

Comprehensive Cardiovascular Care

Mahir Elder, M.D.

Asst. Program Director of Cardiac CT Angiogram
Asst. Clinical Chief of Cardiology, Ambulatory Services

Delair Gardi, M.D.

Director of Catheterization Lab, Harper Hospital
Board Certified in Cardiology/ Interventional Cardiology

August 23, 2007

UNITED STATES NUCLEAR REGULATORY COMMISSION

Region III, Materials Licensing Section
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352

Re: Amendment of NRC License No. 21-32562-01
Add Authorized User

Dear Sir/Madam:

We wish to provide the following information, in an effort to amend our NRC license.

The purpose of this letter is to notify you of the addition of a authorized user and to amend our current NRC license.

Please add the following physician to our current NRC license.

Mahir Elder, MD. Group 35.200 (Cardiac Procedures Only)

We have enclosed a copy of his preceptor statements and a copy of his State of Michigan license to practice medicine.

If you have any questions, please contact our physicist by phone at (734) 662-3197 or by email at jbotti@mpcphysics.com.

Respectfully Yours,

James M. Botti, MS
Board Certified, ABR, ABMP
Radiation Safety Officer

Enclosures

RECEIVED AUG 29 2007

Harper Professional Building

4160 John R.
Suite 510
Detroit, MI 48201
313-993-7777
313-993-2563 Fax

E-mail
hvp_dearborn@hotmail.com

Dearborn Professional Building

2021 Monroe
Suite 203
Dearborn, MI 48124
313-581-3600
313-216-9255 Fax

**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: 10/31/2008

Name of Proposed Authorized User

Mahir Elder M.D.

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	See additional preceptor form		
Radiation protection	See additional preceptor form		
Mathematics pertaining to the use and measurement of radioactivity	See additional preceptor form		
Chemistry of byproduct material for medical use (<i>not required for 35.590</i>)	See additional preceptor form		
Radiation biology	See additional preceptor form		

Total Hours of Training:

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:	>700Hours
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	NRC Licence # 21-26306-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/02- 6/30/05
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	NRC Licence # 21-26306-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/02- 6/30/05

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	NRC Licence # 21-26306-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/02- 6/30/05
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	NRC Licence # 21-26306-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/02- 6/30/05
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	NRC Licence # 21-26306-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/02- 6/30/05
Administering dosages of radioactive drugs to patients or human research subjects	NRC Licence # 21-26306-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/02- 6/30/05
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	Harper Hospital Detroit, Michigan	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/02- 6/30/05

Supervising Individual

Frank M. Fayz, M.D.

License/Permit Number listing supervising individual as an authorized user

NRC Licence # 21-26306-01

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)

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 Mahir Elder M.D. 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 Frank M. Fayz M.D.	Signature 	Telephone Number 313-581-3000	Date 8/17/2007
License/Permit Number/Facility Name NRC # 21-26306-01, Fairview Radiology			

FAIRVIEW RADIOLOGY

ACCREDITED BY AMERICAN COLLEGE OF RADIOLOGY IN MAMMOGRAPHY

AFFILIATED PHYSICIAN OF THE CLEVELAND CLINIC FOUNDATION

FRANK M. FAYZ, M.D.

Diplomate American Board of Radiology

- CT Scan
- Nuclear Medicine
- Nuclear Cardiology/Stress Lab
- Bone Mineral Densitometry

- General Radiology
- Fluoroscopy
- Mammography
- MRI/MRA

- Ultrasound
- Transrectal Ultrasound
- Echo Cardiography
- Color Flow Doppler

March 20, 2007

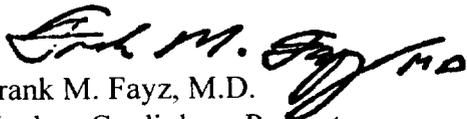
Certification Board in Nuclear Cardiology

Re: **Mahir Elder, M.D.**

To Whom it May Concern:

This letter is to confirm that Mahir Elder, M.D. has completed a training program in nuclear cardiology that meets the requirements for Level 2 training as outlined in the ACC/ASNC COCATS guidelines (revised 2006). Dr. Mahir Elder is competent to independently function as an authorized user under 10CFR35.290 uses.

Sincerely yours,



Frank M. Fayz, M.D.
Nuclear Cardiology Preceptor
NRC authorized user #21-26306-01
FMF/cag

Revised

5245 Schaefer Road, Dearborn, MI 48126 • 313/581-3000

www.fairviewradiology.com



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AFFILIATED PHYSICIAN OF THE CLEVELAND CLINIC FOUNDATION

FRANK M. FAYZ, M.D.

