

## MATERIALS LICENSE

Amendment No. 02

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, 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 byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

302421

## Licensee

In accordance with the letter dated  
March 11, 19973. License Number 21-26393-01 is amended  
in its entirety to read as follows:

1. Eastlake Cardiovascular Associates

2. 25990 Kelly Road, Suite 4  
Roseville, Michigan 48066

4. Expiration Date April 30, 2002

5. Docket or  
Reference No. 030-327006. Byproduct, Source, and/or  
Special Nuclear Material7. Chemical and/or Physical  
Form8. Maximum Amount that Licensee  
May Possess at Any One Time  
Under This LicenseA. Any byproduct  
material identified  
in 10 CFR 35.200A. Any  
radiopharmaceutical  
identified in 10 CFR  
35.200 (excluding  
generators) limited  
to cardiovascular  
clinical procedures

A. As needed

9. Authorized Use:

A. Medical use described in 10 CFR 35.200 (excluding generators) limited to  
cardiovascular clinical procedures.CONDITIONS10. Location of Use: 25990 Kelly Road, Suite 4, Roseville, Michigan and  
24211 Little Mack, St. Clair Shores, Michigan.

11. Radiation Safety Officer: Georges B. Ghafari, M.D.



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MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License Number

21-26393-01

Docket or Reference Number

030-32700

Amendment No. 02

12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users

Material and Use

- |                             |   |
|-----------------------------|---|
| A. Georges B. Ghafari, M.D. | 10 CFR 35.200 (excluding generators) limited to cardiovascular clinical procedures. |
| B. Joan S. Crawford, D.O.   | 10 CFR 35.200 (excluding generators) limited to cardiovascular clinical procedures. |
| C. Thomas P. Davis, M.D.    | 10 CFR 35.200 (excluding generators) limited to cardiovascular clinical procedures. |

13. 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 10 CFR 30.35(d) for establishing decommissioning financial assurance.
14. 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 10 CFR 35.31. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated March 3, 1992; and
- B. Letters dated September 27, 1993 and March 11, 1997.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

4/3/97

By

*Michael F. Webb*

Nuclear Materials Licensing Branch, Region III

COPY

(FOR LFMS USE)  
INFORMATION FROM LTS

BETWEEN:

License Fee Management Branch, ARM  
and  
Regional Licensing Sections

Program Code: 02201  
Status Code: 0  
Fee Category: 7C  
Exp. Date: 20020430  
Fee Comments:  
Decom Fin Assur Req'd N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: EASTLAKE CARDIOVASCULAR ASSOC., P.C.  
Received Date: 970317  
Docket No: 3032700  
Control No.: 302421  
License No.: 21-26393-01  
Action Type: Amendment

2. FEE ATTACHED

Amount: 1400  
Check No.: 7625

3. COMMENTS

Signed  
Date

D. Hersey  
3-18-97

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered)

1. Fee Category and Amount:

7C \$440

2. Correct Fee Paid. Application may be processed for:

Amendment  
Renewal  
License

3. OTHER

Signed  
Date

SC  
3/20/97

MAR 24 1997

Log	Mar 8 TL
Remitter	
Check No.	7625
Amount	\$1400 (440) Refund \$960
Fee Category	7C
Type of Fee	Amnd
Date Check Rec'd	3/19/97
Date Completed	3/20/97
By	SC

1997 MAR 19 AM 11:24

## APPLICATION FOR MATERIAL LICENSE

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

## APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY  
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS  
U.S. NUCLEAR REGULATORY COMMISSION  
WASHINGTON, DC 20555-0001

## ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

## IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND,  
MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA,  
RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION  
NUCLEAR MATERIALS SAFETY BRANCH  
U.S. NUCLEAR REGULATORY COMMISSION, REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO  
RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,  
SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION  
U.S. NUCLEAR REGULATORY COMMISSION, REGION II  
101 MARIETTA STREET, NW, SUITE 2900  
ATLANTA, GA 30323-0199

## IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN,  
SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION  
U.S. NUCLEAR REGULATORY COMMISSION, REGION III  
801 WARRENVILLE RD.  
LISLE, IL 60532-4351

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW  
MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING,  
SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION  
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV  
611 RYAN PLAZA DRIVE, SUITE 400  
ARLINGTON, TX 76011-8064

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S.  
TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

RADIOACTIVE MATERIALS SAFETY BRANCH  
U.S. NUCLEAR REGULATORY COMMISSION, REGION V  
1450 MARIA LANE  
WALNUT CREEK, CA 94596-5368

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

## 1. THIS IS AN APPLICATION FOR (Check appropriate item)



A. NEW LICENSE

B. AMENDMENT TO LICENSE NUMBER

C. ~~RENEWAL~~ OF LICENSE NUMBER 21-26393-01

## 2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip code)

Eastlake Cardiovascular Assoc., P.C.  
25990 Kelly, Suite 4  
Roseville, MI 48066

## 3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Same as Item #2

## 4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Frederick Urban

TELEPHONE NUMBER

(216)982-1110

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

## 5. RADIOACTIVE MATERIAL

a. Element and mass number, b. chemical and/or physical form, and c. maximum amount  
which will be possessed at any one time.

