## Torres, RobertoJ

From:	Ronald Frick [rfrick@gammacorp.com]
Sent:	Friday, August 20, 2010 10:12 PM
То:	Torres, RobertoJ
Subject: Attachments:	Re: Amendment request from North Hawaii Community Hospital (53-29099-01) wiesmann.pdf

Roberto,

The attached file includes Dr. Weismann's ABR certification, and completed forms 313A(aus) and 313A(aut). Please let me know if you need any additional information.

Thank you,

Ron Frick

>>> "Torres, RobertoJ" <<u>RobertoJ.Torres@nrc.gov</u>> 8/4/2010 5:11 AM >>> Mr. Frick:

We have received the attached letter from North Hawaii Community Hospital requesting to add Kevin Weismann, M.D. as an authorized user for 10 CFR 35.100, 35.200 and sodium iodide I-131 greater than 33 mCi uses. The NRC Form 313A that was submitted is an outdated form (outdated content) and also its OMB approval expired on October 31, 2008. Furthermore the preceptor (Brian P. Mullan, M.D.) only attested that Dr. Weismann has achieved a level of competency sufficient to function independently as a 35.100 and 35.200 uses only (Dr. Mullan did not attest to Dr. Weismann's use of I-131). Therefore, please ask the licensee to resubmit the request using the attached updated NRC Form 313A(aus) and 313A(aut). Both forms need to be completed. One form is for 35.100 and 35.200, the other form is for I-131 uses. Thank you.

Roberto J. Torres US NRC Region IV

Certificate No. 55664 Coline 1970 A選 语ligible The American Gauch of Wadinla American College of Nadiology, the American Scientigen Play Society, Imerican College of Nadiology, the American Noentgen Play Society, the American Nadium Society, the Nadiological Society of North America, the Section on Nadiology of the American Medical Association, the American Society for Thorapeutic Nadiology and Oncology, the Association of M. N. leel Dennieles mis Richard T. Maria University Radiologists, and American Association of Physicists in Medicine 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 Kevin Michael Wiesmann, MD Has pursued an accepted course of graduate study that he is qualified to practice the specialty of The American Board of Iladiology On this third day of June, 2008 **Diagnostic Radiology** Hereby certifies that Harry Tocker 10 Walid through 2018 orisusous

NRC FORM 313A	(AUT)	U.S. NUCLEAR REGULATORY COMMISS	SION
(3-2009) Al	JTHORIZED USER TRAIN AND PRECEPTOR (for uses defined [10 CFR 35.390, 35.392,	ATTESTATION under 35.300)	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 3/31/2012
Name of Propos	ed Authorized User	State or Territory Where Li	censed
Kevin M. Wiesm	ann, M.D.	Hawaii	ана али али али али али али али али али ал
Requested Aut	horization(s) (check all that appl	y):	
35.300	Use of unsealed byproduct ma	terial for which a written directive is re	quired
OR			
35.300	Oral administration of sodium i 1.22 gigabecquerels (33 millicu	odide I-131 requiring a written directiv uries)	e in quantities less than or equal to
✔ 35.300	Oral administration of sodium i gigabecquerels (33 millicuries)	iodide I-131 requiring a written directiv	e in quantities greater than 1.22
35.300	Parenteral administration of an than 150 keV for which a writte	ay beta-emitter, or photon-emitting radi en directive is required	ionuclide with a photon energy less
35.300	Parenteral administration of an	ny other radionuclide for which a writte	n directive is required
		I TRAINING AND EXPERIENCE	
of applicat experience to the uses	ion or the individual must have re	certification, must have been obtained elated continuing education and exper , duration, and description of continuir	rience since the required training and
	e a copy of the board certification		
b. For 35		supervised clinical case experience.	The table in section 3.c. may
c. For 35 and su	.396, provide documentation on	classroom and laboratory training, sup e. The tables in sections 3.a., 3.b., ar	
d. Skip to	and complete Part II Preceptor	Attestation.	
2. Curren	t 35.300, 35.400, or 35.600 Aut	horized User Seeking Additional Au	uthorization
a. Authori	zed User on Materials License		under the requirements below or
equiva	lent Agreement State requireme	ents (check all that apply):	
35.	390 35.392	35.394 35.490	35.690
require		linical uses under 35.300, provide doc The table in section 3.c. may be used art II Preceptor Attestation.	
docum clinical	entation on classroom and labor	35.690 and requesting authorization f ratory training, supervised work experi sections 3.a., 3.b., and 3.c. may be us art II Preceptor Attestation.	ence, and supervised
NRC FORM 313A (AUT)	/3 70201	PRINTED ON RECYCLED PAPER	PAGE 1

