April 22, 2010

Nuclear Materials Licensing Branch Nuclear Regulatory Commission Region III 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

Re: Materials License No. 21-32342-01

This letter is to request the addition of Dr. Henry Skye to our materials license for 10CFR 35.100 and 35.200. Enclosed are the NRC Forms 313 (AUD and T), and preceptor statement. Also enclosed are copies of the materials license from Rhinelander, WI., naming him for the equivalent of 35.100 and 200 and his Michigan medical license.

If you have any questions regarding this request, please contact Shan Marlette, consultant, at (906) 225-6967.

Thank you.

Sincerely,

Cawl Joffnett CEO Carol Goffnet, C.E.O.

## NRC FORM 313A (AUD) (3-2009)

### U.S. NUCLEAR REGULATORY COMMISSION

# **AUTHORIZED USER TRAINING AND EXPERIENCE**

AND PRECEPTOR ATTESTATION (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]			EXPIRES: 3/31	/2012
Name of Proposed Authorized User		State or Territory Where Licen	nsed	
Harry W. Skye, M.D.		Michigan		
Requested Authorization(s) (check all that	apply)			
√ 35.100 Uptake, dilution, and excretion	studies			
√ 35.200 Imaging and localization studies	s			
35.500 Sealed sources for diagnosis (s	specify device		)	
		G AND EXPERIENCE hree methods below)		
<ul> <li>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</li> </ul>	rd certification, mu must have obtaine is completed. Pro	ust have been obtained withing related continuing education dates, duration, and de	ion and experier	nce since
1. Board Certification				
a. Provide a copy of the board certific	cation.			
<ul> <li>b. If using only 35.500 materials, stop Preceptor Attestation.</li> </ul>	here. If using 35	5.100 and 35.200 materials,	skip to and com	iplete Part II
2. Current 35.390 Authorized User S	Seeking Addition	al 35.290 Authorization		
<ul> <li>a. Authorized user on Materials Licer State requirements seeking author</li> <li>b. Supervised Work Experience. (If more than one supervising indivicopies of this section.)</li> </ul>	rization for 35.290		·	-
Description of Experience		f Experience/License or t Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs				
	Total Hours	of Experience:	-11	
Supervising Individual		License/Permit Number listin authorized user	ng supervising ind	ividual as an
Supervisor meets the requirements be	•	t Agreement State requirem	ents (check all t	hat apply).

3. Training and Experience for Propo	sed Authorized User		
a. Classroom and Laboratory Training.	<del></del>		
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 (not required for 35.590)			
Radiation biology			
	Total Hours of Training:		
b. Supervised Work Experience (compl (If more than one supervising individ provide multiple copies of this section	letion of this table is not required for 35.590 lual is necessary to document supervised w n.)	)). vork experience,	
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	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper		Yes No	

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

NRC FO (3-2009)	ORM 313A (AUD) AUTHORIZED	USER TRAININ	G AND EXPERIE	NCE AND PRECE	U.S. NUCLEAR REGULA PTOR ATTESTATION (CA	
Note:	individual as long one preceptor is	e completed by g as the precept necessary to do	the individual's pr tor provides, direc	cts, or verifies trainin ice, obtain a separa	TION eptor does not have to be to g and experience required te preceptor statement from	I. If more than
	By checking the position sought a	boxes below, th and not attesting	e preceptor is atto to the individual'	esting that the indivi s "general clinical co	idual has knowledge to fulf ompetency."	ill the duties of the
Check	Section  cone of the follow	ving for each u	se requested:			
<u> </u>	35.190					
	Board Certification	-	sed Authorized User	has satisfactorily	completed the requirement	nts in
	10 CFR 35.1 authorized us	90(a)(1) and ha	s achieved a level	l of competency suf ed under 10 CFR 35	ficient to function independ .100.	dently as an
				OR		
	Training and Exp	<u>perience</u>				
	attest that	Harry G Name of Propos	D. Skye sed Authorized User	has satisfactorily	completed the 60 hours o	f training and
	experience, ii 35.190(c)(1),	ncluding a minin and has achiev	num of 8 hours of ed a level of com	classroom and labo petency sufficient to d under 10 CFR 35	pratory training, required by function independently as .100.	y 10 CFR s an
<u>For</u>	35.290					
	Board Certification	<u>on</u>				
	I attest that	Name of Propos	sed Authorized User	has satisfactorily	completed the requiremen	nts in
				of competency suffed under 10 CFR 35	ficient to function independ .100 and 35.200.	lently as an
	Table and Eve			OR		
	Training and Exp			to a second diagram and a second	1 1 1 1 - 700 h	** * *
			w 5 kye sed Authorized User		completed the 700 hours	· ·
	CFR 35.290(	c)(1), and has a	chieved a level of		d laboratory training, requient to function independen 100 and 35.200.	
	d Section ete the following	for preceptor a	attestation and s	ignature:		
	I meet the red	quirements belo	w, or equivalent A	kgreement State req	uirements, as an authoriz	ed user for:
	35.190	35.290	35.390	35.390 + gen	erator experience	
Name o	f Preceptor		Signature	$\mathcal{A}$	Telephone Number	Date

