U. S. Nuclear Regulatory Commission Materials Licensing Section 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

Dear Sir or Madam:

Deaconess Hospital would like to amend its Byproduct Materials License, Number 13-00142-02, to add Pavel Morozov, M.D. as an Authorized User of materials licensed under 10 CFR 35.100, 35.200, 35.392, and 35.394. Dr. Morozov is certified by the American Board of Radiology with the AU Eligible designation. A copy of his certification and Indiana medical license as well as NRC Forms 313A(AUD) and 313A(AUT) are enclosed.

In addition, we request the removal of Mark Graves, M.D. from the license. Dr. Graves has discontinued practice at our facility.

Should there be any questions concerning this license amendment request, please contact our nuclear medicine physicist, Mr. Patrick Byrne, DABR, CHP, DABSNM, at 1-877-317-5811.

Sincerely,

Carrie Morton, PharmD, MBA

Korton

Director of Radiology

U. S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 01/31/2023



AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION

(for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396]

ame of Proposed Authorized User State or Territory Where Licensed					
Pavel Morozov, M.D. Indiana					
Requested Authorization(s) (check all that apply):					
35.300 Use of u	35.300 Use of unsealed byproduct material for which a written directive is required				
OR					
	35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)				
	300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)				
electron	ral administration of any radioactive emission, beta radiation character han 150 keV, for which a written di	e drug that contains a radionuclide that is primarily used for its istics, alpha radiation characteristics, or photon energy rective is required.			
		AINING AND EXPERIENCE The three methods below)			
date of application of training and experie	ience, including board certification, or the individual must have related	must have been obtained within the 7 years preceding the continuing education and experience since the required es, duration, and description of continuing education and			
✓ 1. <u>Board Certifica</u>	tion				
a. Provide a copy	of the board certification.				
 For 35.390, provide documentation on supervised case experience. The table in section 3.c. may be used to document this experience. 					
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. Skip to and complete Part II Preceptor Attestation.					
d. For a board cer following:	d. For a board certification issued on or before October 24, 2005 that is listed in 10 CFR 35.57(b)(2)(ii), provide the following:				
(i) Documentation that the individual performed each use checked above on or before October 24, 2005.					
(ii) Dates, duration, and description of continuing education and experience within the past seven years for each use checked above.					
e. Stop here.					
2. Current 35.300,	, 35.400, or 35.600 Authorized Us	ser Seeking Additional Authorization			
	on Materials License	under the requirements below or			
equivalent Agre	eement State requirements (check	all that apply):			
35.390	35.392 35.394	35.490 35.690			
supervised case	e experience. The table in section are a copy of the certificate and stop	under 35.300, provide documentation on additional required 3.c. may be used to document this experience. If board here. If not board certified then provide completed Part II			

c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation. 3. Training and Experience for Proposed Authorized User a. Classroom and Laboratory Training 35.390 35.392 35.394 35.396 Clock Dates of Description of Training Location of Training Training* Hours 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:** 35.390 35.392 35.394 35.396 b. Supervised Work Experience (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.) Supervised Work Experience Total Hours of Experience: Location of Experience/License or Dates of Description of Experience Confirm Experience* Must Include: Permit Number of Facility Ordering, receiving, and Yes unpacking radioactive materials safely and performing the Nο related radiation surveys Performing quality control procedures on instruments Yes used to determine the activity of dosages and performing No checks for proper operation of survey meters Calculating, measuring, and Yes safely preparing patient or human research subject No dosages Using administrative controls to Yes prevent a medical event involving the use of unsealed No byproduct material Using procedures to contain Yes spilled byproduct material safely and using proper No decontamination procedures

