

Torres, RobertoJ

From: So, Andrew D.O. [andrew.so@wilcoxhealth.org]
Sent: Tuesday, July 27, 2010 3:18 PM
To: Culliney, John MD; Torres, RobertoJ
Cc: Everett, Samantha; rfrick@gammacorp.com
Subject: RE: Follow up from NRC
Attachments: NRC 313A.pdf

Thank you all for assisting me regarding this matter.
I am enclosing the NRC 313A form
Please contact me with any questions.

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JUL 28 2010

DNMS

Andrew So DO
Cardiologist
Kaua'i Medical Clinic
3-3420 Kuhio Highway, Suite B
Lihue, Kauai, Hawaii 96766-1098
Cell. (808)639-3977
Tel. (808)245-1548
Fax (808) 246-1670
Pager (808)241-0275

From: Culliney, John MD
Sent: Tuesday, July 27, 2010 8:49 AM
To: 'Torres, RobertoJ'; So, Andrew D.O.
Cc: Everett, Samantha; 'rfrick@gammacorp.com'
Subject: FW: Follow up from NRC

Dear Mr. Torres and Ms. Everett,

Thanks so much for your help in amending our license to allow Dr. So to become an authorized user. I'm forwarding this e-mail to the parties also involved in making this happen. I'm certain that the documentation will be sent to make this task a reality. Again, thanks for all of the help and guidance in this matter.

John J. Culliney, M.D., M.S., D.A.B.R.
Chairman Department of Radiology
Radiation Safety Officer
3-3420 Kuhio Highway, Suite B
Lihue, Hawaii 96766
Phone: (808)-245-1293
Fax: (808) 246-2914
jculliney@wilcoxhealth.org

From: Torres, RobertoJ [mailto:RobertoJ.Torres@nrc.gov]
Sent: Tuesday, July 27, 2010 6:16 AM
To: Culliney, John MD
Cc: Everett, Samantha
Subject: Follow up from NRC

Dr. Culliney:

I am working with NRC employee Samantha Everett on Wilcox Memorial Hospital request to add Andrew So, M.D. as a 35.200 authorized user on license 53-15737-01. We have already received from you a copy of a preceptor attestation letter for Dr. So so the only information that we need to add him to this license is:

1. Copy of board certification for Dr. So from the "Certification Board of Nuclear Cardiology".

A copy of Dr. So's board certification in conjunction with the preceptor attestation letter that we have on file will allow the me to amend the license immediately.

If a copy of the board certification is not available then Dr. So's training and experience must be documented in NRC Form313A(aud) as explained by Ms. Everett on her email communication to you dated June 29, 2010.

Roberto J. Torres
Senior Health Physicist
U.S. Nuclear Regulatory Commission - Region IV
Division of Nuclear Materials Safety
Nuclear Materials Safety Branch B
612 East Lamar Boulevard, Suite 400
Arlington, Texas 76011-4125
Telephone 817-860-8189
Facsimile 817-860-8263
robertoj.torres@nrc.gov

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**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]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 3/31/2012

Name of Proposed Authorized User

Andrew So, DO

State or Territory Where Licensed

Hawai

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Requested Authorization(s) (check all that apply)

- 35.100 Uptake, dilution, and excretion studies
- 35.200 Imaging and localization studies
- 35.500 Sealed sources for diagnosis (specify device _____)

JUL 28 2010

DNMS

PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained 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. Provide a copy of the board certification.
- b. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.

2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization

- a. Authorized user on Materials License _____ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.
- b. Supervised Work Experience.
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit 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

Richard J. Butcher, MD

License/Permit Number listing supervising individual as an authorized user

37 01421 01

Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).

