From: Ronald Frick
To: Alldredge, Casey

Subject: [External_Sender] Wilcox Memorial Hospital amendment

Date: Wednesday, July 15, 2020 5:04:00 PM

Attachments: 313(aud) srinivasan.pdf 313 aut srinivasan.pdf

Hi Casey,

Attached are forms 313A(AUD) and 313A(AUT) which you requested for Dr. Srinivasan. Let me know if you need anything else.

Ron Frick

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



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]

Name of Proposed Authorized User		State or Territory Where Licensed		
Ramya Srinivasan, M.D.		Hawaii		
Requested Authorization(s) (check all that	apply)			
\checkmark 35.100 Uptake, dilution, and excretion s	studies 🗸 35	.200 Imaging and localization s	tudies	
35.500 Sealed sources for diagnosis (s	pecify device)			
		G AND EXPERIENCE three methods below)		
* Training and Experience, including board application or the individual must have of and experience was completed. Provide related to the uses checked above.	btained related co	ontinuing education and experie	ence since the	e required training
1. Board Certification	-4: - ·-			
a. Provide a copy of the board certification.b. For a board certification issued on comparison.		: 24, 2005 that is listed in 10 CE	D 25 57/b\/2	Vi) provido
the following:	n belore October	24, 2003 that is listed in 10 CF	N 33.37 (b)(2)(i), provide
(i) Documentation that the individ	dual performed e	ach use checked above on or b	efore Octobe	er 24, 2005.
(ii) Dates, duration, and descriptioneach use checked above.c. Stop here.	on of continuing o	education and experience withir	n the past sev	en years for
2. Current 35.390 Authorized User S	Seeking Addition	nal 35.290 Authorization		
a. Authorized user on Materials Licen	se	meeting 10 CFR 35.39	90, 10 CFR 3	5.57 for 35.300
uses, or equivalent Agreement Sta	te requirements :	seeking authorization for 35.290).	
 b. Supervised Work Experience. (If more than one supervising indivopies of this section.) 	ridual is necessai	ry to document supervised work	c experience,	provide multiple
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:		
Supervising Individual		License/Permit Number listing s authorized user or authorized no		
Supervisor meets the requirements be 35.290 35.390 + generator c. If board certified, provide a copy of	experience in 32	.290(c)(1)(ii)(G) 35.55	35.57 f	or 35.200 uses

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)

3. Training and Experience for Prop	oosed Authorized User		
a. Classroom and Laboratory Trainir			
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:		
	npletion of this table is not required for 35.590). vidual is necessary to document supervised work tion.)	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 No	
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)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience			,		
Description of Experience Must Include:	e l	ocation of Experience/ Permit Number of F		Confirm	Dates of Experience*
Calculating, measuring, and sat preparing patient or human rese subject dosages				☐ Yes	
Using administrative controls to prevent a medical event involvinuse of unsealed byproduct materials	ng the			☐ Yes	
Using procedures to contain spi byproduct material safely and u proper decontamination proced	sing			☐ Yes	
Administering dosages of radio drugs to patients or human resessiblects				Yes No	
Eluting generator systems approfor the preparation of radioactive drugs for imaging and localization studies, measuring and testing eluate for radionuclidic purity, a processing the eluate with reagakits to prepare labeled radioactive drugs	e on the nd ent			☐ Yes ☐ No*	
Supervising Individual License/Permit Number listing supervising individual as an authorized user or an authorized nuclear pharmacist for generator training					
Supervisor meets the requirement 35.190 35.290 35.57 for 35. *Not required for 10 CFR 35.10	35.390	equivalent Agreement S 5.390 + generator expe			
c. For 35.590 only, provide docu					
Device	Туре	of Training	Loc	cation and Da	tes
d For 35 500 uses only stop h	F 05 40	0		Double Door	4 44

(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)

PART II - PRECEPTOR ATTESTATION

This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising Note: 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)

By checking the boxes below, the preceptor is not attesting	g to the individua	al's "general clinical	competency."		
First Section Check one of the following for each use requested: For 35.190					
I attest that has satisfa	ctorily completed	the 60 hours of tra	ining and		
Name of Proposed Authorized User experience, including a minimum of 8 hours of classroom at and is able to independently fulfill the radiation safety-relate authorized under 10 CFR 35.100.					
<u>For 35.290</u>					
I attest that Name of Proposed Authorized User has satisfa	ctorily completed	the 700 hours of to	raining		
and experience, including a minimum of 80 hours of classro 35.290(c)(1), and is able to independently fulfill the radiation 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 St 35.190 35.290 35.390 35.390 35.390 + gene	ate requirements rator experience	, as an authorized			
Residency Program Director:					
I affirm that the attestation represents the consensus of the faculty member is an authorized user who meets the requirements for:					
35.190 35.290 35.390 35.390 35.390 + gene	rator experience	35.57 for 35	.200 uses		
I affirm that this facility member concurs with the attestation I	am providing as	program director.			
I affirm that the residency training program is approved by the	e:				
Residency Review Committee of the Accreditation Council	il for Graduate M	ledical 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 a 35.190 35.290	and experience s	pecified in:			
Name of Facility:	License/Permit N	lumber:			
Name of Preceptor or Residency Program Director (Typed or Printed)	•	Telephone Number	Date		
Signature		ı			