. <u>Training</u>	Training and Experience for Proposed Authorized User (continued)				
o. Supervis	ed Work Experience	(continued)			
Supervising Individual			License/Permit Number listing supervising individual as an authorized user		
	g individual meets the	requirements below,	or equivalent Agreement State requirements		
· 		administering decage			
35.390 35.392	Oral Nal-131	With 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	! — •	•	than 1.22 gigabecquerels (33 millicuries)		
35.396 35.57	Parenteral administration of any radioactive drug that contains a radionuclide that is primarily				
	g Authorized User must ha requesting authorized user		ering dosages in the same dosage category or categories	as the	
	sed Clinical Case Exp				
•	•		ıment supervised work experience, provide multiple	copies of	
Descript	ion of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*	
iodide I-131 directive in	istration of sodium 1 requiring a written quantities less than 1.22 gigabecquerels ies)				
iodide I-13° directive in	istration of sodium 1 requiring a written quantities greater igabecquerels (33				
any radioad contains a primarily us emission, k characteris characteris energy of le	administration of ctive drug that radionuclide that is sed for its electron octa radiation stics, alpha radiation stics, or photon ess than 150 keV, written directive is				

3. Training and Experience for Proposed Autl	norized User (continued)				
c. Supervised Clinical Case Experience (continu	ued)				
Supervising Individual	License/Permit Number listing supervising individual as an authorized user				
Supervising individual meets the requirements below.	or equivalent Agreement State requirements (check all that apply)**:				
☐ 35.390 With experience administering dosages of: ☐ 35.392 ☐ Oral Nal-131 requiring a written directive in quantities less than or equal to 1.22 ☐ gigabecquerels (33 millicuries)					
	ater than 1.22 gigabecquerels (33 millicuries)				
used for its electron emission,	Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or				
** Supervising Authorized User must have experience as the individual requesting authorized user status.	e in administering dosages in the same dosage category or categories				
d. Provide completed Part II Preceptor Attestation	on.				
PART II –	PRECEPTOR ATTESTATION				
individual as long as the preceptor provide	ual's preceptor. The preceptor does not have to be the supervising s, 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	or is not attesting to the individual's "general clinical competency."				
First Section Check one of the following for the requested au	ithorization:				
For 35.390:					
I attest that	has satisfactorily completed the 700 hours of training				
Name of Proposed Authorized User and experience, including a minimum of 200 10 CFR 35.390 (b)(1).	hours of classroom and laboratory training, as required by				
For 35.392:					
I attest that Name of Proposed Authorized	has satisfactorily completed the 80 hours of classroom				
and laboratory training, as required by 10 experience required in 35.392(c)(2).	CFR 35.392(c)(1), and the supervised work and clinical case				
For 35.394:					
I attest that	has satisfactorily completed the 80 hours of classroom				
Name of Proposed Authorized and laboratory training, as required by 10 experience required in 35.394(c)(2).	CFR 35.394 (c)(1), and the supervised work and clinical case				

-

Board Certification:

has satisfactorily completed the board certification

Name of Proposed Authorized User

photon energy of less than 150 keV, for which a written directive is required.

OR

requirements of 35.396(a)(3), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (b)(1) and the supervised work and clinical case experience required by 35.396(b)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user under 10 CFR 35.300 for:

Fifth Section					
Complete one of the following for the attestation and signature:					
Authorized User					
☐ I meet the requirements below, or equivalent Agreement State re	quirements	, as an authorized user	for:		
☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396	35	.57 for 35.300 uses			
I have experience administering dosages in the following categor requesting authorization:	ies for whic	ch the proposed Authori	zed User is		
Oral Nal-131 requiring a written directive in quantities less that (33 millicuries)	an or equal	to 1.22 gigabecquerels			
Oral Nal-131 in quantities greater than 1.22 gigabecquerels (33 millicurie	es)			
Parenteral administration of any radioactive drug that contain used for its electron emission, beta radiation characteristics, a photon energy of less than 150 keV, for which a written direct	alpha radia	tion characteristics, or			
OR					
Residency Program Director:					
I affirm that the attestation represents the consensus of the resi faculty member is an authorized user who meets the requireme requirements:	dency prog nts below o	ram faculty where at lear r equivalent Agreement	ast one t State		
☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.39	6 🗌 3	35.57 for 35.300 uses			
I affirm that this facility member has experience in administering categories for which the individual is requesting authorized used am providing as program director.	g dosages i r status and	n the same dosage cate I concurs with the attest	egory or tation I		
I affirm that the residency training program is approved by the:	I affirm that the residency training program is approved by the:				
Residency Review Committee of the Accreditation Council	Residency Review Committee of the Accreditation Council for Graduate Medical Education				
Royal College of Physicians and Surgeons of Canada					
Council on Post-Graduate Training of the American Osteopathic Association					
I affirm that the residency training program includes training and experience specified in:					
☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.39	6				
Name of Equility	License/Peri	mit Numher			
Name of Facility:	LICENSE/FEH	increambo.			
Name of Preceptor or Residency Program Director (Typed or Printed)		Telephone Number	Date		
Signature					



