

Sara A.B. Forster
MATERIALS LICENSING BRANCH

TELECON & FAX TRANSMITTAL



TO: Sandy

COMPANY: Lingareddy Devireddy, M.D., P.C.

NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351
(630) 829-9892 FAX: (630) 515-1078

PAGES: 6 TEL.: N/A

FAX #: (586) 574-9321

EMAIL: N/A

CONVERSATION RECORD

|TIME |DATE
1:30 pm March 19, 2012

NAME OF PERSON(S) CONTACTED |TELEPHONE NO. |ORGANIZATION
Sandy, Office Manager (586) 574-0890 Lingareddy Devireddy, M.D., P.C.

REPRESENTED PERSON or PERSONS |ORGANIZATION
Srinivas Koneru, M.D., Radiation Safety Officer Lingareddy Devireddy, M.D., P.C.

SUBJECT
|License No.: 21-32388-01 |Control No.: 576653

SUMMARY

We have reviewed your license amendment request and find that we are unable to continue this action until we have received information regarding the following:

1. The NRC Form 313A (AUD), dated December 6, 2011, lacks sufficient documentation to confirm that the Lingareddy Devireddy, M.D., received the 780 hours of work experience, indicated in Table 3.b., on pages 2-3 of the form, under the supervision of individuals authorized for the use of radioactive materials permitted by 10 CFR 35.200.
Please resubmit the NRC Form 313A (AUD) in its entirety. The form should either: (1) clearly include the license numbers and associated supervising Authorized Users for the experience at Cardian Health – Las Vegas and/or Cardiovascular Consultants of Nevada, or (2) clearly indicate the number of hours of supervised work experience that occurred at the licensee's facilities, NRC License No. 21-32388-01, under the supervision of Srinivas Koneru, M.D. If the resubmitted form includes references to agreement state license(s), a copy should be attached with your response.
 2. The NRC Form 313A (AUD), dated December 6, 2011, lacks sufficient documentation to confirm that classroom and laboratory training was completed during the period from January 30, 2010 to February 24, 2010, as indicated in Table 3.a, on page 2 of the form.
Please attach a copy of the course outline, itinerary, agenda, course completion certificate, or equivalent, clearly indicating that formal training has been completed as required under 10 CFR 35.290 (c)(1)(i). Documentation should list out the topics covered in the formal classroom and laboratory training.
-

We have requested that you submit the referenced items:

- Additional Work Experience documentation
- Additional Classroom and Laboratory Training documentation

– via facsimile, to (630) 515-1078. Please reference the Control No. 576653, as listed at the top of this memo. We expect to hear from you on or before March 29, 2012.

For future reference, please always include the name, phone number and fax number of at least one person whom we may contact for additional information when reviewing your licensing correspondence and requests.

Please submit the requested information within 10 days of this record. **Include reference control number 576689, Please FAX your response to my attention at (630) 515-1078.** You may also scan your response and send to me via email, as a pdf file.

Please direct any questions you have to me at (630) 829-9892 or sara.forster@nrc.gov.

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Sara A.B. Forster

Sara A. B. Forster 03/19/2012

**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
Lingareddy Devireddy, MD

State or Territory Where Licensed
Michigan

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 _____)

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 _____ License/Permit Number listing supervising individual as an authorized user _____

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	St. John Hospital & Medical Center 22101 Moross Street Detroit, MI 48236 #21-03210-01	25	1/30/10 - 2/24/10
Radiation protection	St. John Hospital & Medical Center 22101 Moross Street Detroit, MI 48236 #21-03210-01	25	1/30/10 - 2/24/10
Mathematics pertaining to the use and measurement of radioactivity	St. John Hospital & Medical Center 22101 Moross Street Detroit, MI 48236 #21-03210-01	10	1/30/10 - 2/24/10
Chemistry of byproduct material for medical use (not required for 35.590)	St. John Hospital & Medical Center 22101 Moross Street Detroit, MI 48236 #21-03210-01	10	1/30/10 - 2/24/10
Radiation biology	St. John Hospital & Medical Center 22101 Moross Street Detroit, MI 48236 #21-03210-01	10	1/30/10 - 2/24/10
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 Experience:		
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	780	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	Cardian Health - Las Vegas Cardiovascular Consultants of Nevada and Devireddy, MD #21-32388-01		<input checked="" type="checkbox"/> Yes	1/30/10-2/24/10 and 2/28/10 - 6/1/2011
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Cardian Health - Las Vegas Cardiovascular Consultants of Nevada and Devireddy, MD #21-32388-01		<input checked="" type="checkbox"/> Yes	1/30/10-2/24/10 and 2/28/10 - 6/1/2011

*Does Not Correlate with submitted documentation
See Item #2 in attached sheet

No license No. supervising individual, 2 hours indicated
See item #1 in attached sheet.

indicate hours under each license / Au.

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	Cardian Health - Las Vegas Cardiovascular Consultants of Nevada and Devireddy, MD #21-32388-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	1/30/10-2/24/10 and 2/28/10 - 6/1/2011
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Cardian Health - Las Vegas Cardiovascular Consultants of Nevada and Devireddy, MD #21-32388-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	1/30/10-2/24/10 and 2/28/10 - 6/1/2011
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Cardian Health - Las Vegas Cardiovascular Consultants of Nevada and Devireddy, MD #21-32388-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	1/30/10-2/24/10 and 2/28/10 - 6/1/2011
Administering dosages of radioactive drugs to patients or human research subjects	Cardian Health - Las Vegas Cardiovascular Consultants of Nevada and Devireddy, MD #21-32388-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	1/30/10-2/24/10 and 2/28/10 - 6/1/2011
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	Cardian Health - Las Vegas Cardiovascular Consultants of Nevada and Devireddy, MD #21-32388-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	1/30/10-2/24/10 and 2/28/10 - 6/1/2011

Supervising Individual

Srimivas Komaru

others?

License/Permit Number listing supervising individual as an authorized user

21-32388-01

others?

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 _____ 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 Lingareddy Devireddy 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

Srinivas Koneru

Signature

Telephone Number

(586) 574-0890

Date

12/06/2011

License/Permit Number/Facility Name

21-32388-01

Please re submit including signature.

TRANSMISSION VERIFICATION REPORT

TIME : 03/19/2012 14:04
NAME : USNRC RIII
FAX : 6308299782
TEL :
SER. # : 000A7J925774

DATE, TIME	03/19 14:02
FAX NO./NAME	85865749321
DURATION	00:01:26
PAGE(S)	06
RESULT	OK
MODE	STANDARD ECM

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REPRESENTED PERSON or PERSONS		ORGANIZATION	
Srinivas Koneru, M.D., Radiation Safety Officer		Lingareddy Devireddy, M.D., P.C.	
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