AUTHORIZED USER TRAIL	NING AND EXPERIENCE AND PREC		REGULATORY COMMISS
3. <u>Training and Experience for</u>	Proposed Authorized User		
<ul> <li>Classroom and Laboratory Tr</li> </ul>	aining 35.390 35.392	✓ 35.394	35.396
Description of Training	Location of Training		Clock Dates of lours Training*
Radiation physics and instrumentation	Mayo Clinic College of Mcdicine Rochester, MN	110	June 2004-Jun 2008
Radiation protection	Mayo Clinic College of Medicine Rochester, MN	30	June 2004-Ju 2008
Mathematics pertaining to the use and measurement of radioactivity	Mayo Clinic College of Medicine Rochester, MN	35	June 2004-Jan 2008
Chemistry of byproduct material for medical use	Mayo Clinic College of Medicine Rochester, MN	20	June 2004-Ju 2008
Radiation biology	Mayo Clinic College of Medicine Rochester, MN	40	June 2004-Ju 2008
	Total Hours of Training:	235	
Supervised Work Experience	Expe	l Hours of erience:	
Description of Experience Must Include:	Location of Experience/Licer Permit Number of Facilit	y Co	onfirm Dates of Experience
Ordering, receiving, and unpacking radioactive materials safely and performing	Mayo Clinic Rochester NRC License #22-00519-03	V	Yes June 2004-Jun
the related radiation surveys			2008 No
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Mayo Clinic Rochester NRC License #22-00519-03		2008
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 dosages	•		2008 No Yes June 2004-Ju 2008 No
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	NRC License #22-00519-03 Mayo Clinic Rochester NRC License #22-00519-03		2008           No           Yes           June 2004-Jun           2008           No           Yes           June 2004-Jun           Yes           June 2004-Jun           2008

NRC FORM 313A (AUT) 3-2009)		U.S. NUCLEAR REGULA	TORY COMMISSION
•	NING AND EXPERIE	NCE AND PRECEPTOR ATTESTATION (co	ntinued)
3. Training and Experience for P	roposed Authorized	User (continued)	
b. Supervised Work Experience	e (continued)		
Supervising Individual		License/Permit Number listing supervising ind authorized user	ividual as an
Brian P. Mullan, M.D.		NRC License #22-00519-03	
Supervising individual meets the apply)**:	e requirements below	, or equivalent Agreement State requirements	(check all that
✓ 35.390 With experience	administering dosage	s of:	
digabecquere	requiring a written dir els (33 millicuries)	ective in quantities less than or equal to 1.22	
33.394		han 1.22 gigabecquerels (33 millicuries)	
Parenteral ad	lministration of beta-e han 150 keV requiring	mitter, or photon-emitting radionuclide with a p a written directive is required	photon
Parenteral ad	Iministration of any ot	her radionuclide requiring a written directive	
** Supervising Authorized User must h requesting authorized user status.	ave experience in administ	tering dosages in the same dosage category or categories	s as the individual
c. Supervised Clinical Case Ex If more than one supervising multiple copies of this page. Description of Experience		ry to document supervised work experience, p Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium	16	Mayo Clinic Rochester NRC License #22-00519-03	June 2004-June
iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)		NC Litense #22-00519-05	2008
		Mayo Clinic Rochester	June 2004 June
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	• •	NRC License #22-00519-03	June 2004-June 2008
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required			
Parenteral administration of any other radionuclide for which a written directive is required			
(List radionuclides)			

