

Rami M. Akel, MD, FACC  
Phillip G. Apprill, MD, FACC  
Manoj K. Eapen, MD, FACC  
Darlene L. Eyster, MD, FACC  
Mark A. Friedman, MD  
M. Carolyn Gamache, MD, FACC  
M. Kiran Kancherla, MD, FACC  
David J. Kardesch, MD, FACC

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# METRO

## HEART GROUP

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OF ST. LOUIS, INC.

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John W. Kilgore, MD, FACC  
Roberto Pacheco-Coronado, MD  
Jeffrey T. Reese, MD, FACC  
Bassam A. Roukoz, MD, FACC  
Robert Snitzer, MD, FACC  
Mark D. Taber, MD, FACC  
Richard B. Whiting, MD, FACC

August 29, 2011

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

**License Number 24-32184-01**

**Control Number 316631**

**Re: Verification of generator and kit training and experience for Dr. Roukoz.**

Dear Ms. Casey:

We are requesting continued review, as stated in the cover letter for Amendment No.21, dated April 18, 2008, to add Dr. Roukoz as an Authorized User on our license. The Director of Nuclear Cardiology for Metro Heart contacted personnel at MCP Hahnemann University and inquired if they had any original preceptor training documents on file for Dr. Roukoz. They did and the documents sent to us show he did have generator and kit experience. As noted in your April 18, 2008, letter we are attaching a copy of Dr. Roukoz's preceptor documents showing generator and kit experience. Dr. Roukoz has had continued involvement in Nuclear Cardiology under the general supervision of our Medical Director, Madhu Kancherla, M.D., Authorized User, since the original application request was filed with NRC on January 10, 2008. Please continue the review to add Dr. Roukoz as an Authorized User for material permitted in 35.200 Imaging and Localization Studies.

If you have any additional questions, please contact me or John Derhake (Director Nuclear Cardiology) at (314) 880-6100.

Sincerely,

  
N. Rock Ereksan  
Executive Director



RECEIVED SEP 07 2011





UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
2443 WARRENVILLE ROAD, SUITE 210  
LISLE, ILLINOIS 60532-4362

APR 18 2008

Tiffany A. Door, CNMT  
Radiation Safety Officer  
Metro Heart Group of St. Louis, Inc.  
12855 N. Forty Road  
Suite 300  
St. Louis, MO 63141

Dear Ms. Door:

Enclosed is Amendment No. 21 to your NRC Material License No. 24-32184-01 in accordance with your request. Please note that some of the changes made to your license are printed in bold font.

Please be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

**Please note that we were unable to approve Manoj K. Eapen, M.D., and Bassam A. Roukoz, M.D. as Authorized Users for the use of materials in 10 CFR 35.200, at this time because the information in your letter dated January 10, 2008, was insufficient to complete our review.**

If you wish to pursue this matter, please submit the following information, addressed to my attention and referenced as "additional information to control number 316631."



**Drs. Eapen and Roukoz were not approved as Authorized Users for the use of materials in 10 CFR 35.200 because neither physician met the requirement in 10 CFR 35.290(c)(1)(ii)(G) concerning training and experience eluting generator systems appropriate for 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.**

**Please refer to the regulatory requirements in 10 CFR 35. 35.290(c)(1)(ii)(G) and 35.59, as well as section 8.11, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Rev. 2, for assistance in preparing your written response to demonstrate that Drs. Eapen and Roukoz' training and experience meet the appropriate regulatory requirements for the modality they seek authorization for.**

If Forms 313a will be used in support of your response, please use the newly revised Forms found on our website at:

[http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a\(aud\).pdf](http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(aud).pdf)

**Please do not submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc.**

T. Door

**If you have any questions concerning this amendment please contact me at (630) 829-9841.**

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS, the NRC's electronic document system.

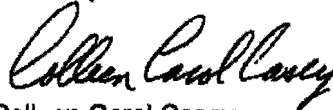
Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390, the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability.