Indiana Professional Licensing Agency Medical Licensing Board of Indiana 402 W. Washington Street, W072 Indianapolis, IN 46204

Physician

License Number	Expire Date
01081812A	10/31/2021

Pavel P. Morozov

Eric J. Holcomb Governor State of Indiana Deborah J. Frye Executive Director Indiana Professional Licensing Agency



Indiana Professional Licensing Agency 402 W. Washington Street, W072 Indianapolis, IN 46204

Physician

License Number	Expire Date
01081812A	10/31/2021

Pavel P. Morozov

Signature

The American Board of Radiology hereby certifies that

Pavel Morozov, MD

has pursued an accepted course of graduate study and clinical work; has met certain standards and qualifications, including passing the examinations conducted under the authority of The American Board of Radiology, demonstrating to the satisfaction of the Board qualification to practice; and is therefore awarded the Board's certification in

Diagnostic Radiology

AU Eligible



Ongoing validity of this certificate is contingent upon meeting the requirements of Continuous Certification.

Bl. Lagra-

Polich My Jan 1900 Secretary Treasurer

Valeni B. Julionwas

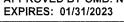
Executive Director

DABR



Effective: September 27, 2019

APPROVED BY OMB: NO. 3150-0120





AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.57, 35.190, 35.290, and 35.590]

ame of Proposed Authorized User State or Territory Where Licensed					
Pavel Morozov, M.D. Indiana					
equested Authorization(s) (check all that a	apply)				
35.100 Uptake, dilution, and excretion s	studies 🗸 35	5.200 Imaging and I	ocalization	studies	
35.500 Sealed sources for diagnosis (sp	oecify device)				
		G AND EXPERIEN			
'		three methods be	•		
Training and Experience, including board application or the individual must have obtained experience was completed. Provide related to the uses checked above.	otained related c	ontinuing educatior	n and exper	ience since th	e required training
/ 1. Board Certification					
a. Provide a copy of the board certifica	ition.				
b. For a board certification issued on o the following:	r before Octobe	r 24, 2005 that is lis	sted in 10 C	FR 35.57(b)(2	?)(i), provide
(i) Documentation that the individ	lual performed e	each use checked a	bove on or	before Octobe	er 24, 2005.
(ii) Dates, duration, and descriptioneach use checked above.c. Stop here.	on of continuing	education and expe	erience with	nin the past se	ven years for
2. Current 35.390 Authorized User S	eeking Additio	nal 35.290 Authori	zation		
a. Authorized user on Materials Licens	se	meeting 1	0 CFR 35.	390, 10 CFR 3	5.57 for 35.300
uses, or equivalent Agreement Stat		seeking authorizati	on for 35.29	90.	
b. Supervised Work Experience.					
(If more than one supervising indivi- copies of this section.)	idual is necessa	ry to document sup	ervised wo	rk experience,	provide multiple
Description of Experience		of Experience/Licentit Number of Facilit		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					
1	Total Hours	s of Experience:			
Supervising Individual		License/Permit No authorized user o			
Supervisor meets the requirements be					
35.290 35.390 + generatorc. If board certified, provide a copy of Part II Preceptor Attestation.	•		35.55 t board cerf	_	for 35.200 uses nd complete

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.57, 35.190, 35.290, and 35.590](continued)

Training and Experience for Property 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 (not required for 35.590)			
Radiation biology			
	Total Hours of Training:		
	pletion of this table is not required for 35.590). idual is necessary to document supervised wor ion.)	k 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	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		Yes No	

(01-2020)

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.57, 35.190, 35.290, and 35.590](continued)