NRC FOF (3-2009)		U.S. NUCLEAR REGULATORY COMMISSION CE AND PRECEPTOR ATTESTATION (continued)
3. <u>Tra</u>	aining and Experience for Proposed Authorized U	
C.	Supervised Clinical Case Experience (continued)	
Su	pervising Individual	License/Permit Number listing supervising individual as an authorized user
Bri	an P. Mullan, M.D.	NRC License #22-00519-03
	pervising individual meets the requirements below, c <i>ply</i> )**:	r equivalent Agreement State requirements (check all that
1	35.390 With experience administering dosages	of:
	35.392 Voral Nal-131 requiring a written direct gigabecquerels (33 millicuries)	ctive in quantities less than or equal to 1.22
· · · · · ·	oral Nal-131 in quantities greater that	an 1.22 gigabecquerels (33 millicuries) itter, or photon-emitting radionuclide with a photon
	energy less than 150 keV requiring a	a written directive is required
	Parenteral administration of any othe	er radionuclide requiring a written directive
**		ing dosages in the same dosage category or categories as the individual
d.	Provide completed Part II Preceptor Attestation.	
	PART II PRECEP	TOR ATTESTATION
Note:		ceptor. The preceptor does not have to be the supervising , or verifies training and experience required. If more than e, obtain a separate preceptor statement from each.
	By checking the boxes below, the preceptor is attest position sought and not attesting to the individual's "	ting that the individual has knowledge to fulfill the duties of the general clinical competency."
First S Check	ection one of the following for each requested authoriza	ation:
Fo	<u>r 35.390:</u>	
	Board Certification	
	I attest that Name of Proposed Authorized User	has satisfactorily completed the training and experience
	requirements in 35.390(a)(1).	
	(	DR
	Training and Experience	
	Name of Proposed Authorized User	has satisfactorily completed the 700 hours of training
i	and experience, including a minimum of 200 hou 10 CFR 35.390 (b)(1).	urs of classroom and laboratory training, as required by

p	•	6
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C FORM 313A (AUT)	U.S. NUCLEAR REGULATORY COMMISSIO
AUTHORIZE	D USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)
eceptor Attestation	(continued)
First Section (con	tinued)
For 35 392 (Identi	cal Attestation Statement Regardless of Training and Experience Pathway):
I attest that	has satisfactorily completed the 80 hours of classroom
	ory training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case required in 35.392(c)(2).
For 35.394 (Identi	cal Attestation Statement Regardless of Training and Experience Pathway):
✓ I attest that	Kevin M. Wiesmann, M.D. has satisfactorily completed the 80 hours of classroom
	bry training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case required in 35.394(c)(2).
Second Section	
✓ I attest that	Kevin M. Wiesmann, M.D.         has satisfactorily completed the required clinical case           Name of Proposed Authorized User         Name of Proposed Authorized User
experience r	required in 35.390(b)(1)(ii)G listed below:
	-131 requiring a written directive in quantities less than or equal to 1.22 querels (33 millicuries)
🗸 Oral Nal	-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
	al administration of beta-emitter, or photon-emitting radionuclide with a photon ess than 150 keV requiring a written directive is required
Parenter	al administration of any other radionuclide requiring a written directive
Third Section	
$\checkmark$ ] I attest that	Kevin M. Wiesmann, M.D. has satisfactorily achieved a level of competency to Name of Proposed Authorized User
function inde	ependently as an authorized user for:
Gigabeco	131 requiring a written directive in quantities less than or equal to 1.22 puerels (33 millicuries)
<b>F</b> (1)	-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
Parenter	al administration of beta-emitter, or photon-emitting radionuclide with a photon ess than 150 keV requiring a written directive is required
	al administration of any other radionuclide requiring a written directive