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]

Name of Proposed Authorized User	State or Territory Where Licensed					
nya Srinivasan, M.D. Hawaii						
Requested Authorization(s) (check all that apply):						
35.300 Use of unsealed byproduct material for which	h a written directive is required					
OR						
35.300 Oral administration of sodium iodide I-131 re 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 regigabecquerels (33 millicuries)	equiring a written directive in quantities greater than 1.22					
	drug that contains a radionuclide that is primarily used for its tics, alpha radiation characteristics, or photon energy ctive is required.					
	NING AND EXPERIENCE he three methods below)					
* Training and Experience, including board certification, r date of application or the individual must have related c training and experience was completed. Provide dates experience related to the uses checked above.	ontinuing education and experience since the required					
✓ 1. Board Certification						
a. Provide a copy of the board certification.						
 For 35.390, provide documentation on supervised of document this experience. 	ase experience. The table in section 3.c. may be used to					
	nd laboratory training, supervised work experience, and sections 3.a., 3.b., and 3.c. may be used to document this Attestation.					
 d. For a board certification issued on or before Octobe following: 	r 24, 2005 that is listed in 10 CFR 35.57(b)(2)(ii), provide the					
(i) Documentation that the individual performed ea	ach use checked above on or before October 24, 2005.					
(ii) Dates, duration, and description of continuing e each use checked above.	education and experience within the past seven years for					
e. Stop here.						
2. Current 35.300, 35.400, or 35.600 Authorized Use	r Seeking Additional Authorization					
a. Authorized User on Materials License	under the requirements below or					
equivalent Agreement State requirements (check al	I that apply):					
35.390 35.392 35.394	35.490 35.690					
supervised case experience. The table in section 3.	nder 35.300, provide documentation on additional required c. may be used to document this experience. If board ere. If not board certified then provide completed Part II					

c. If currently authorized under 38 classroom and laboratory training in sections 3.a., 3.b., and 3.c. ma Attestation.	g, supervised work ex ay be used to docume	xperience, and super ent this experience.	rvised clinica	al case experi	ence. The tables
 3. <u>Training and Experience fo</u> a. Classroom and Laboratory Tr 		ized User 35.392	35.3	394	35.396
Description of Training		ation of Training		Clock Hours	Dates of Training*
Radiation physics and instrumentation				Tiodio	Training
Radiation protection					
Mathematics pertaining to the use and measurement of radioactivity					
Chemistry of byproduct material for medical use					
Radiation biology					
	Total Hours of Tra	aining:			
b. Supervised Work Experience (If more than one supervising individ Supervised Wo Description of Experience	ork Experience	·	urs of Expe	multiple copies	35.396 of this page.)
Must Include:		Number of Facility	OI	Confirm	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 No	
Calculating, measuring, and safely preparing patient or human research subject dosages				Yes No	
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	

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			
Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**:						
35.390	With experience	administering dosage	es of:			
35.392	Oral Nal-131		rective in quantities less than or equal to 1.22			
35.394		•	than 1.22 gigabecquerels (33 millicuries)			
35.396			dioactive drug that contains a radionuclide tha			
35.57			a radiation characteristics, alpha radiation char keV, for which a written directive is required.	acteristics,		
	Authorized User must ha uesting authorized user		ering dosages in the same dosage category or categories	as the		
c. Supervised	d Clinical Case Exp	perience				
If more than on this page.	ne supervising individ	ual is necessary to docu	ment supervised work experience, provide multiple	copies of		
Description	Description of Experience Number of Cases Involving Personal Participation Location of Experience/License or Permit Number of Facility Dates of Experience*					
iodide I-131 re directive in qu	ration of sodium equiring a written antities less than 22 gigabecquerels					
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)						
any radioactive contains a radioactive contains a radioactive emission, between characteristics energy of less	dionuclide that is differ its electron a radiation s, alpha radiation					