grand View Health System

License/Permit Number/Facility Name

21-32342-01

### NRC FORM 313A (AUT)

### U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 3/31/2012

	(for uses defined under 35 [10 CFR 35.390, 35.392, 35.394, a		EAPIRES: 3/3/1/2012
Name of Propos	sed Authorized User	State or Territory Where License	ed
Harry W. Skye	, M.D.	Michigan	
Requested Au	thorization(s) (check all that apply):		
35.300	Use of unsealed byproduct material for wh	hich a written directive is require	ed .
OR			
35.300	Oral administration of sodium iodide I-131 1.22 gigabecquerels (33 millicuries)	requiring a written directive in o	quantities less than or equal to
35.300	Oral administration of sodium iodide I-131 gigabecquerels (33 millicuries)	requiring a written directive in o	quantities greater than 1.22
35.300	Parenteral administration of any beta-emit than 150 keV for which a written directive		clide with a photon energy less
35.300	Parenteral administration of any other rad	ionuclide for which a written dire	ective is required
		NG AND EXPERIENCE three methods below)	
of applicat experience	nd Experience, including board certification, tion or the individual must have related conti e was completed. Provide dates, duration, a s checked above.	inuing education and experience	e since the required training and l
✓ 1. Board	<u>Certification</u>		
a. Provid	e a copy of the board certification.		
b. For 35 be use	.390, provide documentation on supervised ed to document this experience.	clinical case experience. The t	able in section 3.c. may
and su	.396, provide documentation on classroom apervised clinical case experience. The tablement this experience.		
d. Skip to	and complete Part II Preceptor Attestation.		
	t 35.300, 35.400, or 35.600 Authorized Us		ization
a. Authori	zed User on Materials License $$ $085-1296-01$ (	(WI) unde	er the requirements below or
equiva	lent Agreement State requirements (check a	all that apply):	
35.	.390 35.392 35.394	35.490 35.69	0
require	ently authorized for a subset of clinical uses ed supervised case experience. The table in ence. Also provide completed Part II Precep	section 3.c. may be used to do	
docum clinical	ently authorized under 35.490 or 35.690 and entation on classroom and laboratory training case experience. The tables in sections 3. ence. Also provide completed Part II Preceptors	ng, supervised work experience, a., 3.b., and 3.c. may be used to	, and supervised

FORM 313A (AUT) ) AUTHORIZED USER TRAINI	ING AND EXPERIENCE AND PRECER	U.S. NUCLEAR REGULA	
3. <u>Training and Experience for F</u>			
a. Classroom and Laboratory Trai		35.394	35.396
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			
Radiation biology			
-	Total Hours of Training:		
<ul> <li>b. Supervised Work Experience         If more than one supervising incomplete of this page.     </li> <li>Supervised Work Experience</li> </ul>	35.390 35.392  idividual is necessary to document supe	ervised training, provide m	35.396 nultiple copies
Supervised from Experience	Total Ho Experie		
Description of Experience Must Include:	Location of Experience/License Permit Number of Facility	e 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	
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	
		Yes	