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NRC FORM 313A (AUT)	,			U.S. NUCLEAR REGULATORY COMMISSION
(3-2009) AUTHORIZE	D USER TRAINI	NG AND EXPERI	ENCE AND PRECEPT	OR ATTESTATION (continued)
Fourth Section				
For 35.396:				
Current 35.490	or 35.690 autho	rized user:		
I attest that	Name of Pro	posed Authorized User	is an authorized u	user under 10 CFR 35.490 or 35.690
laboratory tra experience r	t Agreement Stat aining, as require	te requirements, h ed by 10 CFR 35.3 (6(d)(2), and has a	96 (d)(1), and the sup	eted the 80 hours of classroom and ervised work and clinical case npetency sufficient to function
		of any beta-emitte written directive is		adionuclide with a photon energy less
Parenter	al administration	of any other radio	nuclide for which a wri	tten directive is required
			OR	
Board Certifica	<u>ation:</u>			
I attest that			has satisfactorily	completed the board certification
		posed Authorized User		
required by	10 CFR 35.396 (0) ), and has achiev	d)(1) and the supe	ervised work and clinica	of classroom and laboratory training al case experience required by nction independently as an
		of any beta-emitte written directive is		adionuclide with a photon energy less
Parenter	al adminstration	of any other radio	nuclide for which a writ	tten directive is required
Fifth Section Complete the followi	na for preceptor	attestation and	cianature.	
			-	
V I meet the requ	irements below, o	or equivalent Agre	ement State requirement	ents, as an authorized user for:
✓ 35.390	35.392	35.394	35.396	
have experien requesting auth		dosages in the fo	llowing categories for v	which the proposed Authorized User is
✓ Oral Nal-13 millicuries)	1 requiring a writt	en directive in qu	antities less than or eq	ual to 1.22 gigabecquerels (33
🗸 Oral Nal-13	1 in quantities gre	eater than 1.22 gi	gabecquerels (33 millic	curies)
Parenteral a 150 keV req	idministration of t	oeta-emitter, or ph irective is required	oton-emitting radionuc	lide with a photon energy less than
Parenteral a	dministration of a	any other radionuo	clide requiring a written	directive
Name of Preceptor				
Brian P. Mullan, M.D.		Signature Snan	" Mullon	Telephone Number Date 507-284-9599 08/112010
License/Permit Number/F	acility Name		· · · · · · · · · · · · · · · · · · ·	
Mayo Clinic Rochester, N	RC License #22-005	519-03		

NDC FORM 2424 (AUD)			
NRC FORM 313A (AUD) (3-2009)	U.S. NUCLEAR REGULATORY COMMISS		
AND PRECEPTO (for uses defined under 3	INING AND EXPERIENCE OR ATTESTATION 5.100, 35.200, and 35.500) 5.290, and 35.590]	APPROVED BY EXPIRES: 3/31/	OMB: NO. 3150-0120 2012
Name of Proposed Authorized User	State or Territory Where Li	censed	
Kevin M. Wiesmann, M.D.	Hawaii		
Requested Authorization(s) (check all that a	ppły)		
$\checkmark$ 35.100 Uptake, dilution, and excretion st	tudies		
$\checkmark$ 35.200 Imaging and localization studies			
35.500 Sealed sources for diagnosis (sp	ecify device	)	
	RT I TRAINING AND EXPERIENCE ect one of the three methods below)		
<ul> <li>Training and Experience, including board the date of application or the individual m the required training and experience was education and experience related to the u</li> </ul>	ust have obtained related continuing edu completed. Provide dates, duration, and	cation and experier	nce since
✓ 1. Board Certification			
a. Provide a copy of the board certification	ation.		
<ul> <li>b. If using only 35.500 materials, stop Preceptor Attestation.</li> </ul>	here. If using 35.100 and 35.200 materia	als, skip to and com	plete Part II
2. Current 35.390 Authorized User Se	eeking Additional 35.290 Authorization	n	
a. Authorized user on Materials Licens State requirements seeking authoriz	se meeting 10 CFF	- R 35.390 or equival	ent Agreement
<ul> <li>b. Supervised Work Experience, (If more than one supervising individual copies of this section.)</li> </ul>	dual is necessary to document supervise	d work experience,	provide multiple
Description of Experience	Location of Experience/License or Permit Number of Facility	Ciock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			
	Total Hours of Experience:		**************************************
Supervising Individual	License/Permit Number I authorized user	isting supervising ind	ividual as an
	i low, or equivalent Agreement State requi erator experience in 32.290(c)(1)(ii)(G)	rements <i>(check all</i> )	that apply).
	a na antar an an anna an an anna an an anna an an		·

. Training and Experience for Propose	ed 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:		
<ul> <li>b. Supervised Work Experience (comple (If more than one supervising individu provide multiple copies of this section</li> </ul>	etion of this table is not required for 35.590) ual is necessary to document supervised wo n.)	I. ork experience,	
Supervised Work Experience	Total Hours of Experience:		1
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		[ Yes	
performing the related radiation surveys		[] No	1
Performing quality control procedures on instruments used to determine the activity of dosages		Yes	
and performing checks for proper operation of survey meters		No No	

