document supervised tra		multiple copies
Description of Francisco	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	Mayo Clinic Rochester, MN 22-00519-03 Billings Clinic, Billings, MT 25-01051-01	✓ Yes No	07/01 - 07/05 08/05 - 01/09
safely and performing the related radiation surveys			
	Mayo Clinic Rochester, MN 22-00519-03 Billings Clinic, Billings, MT 25-01051-01	✓ Yes No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of			07/01 - 07/05 08/05 - 01/09 07/01 - 07/05 08/05 - 01/09
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	Billings Clinic, Billings, MT 25-01051-01 Mayo Clinic Rochester, MN 22-00519-03	No √ Yes	08/05 - 01/09 07/01 - 07/05

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 25-01051-01 Dean A. Bruschwein, M.D. Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**: With experience administering dosages of: **√** 35.390 35.392 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) 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.

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)	3	Billings Clinic, Billings, MT 25-01051-01	1 6 /08 to 01/09
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	4	Billings Clinic, Billings, MT 25-01051-01	10/05 to 01/09
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	5	Billings Clinic, Billings, MT 25-01051-01	10/05 to 01/09
Parenteral administration of any other radionuclide for which a written directive is required			
(List radionuclides)			1

	FORM 313A (AUT)	U.S. NUCLEAR REGULATORY COMMISSION		
(10-200	•	NCE AND PRECEPTOR ATTESTATION (continued)		
3.	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		
	Supervising individual meets the requirements below, apply)**:	or equivalent Agreement State requirements (check all that		
	35.390 With experience administering dosages	of:		
	35.392 Oral Nal-131 requiring a written dire	ective in quantities less than or equal to 1.22		
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 oth	er radionuclide requiring a written directive		
** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the indiversely requesting authorized user status.				
	d. Provide completed Part II Preceptor Attestation.			
	PART II – PRECE	PTOR ATTESTATION		
Note	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.			
	By checking the boxes below, the preceptor is atterposition sought and not attesting to the individual's	sting that the individual has knowledge to fulfill the duties of the "general clinical competency."		
	t Section ck one of the following for each requested authoriz	ration:		
	For 35.390:			
	Board Certification			
	I attest that Name of Proposed Authorized User	has satisfactorily completed the training and experience		
	requirements in 35.390(a)(1).			
		OR		
	Training and Experience			
	John M. Schallenkamp, M.D. Name of Proposed Authorized User	has satisfactorily completed the 700 hours of training		
	and experience, including a minimum of 200 hours 10 CFR 35.390 (b)(1).	ours of classroom and laboratory training, as required by		

NRC FORM 313A (AUT) (10-2007)		U.S. NUCLEAR REGULATORY COMMISSION
	USER TRAINING AND EXP	PERIENCE AND PRECEPTOR ATTESTATION (continued)
Fourth Section		
For 35.396:		
Current 35.490	or 35.690 authorized user:	
attest that		is an authorized user under 10 CFR 35.490 or 35.690
laboratory tra experience r	aining, as required by 10 CFR	User hts, has satisfactorily completed the 80 hours of classroom and 35.396 (d)(1), and the supervised work and clinical case has achieved a level of competency sufficient to function
	al administration of any beta-e keV for which a written directi	emitter, or photon-emitting radionuclide with a photon energy less ive is required
Parentera	al administration of any other	radionuclide for which a written directive is required
		OR
Board Certifica	tion:	
I attest that		has satisfactorily completed the board certification
required by	10 CFR 35.396 (d)(1) and the , and has achieved a level of c	User ily completed the 80 hours of classroom and laboratory training supervised work and clinical case experience required by competency sufficient to function independently as an
	al administration of any beta-e keV for which a written directi	emitter, or photon-emitting radionuclide with a photon energy less ive is required
Parentera	al adminstration of any other r	adionuclide for which a written directive is required
		• • • • • • • • • • • • • • • • • • • •
Fifth Section Complete the followir	ng for preceptor attestation	and signature:
		Agreement State requirements, as an authorized user for:
√ 35.390	35.392 35.394	4 35.396
I have experient requesting auth		he following categories for which the proposed Authorized User is
✓ Oral Nal-131 millicuries)	requiring a written directive i	n quantities less than or equal to 1.22 gigabecquerels (33
✓ Oral Nal-131	in quantities greater than 1.2	22 gigabecquerels (33 millicuries)
✓ Parenteral a	dministration of beta-emitter.	or photon-emitting radionuclide with a photon energy less than
requesting auth Oral Nal-131 millicuries) Oral Nal-131	orization. I requiring a written directive in the interpretation in quantities greater than 1.2	n quantities less than or equal to 1.22 gigabecquerels (33