- 35.290
- 35.390 + generator experience in 32.290(c)(1)(ii)(G)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	Health Radiological Seminars Inc. 366 Route 18 Monaca, PA 15061	25	7/1/06 to 6/30/2009
Radiation protection	Health Radiological Seminars Inc. 366 Route 18 Monaca, PA 15061	20	7/1/06 to 6/30/2009
Mathematics pertaining to the use and measurement of radioactivity	Health Radiological Seminars Inc. 366 Route 18 Monaca, PA 15061	15	7/1/06 to 6/30/2009
Chemistry of byproduct material for medical use <i>(not required for 35.590)</i>	Health Radiological Seminars Inc. 366 Route 18 Monaca, PA 15061	10	7/1/06 to 6/30/2009
Radiation biology	Health Radiological Seminars Inc. 366 Route 18 Monaca, PA 15061	10	7/1/06 to 6/30/2009
Total Hours of Training: 80			

b. Supervised Work Experience (completion of this table is not required for 35.590).
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervised Work Experience		Total Hours of 700 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	Geisinger Medical Center Danville, PA 17822 37 01421 01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/06 to 6/30/2009
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Geisinger Medical Center Danville, PA 17822 37 01421 01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/06 to 6/30/2009

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

b. Supervised Work Experience. (continued)

Description of Experience Must include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages	Geisinger Medical Center Danville, PA 17822 37 01421 01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/06 to 6/30/2009
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Geisinger Medical Center Danville, PA 17822 37 01421 01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/06 to 6/30/2009
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Geisinger Medical Center Danville, PA 17822 37 01421 01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/06 to 6/30/2009
Administering dosages of radioactive drugs to patients or human research subjects	Geisinger Medical Center Danville, PA 17822 37 01421 01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/06 to 6/30/2009
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	Geisinger Medical Center Danville, PA 17822 37 01421 01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/06 to 6/30/2009

Supervising Individual Richard J. Butcher, MD	License/Permit Number listing supervising individual as an authorized user 37 01421 01
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Supervisor meets the requirements below, or equivalent Agreement State requirements (*check one*).

- 35.190 35.290 35.390 35.390 + generator experience in 35.290(c)(1)(ii)(G)

c. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

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

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

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. (Not required to meet training requirements in 35.590)

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each use requested:

For 35.190

Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed 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.

OR

Training and Experience

I attest that Andrew So has satisfactorily completed the 60 hours of training and
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(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.

For 35.290

Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.290(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 and 35.200.

OR

Training and Experience

I attest that Andrew So has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

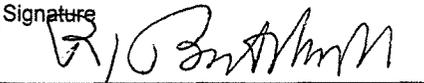
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

Second Section

Complete the following for preceptor attestation and signature:

I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

- 35.190
- 35.290
- 35.390
- 35.390 + generator experience

Name of Preceptor Richard J. Butcher, MD	Signature 	Telephone Number (570) 271-8053	Date 07/23/2010
---	--	------------------------------------	--------------------

License/Permit Number/Facility Name
37 01421 01 Geisinger Medical Center; Danville, PA 17822

Health & Radiological Seminars, Inc.

Hereby certifies that

Andrew U. So M.D.

has successfully completed the 80 Hour Physician Training
Program in Basic Radioisotope Handling conducted
in accordance with the requirements of the
U.S. Nuclear Regulatory Commission (10 CFR 35).

COURSE OUTLINE

Radiation Physics and Instrumentation – 40 hours

Mathematics pertaining to the use and measurement of radioactivity - 15 hours

Radiation Protection – Radiopharmaceutical Chemistry - 15 hours

Radiation Biology – 10 hours

June 30, 2008



Elise R. Wright
Program Director



Peggy Tideman
Executive Director



Health and Radiological Seminars, Inc.

Dear Dr. Andrew U. So,

It is with great pleasure that I reward you with this certificate as recognition of your completion of the Health and Radiological Seminars, Inc. (HRSI) Nuclear Cardiology License Preparation Course.

Now that you have successfully completed your requirements for the course, and have seen first-hand what HRSI has to offer, we ask that you consider telling others about our class. If you know of any colleagues who may benefit from taking our course, pass on our information www.hrsi-seminars.net. Your assistance towards continuing the advancement of quality education in the field of nuclear medicine, would be greatly appreciated.

Should there be any way that we can assist you in the future please do not hesitate to contact us, and I wish you the best of success in your professional endeavors.

