Sara A.B. Forster
MATERIALS LICENSING BRANCH
U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD
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(630) 829-9892 FAX: (630) 515-1078

TELECON & FAX TRANSMITTAL

TO: T. Harrigan, CNMT, RSO

COMPANY: Franciscan d/b/a St. Marg.

PAGES: 6 TEL. : N/A .

FAX #: (219) 852-2470 .

EMAIL: N/A .

CONVERSATION RECORD

TIME	DATE
9:45 am	September 13, 2012

NAME OF PERSON(S) CONTACTED	TELEPHONE NO.	ORGANIZATION
"Mike" Muveski, Nuclear Medicine	(219) 932-2300	Franciscan Alliance, Inc., d/b/a Franciscan St. Margaret Health
REPRESENTED PERSON or PERSONS		ORGANIZATION
Theresa Harrigan, Radiation Safety Officer		Franciscan Alliance, Inc., d/b/a Franciscan St. Margaret Health

SUBJECT

License No.: 13-02047-02 Control No.: 578131

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:

To add PRODDUTUR R. REDDY, M.D. as an AUTHORIZED USER (AU):

1. Please **clarify what authorizations** (10 CFR 35.100, 35.200, etc.) **you are seeking** for Dr. Reddy.

   Include a copy of the St. James Hospital and Health Centers radioactive materials license, License No. IL-01289-01, with your request.

   In addition, if that license does not list his authorizations, please submit a letter from St. James Hospital and Health Centers, clearly indicating that Dr. Reddy has been approved as the equivalent of an AU for all requested authorizations.

To add RAVI S. BHAGWAT, SATAYAPRAKASH N. MAKAM, & JAY N. PANDHI, M.D.'s, as AUs:

2. The submitted NRC Form 313A (AUD), for each of the three referenced proposed AUs, lacks sufficient detail to demonstrate the physician's completion of Training and Experience, as required under 10 CFR 35.190(c) and 10 CFR 35.290(c). Please **resubmit a complete NRC Form 313A (AUD) for each** of Drs. Bhagwat, Makam, and Pandhi. **Each form should contain the information noted on the attached sheets**, including details for Item 3:

CLASSROOM and LABORATORY (C&L) training:

a. For each C&L category (radiation physics and instrumentation, radiation protection, etc.) of required training, include the name of company and/or persons providing the training, including the city and state where the training was completed.

Please be reminded that 10 CFR 30.9 requires that all submitted information be complete and accurate in all material respects.

List the total clock hours of training for each training category, and note the dates on which the training was completed. Include the total hours of training received. The total hours of training received should equal the sum of the clock hours received for each of the five categories of training. The training dates should correspond with any training certificates included in the request.

SUPERVISED WORK EXPERIENCE (SWE):

b. Under 10 CFR 35.190(c)(1)(ii) and 35.290(c)(1)(ii), work experience must be completed under the supervision of an AU authorized to use 10 CFR 35.100 or 35.200 materials, respectively, or equivalent. The listed location of training, supervising individual, and supervisor's license number should all correspond with this requirement.

Further, for a 10 CFR 35.200 radioactive materials authorization, 10 CFR 35.290(c)(1)(ii) requires any proposed AU to have completed at least 700 hours of combined C&L and SWE. List Total SWE hours, and dates during which the SWE was completed on each NRC Form 313A (AUD).

We have requested that you submit the referenced items:

- Copy of St. James Hospital and Health Centers **License IL-01289-01**
- Resubmitted **NRC Forms 313A (AUD)** for Drs. Bhagwat, Makam & Pandhi

– via facsimile, to (630) 515-1078. Please reference the Control No. 578131, as listed at the top of this memo. **We expect to hear from you on or before October 4, 2012.** Please **include a cover letter with your response, signed and dated** by an authorized management official.

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 **21** days of this record. **Include reference control number 578131, 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	09/13/2012

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NRC FORM 313A (AUD) (05-2012) 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]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: (05/31/2015)

Name of Proposed Authorized User	State or Territory Where Licensed
ACCESS this form at http://portal.nrc.gov/nrcformsportal	RESUBMIT for Drs. BHAGWAT, MAKAM, and PANDHI

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) Indicate 35.100/200/500 in boxes at left.

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	Items 1 & 2 do not apply for these physicians; N/A see notes re Item 3, next page.		
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)

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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			
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:		

Include name of company and/or person(s) providing the training.

Include, at a minimum, the cities and/or states where training was conducted.

List clock hours & training dates for EACH of the 5 subject areas in EACH of the 5 pairs of boxes at right.

Confirm that the training dates are consistent with any previously submitted training certifiicates, or explain any inconsistencies.

For 10 CFR 35.100 authorization only, a minimum of 60 hrs Classroom & Lab training are required. For 35.200, the minimum is 80 hrs.

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	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	For 35.100 only, there is no min. number of hours required. However, for 10 CFR 35.100 & 35.200 min. combined (class/lab & work) must add total	☐ Yes ☐ No	List dates for trng & work experience
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	work experienence to the classroom & lab. No minimum is required for 35.100 but for both 35.100 & 35.200, the total for class/lab and work is 700 hrs.	☐ Yes ☐ No	

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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	Include name of company and Authorized User providing the training.	☐ Yes ☐ No	List dates for trng & experience
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	
Administering dosages of radioactive drugs to patients or human research subjects		☐ Yes ☐ No	
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		☐ Yes ☐ No	

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
List name of the 35.100/200 AU	License number should agree w/AU name above.

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check one)*.

☐ 35.190 ☐ 35.290 ☐ ~~35.390~~ N/A ☐ ~~35.390 + generator experience~~ N/A 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
	N/A	

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

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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 N/A 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 N/A 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 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	Signature	Telephone Number	Date

License/Permit Number/Facility Name