

Elkhart Clinic

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Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Attn: Jose Macatangay
Fax number 630-515-1078

Re: Control no. 318787

April 1, 2010

Dear Mr. Macatangay

Enclosed please find the additional information requested in order to amend license number 13-32515-01. Specifically, a completed NRC form 313A (RSO) for Dr. Gonzales, the Oklahoma materials license on which his preceptor RSO is named and documentation of the actual training. We hope you find this to be satisfactory. If you have any questions, please call me or our Medical Physics Consultant, Linda Ramirez with Associates in Medical Physics, (216) 663-7000.

Sincerely,



Darryl Busby,
Executive Administrator

**RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION
[10 CFR 35.50]**

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

Name of Proposed Radiation Safety Officer

Luisito Gonzales, M.D.

Requested Authorization(s) *The license authorizes the following medical uses (check all that apply):*

- 35.100 35.200 35.300 35.400 35.500 35.600 (remote afterloader)
 35.600 (teletherapy) 35.600 (gamma stereotactic radiosurgery) 35.1000 (_____)

PART I -- TRAINING AND EXPERIENCE
(Select one of the four 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. Use Table 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.
- c. Skip to and complete Part II Preceptor Attestation.

OR

2. Current Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety Officer for the Additional Medical Uses Checked Above

- a. Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for the additional types of medical use for which recognition as RSO is sought.
- b. Skip to and complete Part II Preceptor Attestation.

OR

3. Structured Educational Program for Proposed Radiation Safety Officer

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			
Radiation biology			
Radiation dosimetry			

Total Hours of Training:

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

b. Supervised Radiation Safety 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 Training/ License or Permit Number of Facility	Dates of Training*
Shipping, receiving, and performing related radiation surveys		
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides		
Securing and controlling byproduct material		
Using administrative controls to avoid mistakes in administration of byproduct material		
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures		
Using emergency procedures to control byproduct material		
Disposing of byproduct material		
Licensed Material Used (e.g., 35.100, 35.200, etc.)+ _____ _____ _____		

+ Choose all applicable sections of 10 CFR Part 35 to describe radioisotopes and quantities used: 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 remote afterloader units, 35.600 teletherapy units, 35.600 gamma stereotactic radiosurgery units, emerging technologies (provide list of devices).

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

b. Supervised Radiation Safety Experience (continued)

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervising Individual	License/Permit Number listing supervising individual as a Radiation Safety Officer
This license authorizes the following medical uses:	
<input type="checkbox"/> 35.100 <input type="checkbox"/> 35.200 <input type="checkbox"/> 35.300 <input type="checkbox"/> 35.400	
<input type="checkbox"/> 35.500 <input type="checkbox"/> 35.600 (remote afterloader) <input type="checkbox"/> 35.600 (teletherapy)	
<input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery) <input type="checkbox"/> 35.1000 (_____)	

c. Describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

Description of Training	Training Provided By	Dates of Training*
Radiation safety, regulatory issues, and emergency procedures for 35.100, 35.200, and 35.500 uses	Linda Ramirez, Associates in Medical Physics, LLC.	3/31/10
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses		
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - teletherapy uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - remote afterloader uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma stereotactic radiosurgery uses		
Radiation safety, regulatory issues, and emergency procedures for 35.1000, specify use(s):		

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

Check one of the following:

3. Additional Authorization as Radiation Safety Officer

I attest that Luisito Gonzales, M.D. is an
Name of Proposed Radiation Safety Officer

- Authorized User Authorized Nuclear Pharmacist
 Authorized Medical Physicist

identified on the Licensees license and has experience with the radiation safety aspects of similar type of use of byproduct material for which the individual has Radiation Safety Officer responsibilities

AND

Second Section

Complete for all (check all that apply):

I attest that Luisito Gonzales, M.D. has training in the radiation safety, regulatory issues, and
Name of Proposed Radiation Safety Officer

emergency procedures for the following types of use:

- 35.100
 35.200
 35.300 oral administration of less than or equal to 33 millicuries of sodium iodide I-131, for which a written directive is required
 35.300 oral administration of greater than 33 millicuries of sodium iodide I-131
 35.300 parenteral administration of any beta-emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required
 35.300 parenteral administration of any other radionuclide for which a written directive is required
 35.400
 35.500
 35.600 remote afterloader units
 35.600 teletherapy units
 35.600 gamma stereotactic radiosurgery units
 35.1000 emerging technologies, including:

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

AND


**Third Section
Complete for ALL**

I attest that Luisito Gonzales, M.D. has achieved a level of radiation safety knowledge
Name of Proposed Radiation Safety Officer
sufficient to function independently as a Radiation Safety Officer for a medical use licensee.

**Fourth Section
Complete the following for Preceptor Attestation and signature**

I am the Radiation Safety Officer for RCOA Imaging Services, Inc.
Name of Facility

License/Permit Number: OK-31048-01 (attached)

Name of Preceptor	Signature	Telephone Number	Date
Frank Bloe		(216) 663-7000	03/31/2010