PAGE 2

Fraining and Experience for Propose	ed Authorized User (continued)			
o. Supervised Work Experience. (con				
Description of Experience Must Include:	Location of Experience/Licens 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	
Supervising Individual	License/Permit Nun authorized user	nber listing sup	ervising ind	ividual as an
Supervisor meets the requirements be	low, or equivalent Agreement State r	-		
c. For 35.590 only, provide document	ation of training on use of the device	•		
Device	Type of Training	Locati	on and Da	ates

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 (AU				U.S. NUCLEAR REGULATO	
AUTHOR	ZED USER TRAINI				unaca)
individual one prece	as long as the prece	y the individual's p otor provides, direc document experier	cts, or verifies training nce, obtain a separate	ON otor does not have to be the g and experience required. e preceptor statement from o	If more than
By checki position se	ig the boxes below, j bught and not attesti	the preceptor is att ng to the individual	testing that the individ 's "general clinical co	lual has knowledge to fulfill mpetency."	the duties of the
First Section Check one of the	following for each	use requested:			
<u>For 35.190</u>					
Board Ce	tification				
🖌 I attes		ann, M.D.	has satisfactorily	completed the requirements	s in
	R 35.190(a)(1) and h	as achieved a leve	el of competency suff ed under 10 CFR 35.	icient to function independent 100.	ntly as an
			OR		
<u>Training a</u>	nd Experience				
attes			has satisfactorily	completed the 60 hours of t	raining and
		posed Authorized User	.     •	·	-
35.190	)(c)(1), and has achie	eved a level of con	of classroom and labo npetency sufficient to red under 10 CFR 35.	ratory training, required by function independently as a 100.	10 CFR an
For 35.290					
Board Ce	tification				
✓ I attes	t that Kevin Wiesma	nn, M.D.	has satisfactorily	completed the requirements	s in
	R 35.290(a)(1) and h	as achieved a levi	el of competency suff ed under 10 CFR 35.	icient to function independe 100 and 35.200.	ntly as an
			OR		
<u>Training a</u>	nd Experience		0.1		
[] I attes	• · · · • · · · · · · · · · · · · · · ·	posed Authorized User	has satisfactorily	completed the 700 hours of	training
CFR 3	5.290(c)(1), and has	achieved a level of		d laboratory training, require ent to function independently 100 and 35.200.	
Second Section	) # # # # # # # # # # # # # # # # # # #	ر بران 100 100 100 100 100 100 100 100 100 10	بدن بدل امار هي هي هند الله الله الله الله بي يوم جد هم هد الله الله الله بي يوم مع هد الله الله ال	اد این اور هو هار ها، این	ر حک کیا این اینٹر بانٹر اینٹر اوپر ہونے ہونے کے کرنے ہیں جو پر
Complete the fol	lowing for precepto	r attestation and	signature:		
🖌 I mee	the requirements be	low, or equivalent	Agreement State rec	uirements, as an authorized	d user for:
√ 35	.190 🖌 35.290	✓ 35.390	( 35.390 + gen	erator experience	
Name of Preceptor		Signature		Telephone Number	Date
Brian P. Mullan, M.	D.	Boian	Mullon	507-244-9599	08/11/2010
License/Permit Nun Mayo Clinic Roches	ber/Facility Name ter, NRC License #22-0		······································		-I
					PAGE 4

## **Torres, RobertoJ**

From:Torres, RobertoJSent:Wednesday, August 04, 2010 10:12 AMTo:'rfrick@gammacorp.com'Subject:Amendment request from North Hawaii Community Hospital (53-29099-01)Attachments:amendment request letter.pdf; nrc313a(aut).pdf; nrc313a(aud).pdf

Mr. Frick:

We have received the attached letter from North Hawaii Community Hospital requesting to add Kevin Weismann, M.D. as an authorized user for 10 CFR 35.100, 35.200 and sodium iodide I-131 greater than 33 mCi uses. The NRC Form 313A that was submitted is an outdated form (outdated content) and also its OMB approval expired on October 31, 2008. Furthermore the preceptor (Brian P. Mullan, M.D.) only attested that Dr. Weismann has achieved a level of competency sufficient to function independently as a 35.100 and 35.200 uses only (Dr. Mullan did not attest to Dr. Weismann's use of I-131). Therefore, please ask the licensee to resubmit the request using the attached updated NRC Form 313A(aus) and 313A(aut). Both forms need to be completed. One form is for 35.100 and 35.200, the other form is for I-131 uses. Thank you.

Roberto J. Torres US NRC Region IV