## 6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

## 7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

## 8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

## 9. FACILITIES AND EQUIPMENT

## 10. RADIATION SAFETY PROGRAM

## 11. WASTE MANAGEMENT

## 12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY

7C

AMOUNT

ENCLOSED \$1400.00

## 13. CERTIFICATION (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

## CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

x GEORGES B. GHAFARI M.D.

## SIGNATURE

x George B. Ghafari

## DATE

3/17/97

## FOR NRC USE ONLY

## TYPE OF FEE

## FEE LOG

## FEE CATEGORY

## AMOUNT RECEIVED

## CHECK NUMBER

## COMMENTS

\$

## APPROVED BY

## DATE

302421  
pm: 3-12-97

MAR 17 1997

REGION III



EASTLAKE CARDIOVASCULAR ASSOCIATES, P.C.  
25990 KELLY ROAD, SUITE 4  
ROSEVILLE, MI 48066  
TELEPHONE: (810) 771-3400  
FAX: (810) 771-1061

VICTOR ABIRAGI, M.D.  
ROBERT M. CLEARY, M.D.  
JOAN S. CRAWFORD, D.O.  
THOMAS P. DAVIS, M.D.

GEORGES B. GHAFARI, M.D.  
GEORGE B. GHANEM, M.D.  
THOMAS A. LALONDE, M.D.

March 11, 1997

Materials and Licensing Section  
U.S. Nuclear Regulatory Commission, Region III  
801 Warrensville Road  
Lisle, IL 60532-4351

**RE: NRC LICENSE #21-26393-01**

To Whom It May Concern:

The purpose of this correspondence is to request that our nuclear materials license be renewed with the following changes:

AUTHORIZED USERS

- Add Joan Crawford, D.O. for 10 CFR 35.100 and 35.200 authorization. Dr. Crawford is listed as an authorized user on NRC License #21-26635-01 (see attached documentation).
- Add Thomas P. Davis, M.D. for 10 CFR 35.100 and 35.200 authorization. See enclosed documentation for evidence of his training and experience.

LOCATION OF USE CHANGE

- We will be moving our operations to the following address  
Eastlake Cardiovascular Associates, P.C.  
24211 Little Mack  
St. Clair Shores, Michigan 48080
- The move will take place in July or August 1997. Please see enclosed map of the new department.
- Before the equipment is moved from the Roseville, Michigan facility, it will be monitored for contamination. This survey will be documented and kept on file for review.
- A complete decommissioning survey will be performed on the Roseville, Michigan Nuclear Medicine Department. This survey will consist of wipe tests for removable contamination as well as surveys with a radiation detection device.

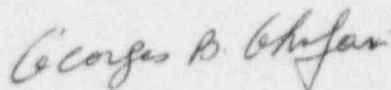
MAR 17 1997

U.S. Nuclear Regulatory Commission  
March 11, 1997  
Page Two

- This facility will be free from any removable contamination. The radiation detection surveys will yield nothing above normal background levels. These two criteria must be met prior to release of that area of the building where radioactive materials were used or stored. These surveys will be documented and placed on file for review.

Any questions regarding this correspondence may be directed to me at (810)771-1260 or Frederick W. Urban at (216)982-1110.

Sincerely,

A handwritten signature in cursive script, reading "Georges B. Ghafari".

Georges B. Ghafari, M.D., F.A.C.C.

GBG/kg

**MATERIALS LICENSE**

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, 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 byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee

1. Consultants in Cardiology, P.C.

3. License Number 21-26635-01

2. 29255 Northwestern Hwy.  
Suite 201  
Southfield, MI 48034

4. Expiration Date March 31, 2000

5. Docket or Reference No. 030-33785

6. Byproduct, 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. Any byproduct material identified in 10 CFR 35.200

A. Any radiopharmaceutical identified in 10 CFR 35.200 (excluding generators, xenon, and radioactive aerosols) limited to cardiovascular clinical procedures

A. As needed

9. Authorized Use:

A. Medical use described in 10 CFR 35.200 (excluding generators, xenon, and radioactive aerosols) limited to cardiovascular clinical procedures.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 29255 Northwestern Hwy., Suite 201, Southfield, Michigan.

11. Radiation Safety Officer: Joan Crawford, D.O.

MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License number  
21-26635-01  
Docket or Reference number  
030-33785

12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users

Joan Crawford, D.O.