Signature Dean A. Bruschwein, M.D. License/Permit Number/Facility Name

✓ Parenteral administration of any other radionuclide requiring a written directive

Telephone Number (406) 237-1300

25-01051-01

Name of Preceptor

ACCEPTANCE REVIEW MEMO (ARM)

License No.: 25-01051-01

Billings Clinic

Licensee:

Docket No.: 030-02389 Mail Control No.: 472184 Type of Action: Date of Requested Action: 02/23/09 Amend Reviewer ARM reviewer(s): Torres Assigned: Response **Deficiencies Noted During Acceptance Review** Den ended possession limits. Submit inventory, Limit possession. [] Submit copies of latest leak test results. [] Add IC L.C./Fingerprint LC, add SUNSI markings to license. [] Confirm with licensee if they have NARM material. Reviewer's Initials: Date: ☐ Yes ☐ No Request for unrestricted release Group 2 or >. Consult with Bravo Branch. ☐ Yes ☐ No Termination request < 90 days from date of expiration ☐ Yes ☐ No Expedite (medical emergency, no RSO, location of use/storage not on license, RAM in possession not on license, other) ☐ Yes ☐ No. TAR needed to complete action. Branch Chief's and/or HP's Initials: Date: SUNSI Screening according to RIS 2005-31 ☐Yes 🛂No Sensitive and Non-Publicly Available if any item below is checked General guidance: RAM = or > than Category 3 (Table 1, RIS 2005-31), use Unity Rule Exact location of RAM [suite #, bldg. #, location different from mailing address] (whether = or > than Category 3 or not) Design of structure and/or equipment (site specific) Information on nearby facilities Detailed design drawings and/or performance information Emergency planning and/or fire protection systems Specific quidance for medical, industrial and academic (above Category 3): RAM quantities and inventory Manufacturer's name and model number of sealed sources & devices Site drawings with exact location of RAM, description of facility RAM security program information (locks, alarms, etc.) Emergency Plan specifics (routes to/from RAM, response to security events) Vulnerability/security assessment/accident-safety analysis/risk assess Mailing lists related to security response MAR 2 6 2009 Branch Chief's and/or HP's Initials: Date:

	is to acknowledge the receipt of your lette 2 - 23 - 09 , and to inform you that ich includes an administrative review, has l	the initial processing,	DATE
Ø	There were no administrative omissions. reviewer. Please note that the technical additional information.		
	Please provide to this office within 30 day	s of your receipt of this ca	ard:
The	action you requested is normally processed	ed within <i>GO</i> days.	
	A copy of your action has been forwarded Branch, who will contact you separately it		
Wh	ir action has been assigned Mail Contro en calling to inquire about this action, pleas i may call me at 817-860-8103.	Number <u>473/</u> se refer to this mail contro	84. I number.
		Sincerely,	
		Colleen H,	unahan
NRC	FORM 532 (RIV)	I icaneina Assistant	

		(707) 700 (07)
		: (FOR LFMS USE) : INFORMATION FROM LTS
3E T	WEEN:	:
ic	ense Fee Management Branch, ARM	Program Code: 02230: Status Code: 0
Reg	and ional Licensing Sections	: Fee Category: 7C
		: Exp. Date: 20150430 : Fee Comments: CODE 23
		: Decom Fin Assur Reqd: N
_10	ENSE FEE TRANSMITTAL	
۹.	REGION	
1.	APPLICATION ATTACHED	
١.	Applicant/Licensee: BILLINGS CLINIC	
	Received Date: 20090309 Docket No: 3002389	
	Control No.: 472184 License No.: 25-01051-01	
	Action Type: Amendment	
2.	FEE ATTACHED Amount:	
	Check No.:	
3.	COMMENTS	1
	Signed Z	allen Murrahan
В.	LICENSE FEE MANAGEMENT BRANCH (Check	when milestone 03 is entered //)
1.	Fee Category and Amount:	
2.		e processed for:
	Amendment Renewal	
	License	
3.	OTHER	
	Signed	
	Date _	

Billings Clinic 2800 10th Auc Horth Billings, MT 59107-7000

1001423857 LEC First US F Bil Per

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ZIP 76011

Harldfollorrolfrolfdaladfoldadffdalddoldal

REQUESTED REPVICE

472184

US NRC, Region IV
612 E. Lamer Blud., Suite 400
Arlingtin, TX 76011-4125
Attn: Roberto J. Torres