3. Training and	d Experience for Proposed Authorize	ed User (continued)		
c. Supervised (Clinical Case Experience (continued)			
Supervising Indiv	idual	License/Permit Number listing supervising individual as an authorized user		
Supervising indiv	idual meets the requirements below, or equ	uivalent Agreement State requirements (check all that apply)**:		
35.390 V	Vith experience administering dosages	s of:		
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 th	nan 1.22 gigabecquerels (33 millicuries)		
35.396 35.57	used for its electron emission, beta	lioactive drug that contains a radionuclide that is primarily radiation characteristics, alpha radiation characteristics, or , for which a written directive is required.		
	uthorized User must have experience in ad al requesting authorized user status.	dministering dosages in the same dosage category or categories		
d. Provide com	pleted Part II Preceptor Attestation.			
	DART II DREG	CEPTOR ATTESTATION		
By checki		ence, obtain a separate preceptor statement from each. ot attesting to the individual's "general clinical competency." ization:		
For 35.390:				
I attest th	nat Name of Proposed Authorized User	has satisfactorily completed the 700 hours of training		
and experie 10 CFR 35.3		s of classroom and laboratory training, as required by		
For 35.392:				
I attest th	Name of Proposed Authorized User	has satisfactorily completed the 80 hours of classroom		
	ratory training, as required by 10 CFR ce required in 35.392(c)(2).	35.392(c)(1), and the supervised work and clinical case		
For 35.394:				
I attest th	nat	has satisfactorily completed the 80 hours of classroom		
	Name of Proposed Authorized User			
	ratory training, as required by 10 CFR ce required in 35.394(c)(2).	35.394 (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 require	ed in 35.390(b)(1)(ii)G listed below:
	equiring a written directive in quantities less than or equal to 1.22 s (33 millicuries)
Oral Nal-131 ir	quantities greater than 1.22 gigabecquerels (33 millicuries)
used for its elec	ninistration of any radioactive drug that contains a radionuclide that is primarily ctron emission, beta radiation characteristics, alpha radiation characteristics, or of less than 150 keV, for which a written directive is required.
Third Section	
	is able to independently fulfill the radiation safety-related
I attest that	Name of Proposed Authorized User
duties as an autho	rized user for the medical uses authorized under 10 CFR 35.300 for:
	equiring a written directive in quantities less than or equal to 1.22 s (33 millicuries)
Oral Nal-131 ir	n quantities greater than 1.22 gigabecquerels (33 millicuries)
used for its election photon energy Fourth Section For 35.396:	ninistration of any radioactive drug that contains a radionuclide that is primarily ctron emission, beta radiation characteristics, alpha radiation characteristics, or of less than 150 keV, for which a written directive is required. 35.690 authorized user:
I attest that	is an authorized user under 10 CFR 35.490 or 35.690
	Name of Proposed Authorized User
laboratory training experience require	ement State requirements, has satisfactorily completed the 80 hours of classroom and a required by 10 CFR 35.396 (b)(1), and the supervised work and clinical case and by 35.396(b)(2), and is able to independently fulfill the radiation safety-related brized user under 10 CFR 35.300 for:
used for its ele	ninistration of any radioactive drug that contains a radionuclide that is primarily ctron emission, beta radiation characteristics, alpha radiation characteristics, or of less than 150 keV, for which a written directive is required.
	OR
Board Certification	<u>'n:</u>
I attest that	has satisfactorily completed the board certification Name of Proposed Authorized User
training require	of 35.396(a)(3), has satisfactorily completed the 80 hours of classroom and laboratory and by 10 CFR 35.396 (b)(1) and the supervised work and clinical case experience required by and is able to independently fulfill the radiation safety-related duties as an authorized user 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 r	requirements	s, as an authorized usei	r for:
	35	5.57 for 35.300 uses	
I have experience administering dosages in the following categorequesting authorization:	ories for which	ch the proposed Author	ized User is
Oral Nal-131 requiring a written directive in quantities less the (33 millicuries)	nan or equal	to 1.22 gigabecquerels	;
Oral Nal-131 in quantities greater than 1.22 gigabecquerels	(33 millicuri	es)	
Parenteral administration of any radioactive drug that contains used for its electron emission, beta radiation characteristics, photon energy of less than 150 keV, for which a written direction	, alpha radia	tion characteristics, or	
OR			
Residency Program Director:			
I affirm that the attestation represents the consensus of the restaculty member is an authorized user who meets the requirements:			
☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.39	96 🔲 🤅	35.57 for 35.300 uses	
I affirm that this facility member has experience in administering categories for which the individual is requesting authorized use am providing as program director.			
I affirm that the residency training program is approved by the:			
Residency Review Committee of the Accreditation Council	l for Graduat	te Medical Education	
Royal College of Physicians and Surgeons of Canada			
Council on Post-Graduate Training of the American Osteo	pathic Assoc	ciation	
I affirm that the residency training program includes training ar	nd experienc	ce specified in:	
☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.39	96		
	I		
Name of Facility:	License/Perr	mit Number:	
Name of Preceptor or Residency Program Director (Typed or Printed)		Telephone Number	Date
Signature		1	

From: <u>Alldredge, Casey</u>

To: <u>"ajohnson@wilcoxhealth.org"</u>

Subject: NRC License Amendment; Request for Information

Date: Monday, June 29, 2020 11:05:00 PM

Attachments: Form 313A.pdf

Good evening Dr. Johnson,

I am reviewing the amendment request, dated May 26, 2020, asking to add Dr. Srinivasan as an authorized user. I noted the Board Certification, but could you please fill out the attached Form 313 to accompany the certification?

Thanks very much,

Casey Alldredge Health Physicist Materials Licensing and Decomissioning Branch Region IV, USNRC