Training and Experience for P	roposed Authorized	<u>User</u> (continued)	
b. Supervised Work Experience	(continued)		
Supervising Individual		License/Permit Number listing supervising indi authorized user	vidual as an
Supervising individual meets the apply)**:	e requirements below,	or equivalent Agreement State requirements	(check all tha
35.390 With experience a	administering dosages	s of:	******
35,392 Oral Nal-131 gigabecquere	requiring a written dire Is (33 millicuries)	ective in quantities less than or equal to 1.22	
	in quantities greater t	han 1.22 gigabecquerels (33 millicuries)	
Parenteral ad	ministration of beta-en nan 150 keV requiring	mitter, or photon-emitting radionuclide with a p a written directive is required	photon
Parenteral ad	ministration of any oth	ner radionuclide requiring a written directive	
** Supervising Authorized User must he requesting authorized user status	ave experience in administe	ering dosages in the same dosage category or categories	as the individual
questing demanded deer character			
multiple copies of this page.  Description of Experience	Number of Cases Involving Personal Participation	ry to document supervised work experience, p  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 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 than 150 keV for which a written directive is required			
Parenteral administration of any other radionuclide for which a written directive is required		7/	
(List radionuclides)			

NRC FORM 313A (AUT)	U.S. NUCLEAR REGULATORY COMMISSION
(3-2009) AUTHORIZED USER TRAINING AND E	EXPERIENCE AND PRECEPTOR ATTESTATION (continued)
3. Training and Experience for Proposed Au	thorized User (continued)
c. Supervised Clinical Case Experience (co	ntinued)
Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Supervising individual meets the requirement apply)**:	ts below, or equivalent Agreement State requirements (check all that
35,390 With experience administering	dosages of:
35.392 Oral Nal-131 requiring a w gigabecquerels (33 millicut	ritten directive in quantities less than or equal to 1.22 ries)
The second secon	greater than 1.22 gigabecquerels (33 millicuries)
Parenteral administration of	of beta-emitter, or photon-emitting radionuclide with a photon requiring a written directive is required
Parenteral administration of	of any other radionuclide requiring a written directive
<ul> <li>Supervising Authorized User must have experience requesting authorized user status.</li> </ul>	in administering dosages in the same dosage category or categories as the individual
d. Provide completed Part II Preceptor Attes	tation.
PART II -	PRECEPTOR ATTESTATION
individual as long as the preceptor provide	dual's preceptor. The preceptor does not have to be the supervising es, directs, or verifies training and experience required. If more than experience, obtain a separate preceptor statement from each.
By checking the boxes below, the preceptor position sought and not attesting to the inc	or is attesting that the individual has knowledge to fulfill the duties of the lividual's "general clinical competency."
First Section Check one of the following for each requested	authorization:
For 35.390:	
Board Certification	
I attest that Harry W. S	
requirements in 35.390(a)(1).	
	OR

Train	ing a	nd Exp	perience

attest that

Hurry W. Skya
Name of Proposed Authorized User

has satisfactorily completed the 700 hours of training

and experience, including a minimum of 200 hours of classroom and laboratory training, as required by  $10\ \text{CFR}\ 35.390\ (b)(1)$ .