Sincerely,

Elise R. Wright
Program Director
Health & Radiological Seminars, Inc.
www.hrsi-seminars.net
info@hrs-seminars.net
800-969-4774

Torres, RobertoJ

From: Torres, RobertoJ
Sent: Tuesday, July 27, 2010 11:16 AM
To: 'jculliney@wilcoxhealth.org'
Cc: Everett, Samantha
Subject: Follow up from NRC
Attachments: nrc313a(aud).pdf

Dr. Culliney:

I am working with NRC employee Samantha Everett on Wilcox Memorial Hospital request to add Andrew So, M.D. as a 35.200 authorized user on license 53-15737-01. We have already received from you a copy of a preceptor attestation letter for Dr. So so the only information that we need to add him to this license is:

1. Copy of board certification for Dr. So from the "Certification Board of Nuclear Cardiology".

A copy of Dr. So's board certification in conjunction with the preceptor attestation letter that we have on file will allow the me to amend the license immediately.

If a copy of the board certification is not available then Dr. So's training and experience must be documented in NRC Form313A(aud) as explained by Ms. Everett on her email communication to you dated June 29, 2010.

Roberto J. Torres
Senior Health Physicist
U.S. Nuclear Regulatory Commission - Region IV
Division of Nuclear Materials Safety
Nuclear Materials Safety Branch B
612 East Lamar Boulevard, Suite 400
Arlington, Texas 76011-4125
Telephone 817-860-8189
Facsimile 817-860-8263
robertoj.torres@nrc.gov

Everett, Samantha

From: Culliney, John MD [jculliney@WILCOXHEALTH.ORG]
Sent: Tuesday, June 29, 2010 6:22 PM
To: Everett, Samantha
Cc: So, Andrew D.O.; rfrick@gammacorp.com
Subject: RE: REQUEST FOR ADDITIONAL INFORMATION REGARDING LICENSE NO 53-15737-01
Attachments: NRC_FORM313A(AUD).pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Ms. Everett,

It was a pleasure to speak with you this afternoon. We still desire to continue with our action of including Dr. So on our license. I have forwarded the material to the parties involved in order to allow this action to happen. Thanks again for your interest and help in this matter. Have a great day.

John J. Culliney, M.D., M.S., D.A.B.R.
Chairman Department of Radiology
Radiation Safety Officer
3-3420 Kuhio Highway, Suite B
Lihue, Hawaii 96766
Phone: (808)-245-1293
Fax: (808) 246-2914
jculliney@wilcoxhealth.org

From: Everett, Samantha [mailto:Samantha.Everett@nrc.gov]
Sent: Tuesday, June 29, 2010 12:02 PM
To: Culliney, John MD
Subject: REQUEST FOR ADDITIONAL INFORMATION REGARDING LICENSE NO 53-15737-01

License No. 53-15737-01
Docket No. 030-09666
Control No. 472663

Dear Dr. Culliney:

This is in reference to your letter dated April 2, 2010 requesting to add an authorized user to the existing Nuclear Regulatory Commission License 53-15737-01. In order to continue our review we need the following information:

1. Please provide documentation of the authorized user's training. The attached NRC form 313 may be used to provide this information.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region IV Office and refer to Mail Control No. 472663. You can send the response thru e-mail as long as the response is attached and is signed by management. You may also fax the response to 817-860-8263. If we do not receive a reply by **July 6, 2010**, we will assume that you do not wish to pursue your application and we will void the action without prejudice.

If you have any technical questions regarding this deficiency letter, please call me at (817) 860-8040.

Sincerely,

Samantha J. Everett

Student Health Physicist

U.S. Nuclear Regulatory Commission - Region IV

Division of Nuclear Materials Safety

612 East Lamar Boulevard, Suite 400

Arlington, Texas 76011-4125

Telephone 817-860-8040

samantha.everett@nrc.gov

"And the day came when the risk to remain tight in a bud was more painful than the risk it took to blossom." - *Anais Nin*

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