MATERIALS LICENSE

Pursuant to the Oklahoma Radiation Management Act (27A O.S. §2-9-101, *et seq.*) and the Oklahoma Radiation Management Rules (Rules) at Oklahoma Administrative Code (OAC) 252:410, including rules incorporated by reference from Title 10 of the Code of Federal Regulations, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer the source(s) of radiation (byproduct, source and special nuclear material, accelerator produced material, radium sealed sources and/or radiation machines) designated below; to use such source(s) for the purpose(s) and at the place(s) designated below; and to deliver or transfer such material to persons authorized to receive it in accordance with applicable rules. This license is subject to all applicable rules and orders of the Oklahoma Department of Environmental Quality (DEQ) now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with a letter dated June 22, 2009	
1. RCOA Imaging Services, Inc.	3. License number OK-31048-01 is hereby amended in its entirety to read as follows:	
2. 16110 Jog Road, Suite 200 Delray Beach, FL 33446	4. Expiration date June 30, 2016	
	5. DEQ Login No. 197349	
6. Byproduct [as identified in OAC 252:410-10-2(b)(1)], source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Fluorine-18	A. Any	A. as needed
B. Rubidium-82	B. Any	B. 200 millicuries
C. Strontium-82	C. Any	C. 200 millicuries
D. Strontium-85	D. Solid	D. 1000 millicuries

9. Authorized use:
- A. and B. Medical use described in OAC 252:410-10-35(a)(4)(C) {10 CFR 35.200}.
 - C. and D. For use in Bracco Diagnostics RB-82 infusion system.

CONDITIONS

10. Licensed material may also be used at any medical facility located anywhere in Oklahoma where the DEQ maintains jurisdiction for regulating the use of licensed material provided:
- (1) The licensee addresses all use and recordkeeping requirements outlined in OAC 252:410-10-35(a)(3)(I) {10 CFR 35.80}, and
 - (2) The licensee has the prior written permission from the medical facility's administrator, and,
 - (3) The licensee maintains a list of all medical facilities serviced.
- The licensee shall maintain for inspection by the DEQ copies of written permission specified in Sub-item 2 and the list specified in Sub-item 3 above.
11. The Radiation Safety Officer (RSO) for this license is Frank Bloe.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
OK-31048-01DEQ Login No.
197349Amendment No.
04

12. Authorized users:
Dale Brannon, M.D., for material identified in 10 CFR 35.200, as adopted by reference in OAC 252:410-10-35.
James Chapman, M.D., for material identified in 10 CFR 35.200, as adopted by reference in OAC 252:410-10-35.
Richard E. Cooke, M.D., for material identified in 10 CFR 35.200, as adopted by reference in OAC 252:410-10-35.
Bernard L. Fioravanti, M.D., for material identified in 10 CFR 35.200 as adopted by reference in OAC 252:410-10-35.
Dean R. Fullingim, D.O., for material identified in 10 CFR 35.200, as adopted by reference in OAC 252:410-10-35.
Phung Kim Luong, M.D., for material identified in 10 CFR 35.200 as adopted by reference in OAC 252:410-10-35.
Jason D. Martens, M.D., for material identified in 10 CFR 35.200 as adopted by reference in OAC 252:410-10-35.
Timothy T. McCay, D.O., for material identified in 10 CFR 35.200, as adopted by reference in OAC 252:410-10-35.
Frank E. Rabe, M.D., for material identified in 10 CFR 35.200, as adopted by reference in OAC 252:410-10-35.
Stephen G. Salamy, M.D., for material identified in 10 CFR 35.200 as adopted by reference in OAC 252:410-10-35.
Randall H. Stickney, M.D., for material identified in 10 CFR 35.200 as adopted by reference in OAC 252:410-10-35.
Robert A. Straight, M.D., for material identified in 10 CFR 35.200 as adopted by reference in OAC 252:410-10-35.
Stuart K. Strickland, M.D., for material identified in 10 CFR 35.200 as adopted by reference in OAC 252:410-10-35.
13. The licensee shall install, calibrate and operate the rubidium-82 (Rb-82) generator and infusion system according to the manufacturer's instructions
- The licensee may not administer to humans a radiopharmaceutical containing more than 0.02 microcuries of strontium-82 (Sr-82) per millicurie of Rb-82 or 0.2 microcuries of strontium 85 (Sr-85) per millicurie of Rb-82.
 - The licensee shall measure the Sr-82 and Sr-85 concentrations in the first eluate of the Sr-82/Rb-82 generators each day of use to demonstrate compliance with Condition 14-A of the license.
 - The licensee shall maintain a record of each Sr-82 and Sr-85 measurement for at least three years. The record must include, for each measured elution of Rb-82, the ratio of the measures expressed as microcuries of Sr-82 per millicurie of Rb-82 and microcuries of Sr-85 per millicurie of Rb-82, the time and date of the measurement, and the name of the individual who made the measurement.
 - The licensee must use an infusion system specifically labeled for use with the generator and capable of accurate measurement and delivery of doses of rubidium chloride Rb-82 as described on the product insert.
14. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in OAC 252:410-10-30(3)(E){10 CFR 30.35(d)} for establishing decommissioning financial assurance.

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15. Notwithstanding the provisions of 35.80(b) as adopted by reference in OAC 252: 410-10-35, licensed material may be delivered to RCOA Imaging Services' trailer at client addresses in accordance with procedures outlined in the application.
16. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in OAC 252:410-10-35(3)(B){10 CFR 35.26}. The Radiation Management Rules shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the Rules.
- A. Application dated December 29, 2004
 - B. Letter dated March 20, 2006
 - C. Letter dated April 17, 2006
 - D. Letter dated March 12, 2008
 - E. Email dated March 25, 2008
 - F. Letter dated September 1, 2009

FOR THE DEPARTMENT OF ENVIRONMENTAL QUALITY

Date

9/14/09

By



Mike Broderick, Environmental Programs Manager
Land Protection Division
Radiation Management Section

RADIATION SAFETY TRAINING

On March 31, 2010, training in radiation safety, regulatory issues and emergency procedures for uses in 10 CFR 35.200 was given to Luisito Gonzales, M.D. prior to assuming the role of radiation safety officer. Training materials are attached.



Frank Bloe, Radiation Safety Officer

I have received training as described above



Luisito Gonzales, M.D., Authorized User