NRC FORM 313A (AUT)		U.S. NUCLEAR REGULATORY COMMISSION
AUTHORIZED U	SER TRAINING AND EXPERIEN	CE AND PRECEPTOR ATTESTATION (continued)
Preceptor Attestation (c	continued)	
First Section (continu	ued)	
For 35.392 (Identical	Attestation Statement Regardle	ss of Training and Experience Pathway):
I attest that	Name of Proposed Authorized User	has satisfactorily completed the 80 hours of classroom
	raining, as required by 10 CFR 35. uired in 35.392(c)(2).	392(c)(1), and the supervised work and clinical case
For 35.394 (Identical	Attestation Statement Regardles	ss of Training and Experience Pathway):
I attest that	Name of Proposed Authorized User	has satisfactorily completed the 80 hours of classroom
and laboratory to experience requ	raining, as required by 10 CFR 35. uired in 35.394(c)(2).	394 (c)(1), and the supervised work and clinical case
Second Section		
I attest that		has satisfactorily completed the required clinical case
	Name of Proposed Authorized User	
experience requ	ired in 35.390(b)(1)(ii)G listed belo	w:
	requiring a written directive in qua els (33 millicuries)	antities less than or equal to 1.22
Oral Nal-131	in quantities greater than 1.22 gig	abecquerels (33 millicuries)
	dministration of beta-emitter, or phothan 150 keV requiring a written dir	oton-emitting radionuclide with a photon rective is required
Parenteral ad	dministration of any other radionuc	lide requiring a written directive
Third Section		
I attest that		has satisfactorily achieved a level of competency to
	Name of Proposed Authorized User	
function indepen	ndently as an authorized user for:	
	requiring a written directive in qua els (33 millicuries)	intities less than or equal to 1.22
Oral Nal-131	in quantities greater than 1.22 gig	abecquerels (33 millicuries)
	dministration of beta-emitter, or pho han 150 keV requiring a written dir	oton-emitting radionuclide with a photon rective is required
Parenteral ac	dministration of any other radionucl	lide requiring a written directive

Parenteral adminstration of any other radionuclide for which a written directive is required
Fifth Section Complete the following for preceptor attestation and signature:
I meet the requirements 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
Parenteral administration of any other radionuclide requiring a written directive
Iame of Preceptor  Di. Danna Catal Do MD  Signature  906-932-62/1 April 6-2  icense/Permit Number/Facility Name



### STATE OF WISCONSIN DEPARTMENT OF HEALTH SERVICES

### RADIOACTIVE MATERIALS LICENSE

Under s.254.365, Wisconsin Statutes and Chapter DHS 157, Wisconsin Administrative Code, and in reliance on statements and representations made by the licensee, a license is issued authorizing the licensee to receive, acquire, possess and transfer radioactive material designated below; to use the material for the purpose(s) and at the place(s) designated below; and to deliver or transfer the material to persons authorized to receive it in accordance with Chapter DHS 157, Wisconsin Administrative Code. This license is subject to all applicable rules and orders of the Wisconsin Department of Health Services (DHS) including Chapter DHS 157, Wisconsin Administrative Code now or hereafter in effect, and to any conditions specified below.

Licensee Name and Address  1. St. Mary's Hospital - Rhinelander  2. 2251 North Shore Drive, Suite 100 Rhinelander, WI 54501		3. License Number: 08:  is renewed in its entirety t  4. Amendment No.: 06	is renewed in its entirety to read as follows:  4. Amendment No.: 06		
Kilmerander, W	34301	or Expiration Date. [VIa	y 31, 2014		
6. Radioactive material:	7. Chemical and/or physical form:	Maximum amount of radioactive materials that the licensee may possess at any one time under this license:	9. Authorized Use:		
A. Any radioactive material permitted by DHS 157.63(1)	A. Any radiopharmaceutical permitted by DHS 157.63(1)	A. As needed	A. Any uptake, dilution and excretion procedure permitted by DHS 157.63(1).		
B. Any radioactive material permitted by DHS 157,63(2)	B. Any radiopharmaceutical permitted by DHS 157.63(2)	B. As needed	B. Any imaging and localization procedure permitted by DHS 157.63(2).		
C. Any radioactive material permitted by DHS 157.64(1)	C. Any radiopharmaceutical permitted by DHS 157.64(1)	C. As needed (not to exceed 1.0 curie of iodine-131)	C. Any diagnostic study or radiopharmaceutical therapy procedure permitted by DHS 157.64(1).		
D. Any radioactive material permitted by DHS 157.65(1)	D. Any brachytherapy source permitted by DHS 157.65(1)	D. 1 Curie	D. Any brachytherapy procedure permitted by DHS 157.65(1).		