Diplomate American Board of Radiology

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- Ultrasound
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- Echo Cardiography
- Color Flow Doppler

March 20, 2007

Certification Board in Nuclear Cardiology

Re: **Mahir Elder, M.D.**

To Whom it May Concern:

This letter is to confirm that Mahir Elder, M.D. has gained supervised clinical and work experience at Harper University Hospital in nuclear cardiology. The preceptorship began 7-1-02 and continued through 6-30-05. During this period, Dr. Elder actively participated in at least the following number of procedures:

- 700 Sestamibi stress and rest imaging procedures with gated acquisition
- 20 Thallium rest imaging/viability procedures
- 20 Rest Tc-99m radionuclide ventriculography

During this time Dr. Elder also acquired experience in health, physics, radiopharmaceutical preparation, technical and administrative procedures at our facility, as well as general operations as stipulated by our license conditions. Dr. Elder also gained experience in the preparation of radiopharmaceutical kits during this period and eluded to Tc-99m/Mo-99 generator. The hours of nuclear cardiology clinical and work experience accrued during this period total 800 hours. He has additionally received 200 hours of didactic training and has met the criteria established by the Nuclear Regulatory Commission for licensing purposes.

As stipulated by the guidelines for training in nuclear cardiology adult cardiovascular medicine by the American Society of Nuclear Cardiology, Dr. Elder has completed 4 months of specialized training in nuclear perfusion imaging and interpretation, has experience in correlating catheterization/angiographic data with radionuclide-derived data in over fifty patients.

Dr. Elder has completed a training program equivalent to Level 2 training in nuclear cardiology that meets the requirements as outlined in the ACC/ASNC COCATS guidelines (revised 2006).

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AFFILIATED PHYSICIAN OF THE CLEVELAND CLINIC FOUNDATION

FRANK M. FAYZ, M.D.

Diplomate American Board of Radiology

- CT Scan
- Nuclear Medicine
- Nuclear Cardiology/Stress Lab
- Bone Mineral Densitometry
- General Radiology
- Fluoroscopy
- Mammography
- MRI/MRA
- Ultrasound
- Transrectal Ultrasound
- Echo Cardiography
- Color Flow Doppler

Dr. Elder is competent to independently function as an authorized user under NRC 10 35.290 uses.

Sincerely yours,

A handwritten signature in black ink that reads 'Frank M. Fayz, M.D.' with a stylized flourish at the end.

Frank M. Fayz, M.D.
Nuclear Cardiology Preceptor
NRC authorized user #21-26306-01
FMF/cag

Revised

NRC Form 313M SUPPLEMENT A
(8-86)

U.S. NUCLEAR REGULATORY COMMISSION

**TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER**

Approved by OMB
3150-0041
Expires 06-30-89

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER

Mahr Elder, MD

2. STATE OR
TERRITORY IN WHICH
LICENSED TO
PRACTICE MEDICINE
Michigan

3. CERTIFICATION

SPECIALITY 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	
		Lecture/ Laboratory Course/ (Hours) C	Supervised Laboratory Experience (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Harper Hospital - Detroit, MI 10/15/03 - 05/10/04	100	40
b. RADIATION PROTECTION	Harper Hospital - Detroit, MI 10/15/03 - 05/10/04	30	8
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Harper Hospital - Detroit, MI 10/15/03 - 05/10/04	20	
d. RADIATION BIOLOGY	Harper Hospital - Detroit, MI 10/15/03 - 05/10/04	20	
e. RADIOPHARMACEUTICAL CHEMISTRY	Harper Hospital - Detroit, MI 10/15/03 - 05/10/04	30	

5. EXPERIENCE WITH RADIATION (Actual use of Radioisotopes or Equivalent Experience)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Tc-99m	1000	Harper Hospital - Detroit, MI	10/15/03 - 05/10/04	Diagnostic
Mo-99	1000	Harper Hospital - Detroit, MI	10/15/03 - 05/10/04	Diagnostic
Cs-137	0.250	Harper Hospital - Detroit, MI	10/15/03 - 05/10/04	Diagnostic
Ba-133	0.250	Harper Hospital - Detroit, MI	10/15/03 - 05/10/04	Diagnostic

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City Detroit State MI ZIP 48221

2 Year Internal Billing Reference

3 To
Recipient's Name US NRC Phone
Company Region III, Materials handling
Recipient's Address 2443 Wauernville Rd. Suite 210
City hiale State FL ZIP 33012-4352



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33 HOLD at Recipient Location

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10 Direct Signature
11 Indirect Signature

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