Description of Experience		Experience/License	or	Confirm	Dates of
Must Include:	Permit	Number of Facility			Experience
Calculating, measuring, and safely				Yes	
reparing patient or human researd ubject dosages	ch			☐ No	
Ising administrative controls to				Yes	
revent a medical event involving to se of unsealed byproduct material	l .			☐ No	
Ising procedures to contain spilled				Yes	
yproduct material safely and using roper decontamination procedures				☐ No	
dministering dosages of radioactive				Yes	
rugs to patients or human researd ubjects	h			☐ No	
luting generator systems appropri	ate			☐ Yes	
or the preparation of radioactive rugs for imaging and localization					
tudies, measuring and testing the				☐ No*	
luate for radionuclidic purity, and					
rocessing the eluate with reagent its to prepare labeled radioactive					
rugs					
upervising Individual		License/Permit Numbe authorized user or an a training			
		A 1 Ot-1-		(-11	
Supervisor meets the requirements	·	-			
And the second s	.390	enerator expenence i	11 33.290(0)(1)(1)(G)	
35.55 35.57 for 35.200					
Not required for 10 CFR 35.100 u		se of the device.			
For 35.590 only, provide documer			Loc	ation and Da	ites
For 35.590 only, provide document	Type of Traini	ng			
	Type of Traini	ng			
	Type of Traini	ng			
	Type of Traini	ng			
	Type of Traini	ng			

(01-2020)

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.57, 35.190, 35.290, and 35.590](continued)

[10 CFR 35.57, 35.190, 35.290,				
PART II – PRECEPTOR ATT	FESTATION			
Note: This part must be completed by the individual's preceptor. The individual as long as the preceptor provides, directs, or verifice one preceptor is necessary to document experience, obtain a required to meet training requirements in 35.590) By checking the boxes below, the preceptor is not attesting to	es training and experience required. If more than a separate preceptor statement from each. (Not			
First Section				
Check one of the following for each use requested: For 35.190				
I attest that Name of Proposed Authorized User Name of Proposed Authorized User	rily completed the 60 hours of training and			
experience, including a minimum of 8 hours of classroom and la and is able to independently fulfill the radiation safety-related du authorized under 10 CFR 35.100.				
For 35.290				
I attest that Name of Proposed Authorized User Name of Proposed Authorized User	rily completed the 700 hours of training			
and experience, including a minimum of 80 hours of classroom 35.290(c)(1), and is able to independently fulfill the radiation sa medical uses under 10 CFR 35.100 and 35.200.				
Second Section				
Complete one of the following for attestation and signature:				
Authorized User:				
I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:				
35.190 35.290 35.390 35.390 + generato	or experience 35.57 for 35.200 uses			
Residency Program Director:				
I affirm that the attestation represents the consensus of the res faculty member is an authorized user who meets the requirements for: 35.190 35.290 35.390 35.390 4 generated	ents below or equivalent Agreement State			
I affirm that this facility member concurs with the attestation I am	r providing as program director.			
I affirm that the residency training program is approved by the:				
Residency Review Committee of the Accreditation Council for Graduate Medical Education				
Royal College of Physicians and Surgeons of Canada				
Council on Post-Graduate Training of the American Osteopa	athic Association			
I affirm that the residency training program includes training and	l experience specified in:			
35.190 35.290				
Name of Facility:	License/Permit Number:			
Name of Preceptor or Residency Program Director (Typed or Printed)	Telephone Number Date			
Signature				
Digitature				

Song, Taehoon

From: Tomczak, Tammy

Sent:Wednesday, April 15, 2020 1:01 PMTo:Song, Taehoon; Pavon, SandySubject:FW: amendment request

Attachments: NRC ammendment 4-13-20.pdf

Good afternoon, Tae and Sandy 😂

Can you please add the attached to ADAMS?

Thank you, Tammy

From: Cameron Turpin < Cameron. Turpin@deaconess.com>

Sent: Wednesday, April 15, 2020 12:52 PM

To: Tomczak, Tammy <Tammy.Tomczak@nrc.gov> **Subject:** [External_Sender] amendment request

Good afternoon,

Please see the attached amendment request to our NRC license.

Thank you,

Cameron Turpin RT(R)(N), CNMT Nuclear Medicine Team Leader Deaconess Midtown and Deaconess Gateway Hospital

Office: (812) 450-7201

Department: (812) 450-3330

Cell: (618) 262-6439