### RADIOACTIVE MATERIALS LICENSE

SUPPLEMENTARY SHEET

License Number: 085-1296-01

Amendment No:

06

### CONDITIONS

- 10. Licensed material may only be used or stored at the licensee's facilities located at 2251 North Shore Drive, Rhinelander.
- The Radiation Safety Officer for this license is Gary Douglas, M.S.
- Licensed material is only authorized for use by, or under the supervision of:
  - A. Individuals permitted to work as an authorized user in accordance with DHS 157.13(5)(b) and DHS 157.13(5)(c).
  - B. The following individuals are authorized users for medical use as indicated:

Authorized Users	Material and Use
Steven R. Brown, M.D.	DHS 157.63(1), DHS 157.63(2) and DHS 157.64(1).
David P. Cattau, M.D.	DHS 157.65(1).
Sue Hausserman-Dugan, M.D.	DHS 157.63(1), DHS 157.63(2) and DHS 157.64(1).
Theodore J. Shinners, M.D.	DHS 157.63(1), DHS 157.63(2) and DHS 157.64(1) (limited to oral administration of l-131 sodium iodide).
Harry W. Skye, M.D.	DHS 157.63(1), DHS 157.63(2) and DHS 157.64(1).

- 13. The licensee is authorized to transport licensed material in accordance with the provisions of Chapter DHS 157, 'Radiation Protection', Subchapter XIII, 'Transportation'.
- In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in DHS 157.15 for establishing decommissioning financial assurance.
- 15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in DHS 157.61. Chapter DHS 157, 'Radiation Protection' shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the rule.
  - A. Application with attachments dated May 1, 2009 and signed by William Erickson.
  - B. Letter, with attachments, dated August 24, 2009 and signed by Gary Douglas.
  - C. Letter, with attachments, dated December 1, 2009 and signed by Gary Douglas.

FOR THE WISCONSIN DEPARTMENT OF HEALTH SERVICES

Rogers

SIGNATURE

Materials Program Supervisor

12/11/109

# The American Board of Radiology

\*\* Organized through the cooperation of the American College of Radiology, the American Roentgen Ray Society, the American Rociety of North America, \*\* In Section on Radiology of the American Medical Association and the American Society of Therapeutic Radiologists

\*\*Hereby certifies that\*\*

# Harry William Skye, M.A.

Has pursued an accepted course of graduate study and clinical work, has met certain standards and qualifications and has passed the examinations conducted under the authority of The American Board of Radiology

On this third day of June, 1983

Thereby demonstrating to the satisfaction of the Board that he is qualified to practice the specialty of

AMERICAN BOARD

STATE OF MICHIGAN - DEPARTMENT OF COMMUNITY HEALTH

BOARD OF MEDICINE **PHYSICIAN** LICENSE

HARRY WILLIAM SKYE MD P 0 B0X 357 IRONWOOD MT **49938** 

PERMANENTID NO

EXPIRATION DATE

4307063065 07/37/5073 2524945

### COMPLAINT INFORMATION:

The issuance of this license should not be construed as a waiver, dismissal or acquiescense to any complaints or violations pending against the licensee, its agents or employees.

### WALL CERTIFICATE INFORMATION:

If the box is checked, you may purchase a State of Michigan Official Wall Certificate. Please visit http://tbsddp.com/certificates or call

1-800-875-3676

### **FUTURE CONTACTS:**

You should direct all inquires regarding this license or address changes to the:

### DEPARTMENT OF COMMUNITY HEALTH

BOARD OF MEDICINE

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE. REVERSE SIDE OF LICENSE CONTAINS IMPORTANT INFORMATION.

P.O. BOX 30670 LANSING MI 48909-8170

■ 1年 2000 安全 ▲ 12-2010年 1200年 - ▲ 1 JENNIFER M. GRANHOLM GOVERNOR

THE REPORT OF THE PROPERTY AND A SECOND CONTRACT OF THE PROPERTY OF THE PROPER STATE OF MICHIGAN L1669804 DEPARTMENT OF COMMUNITY HEALTH

BOARD OF MEDICINE

PHYSICIAN **LICENSE** 

HARRY WILLIAM SKYE MD

PEPMANENT LD. NO

EXPIRATION DATE

4307063065

07/37/5073 

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

DCHIPLD-300 (4,07)

Grand View Health System NIO 561 Grand View Lane Ironwood, MI 49938