The RIS may be located on the NRC Web site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf> and the link for frequently asked questions regarding protection of security related sensitive information may be located at: <http://www.nrc.gov/reading-rm/sensitive-info/fag.html>.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,



Colleen Carol Casey  
Materials Licensing Branch

License No. 24-32184-01  
Docket No. 030-35037

Enclosure:

Amendment No. 21

EXHIBIT 2  
SUPPLEMENT A

SUPPLEMENT		U.S. NUCLEAR REGULATORY COMMISSION		
TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER				
1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER <b>Bassam A. Roukoz<sup>2</sup>, MD</b>			2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED	
3. CERTIFICATION				
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C		
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES				
FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING		
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE	
a. RADIATION PHYSICS AND INSTRUMENTATION	MCP Hahnemann University	100		
b. RADIATION PROTECTION	MCP Hahnemann University	30		
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Philadelphia, PA	20		
d. RADIATION BIOLOGY	<i>July 2001 - June 2002</i>	20		
e. RADIOPHARMACEUTICAL CHEMISTRY	<i>u</i>	30		
5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)				
ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
201Tl	4.0 mCi	MCP Hahnemann University Hospital		1. Perfusion imaging.
99mTc	40 mCi per patient			2. LV function.
<i>Goldmium line source (Gd-153)</i>				3. Full range of nuclear cardiology applications.

**EXHIBIT 3  
SUPPLEMENT B**

<b>SUPPLEMENT</b>	<b>U. S. NUCLEAR REGULATORY COMMISSION</b>
<b>PRECEPTOR STATEMENT</b>	

*Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.*

<b>1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS</b> FULL NAME <u>Bassam A. Roukoz, MD</u> STREET ADDRESS  CITY _____ STATE _____ ZIP CODE _____	<b>KEY TO COLUMN C</b> <b>PERSONAL PARTICIPATION SHOULD CONSIST OF:</b> 1-Supervised examination of patients to determine the suitability of isotope diagnosis and/or treatment and recommendation of prescribed dosage. 2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, safety measurements and plotting of data. 3-Adequate period of training to enable physician to manage and follow patients through diagnosis and/or course of treatment.
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**2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN**

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS <i>(Additional information or comments may be submitted in duplicate on separate sheets.)</i> D
	Thyroid scan		
	Thyroid uptake		
	Lung perfusion scan		
	Xenon ventilation study		
	Aerosol ventilation scan		
	Renal flow scan		
	Brain scan		
	Liver/spleen scan		
	Bone scan		
	Gastroesophageal study		
	LeVeen shunt study		
	Cystogram		
	Dacryocystogram		
	Cardiac perfusion scan.	7600	
	Cardiac stress ventriculogram	10	
	Cardiac rest ventriculogram	100	
	Gallium scan		

EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER  
*Bassam A. Roukoz, MD*

PRECEPTOR STATEMENT (Continued)

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 (Colloidal)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
As-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or I-192	INTERSTITIAL TREATMENT		
	TELETHERAPY TREATMENT		
Se-80	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	10	
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS	15	
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL/RADIOISOTOPE TRAINING

LOCATION	DATES	CLOCK HOURS OF EXPERI
MCP. Hahnemann University Hospitals Philadelphia, PA	7/1/98 - 6/30/02	> 1,000 hours

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

1. NAME OF SUPERVISOR <i>William A Van Decker MD</i>	5. PRECEPTOR'S SIGNATURE <i>William A Van Decker MD</i>
2. NAME OF INSTITUTION <i>MCP. Hahnemann University</i>	7. PRECEPTOR'S NAME (Please type or print) <i>William A. Van Decker MD</i>
6. MAILING ADDRESS <i>3300 Henry Ave Philadelphia, PA 19129</i>	<i>RAM # 37-30485-01 6/30/02</i>



Metro Heart Group of St. Louis, Inc.  
 12855 N. Forty Dr, Suite 300  
 St. Louis, MO 63141

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 FIRST CLASS



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Ms. Colleen Casey  
 United States Nuclear Regulatory Commission  
 Region III  
 Materials Licensing Section  
 2443 Warrenville Road, Suite 210  
 Lisle, IL 60532-4362



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 LFC

ZIP 60532

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