Material and Use

10 CFR 35.200 (excluding generators, xenon, and radioactive aerosols) limited to cardiovascular clinical procedures.

13. The licensee may not possess and use materials authorized in Items 6, 7, and 8 until:
1. The licensee has constructed the facilities and obtained the equipment described in the application and supporting documentation; and
  2. The U. S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Materials Licensing Section, 801 Warrenville Road, Lisle, IL 60532-4351 has been notified that activities authorized by the license will be initiated.
14. Within 30 days of the date of a decision not to complete the facility, acquire equipment, or possess and use authorized material, the licensee must notify the Commission in writing, of the decision.
15. The licensee is not required to have a Radiation Safety Committee described in 10 - CFR 35.22. The Radiation Safety Officer may make radiation safety program changes permitted by 10 CFR 35.31 with the advice and consent of the licensee's management.
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 10 CFR 35.31. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated February 1, 1995; and
  - B. Letter dated April 18, 1995.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 26 APRIL 1995

By William P. Reinhold  
Materials Licensing Section, Region III



**EXHIBIT 3**  
**SUPPLEMENT B**

SUPPLEMENT		U. S. NUCLEAR REGULATORY COMMISSION	
PRECEPTOR STATEMENT			
<p><i>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.</i></p>			
<b>1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS</b> FULL NAME <u>THOMAS P. DAVIS, M.D.</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 for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage. 2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data. 3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.	
<b>2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN</b>			
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
	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		
	Decryocystogram		
	Cardiac perfusion scan.	1500	
	Cardiac stress ventriculogram		
Cardiac rest ventriculogram	50		
Ballon scan			

PROPOSED PHYSICIAN USER			
PRECEPTOR STATEMENT (Continued)			
2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)			
ISOTOPE A	CONDITIONS DIAGNOSIS 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 (Sodium)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 (Cobalt)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Co-137	INTERSTITIAL TREATMENT INTRACAVITARY TREATMENT		
I-125 or Ir-192 Co-60 or Co-137	INTERSTITIAL TREATMENT TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION	10	
Mo-99/ Tc-99m	GENERATOR	10	
Sr-90/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING	
LOCATION	DATES      CLOCK HOURS OF EXPERIENCE
	Jan 93 - Jan 97      1,250 hrs
	Jan 90 - Jan 93 HFA      300 hrs

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:		5. PRECEPTOR'S SIGNATURE	
a. NAME OF SUPERVISOR GEORGES B GHAFARI		George B. Ghafari	
b. NAME OF INSTITUTION EASTLAKE CARDIOVASCULAR ASSOC PC		6. PRECEPTOR'S NAME (Print type or print)	
c. MAILING ADDRESS 25990 KELLY, SUITE 4		GEORGES B GHAFARI	
d. CITY ROSEVILLE, MI 48066		7. DATE	
e. MATERIALS LICENSE NUMBER(S) 21-26393-01		1-20-97	

# NUCLEAR MEDICAL EDUCATION PROGRAM

## Affidavit of Academic Completion and Competency

*This document is to attest that*

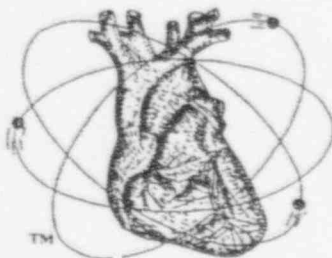
THOMAS P. DAVIS, M.D.

*has successfully completed the didactic program*

### MEDICAL RADIATION PROTECTION

*and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.*

*This program provides the following levels of accomplishment:*

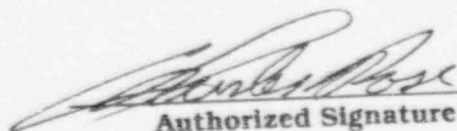


- 50 Didactic Instructional Hours (DIH)  
(In compliance with 10CFR35)
- 5 Continuing Education Units (CEU)
- 50 Continuing Medical Education (CME)
- 50 Technical/Professional Credit specified by the  
American Pharmaceutical Association and the  
American Association of Health Physicists\*

\*additional documentation will be provided to Regulatory Agencies upon participant request



13 June 1992  
Date Class Commenced

  
Authorized Signature

073014  
Affidavit of Competency

## INSTITUTE FOR NUCLEAR MEDICAL EDUCATION

5785 Arapahoe, Suite D, Boulder, CO 80303 800-548-4024

Certified as an Approved Educational Institution by the Department of Higher Education, State of Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education.

# NUCLEAR MEDICAL EDUCATION PROGRAM

## Affidavit of Academic Completion and Competency

*This document is to attest that*

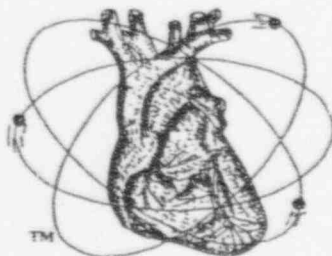
THOMAS P. DAVIS, M.D.

*has successfully completed the didactic program*

### RADIOPHARMACEUTICALS AND CHEMISTRY

*and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.*

*This program provides the following levels of accomplishment:*



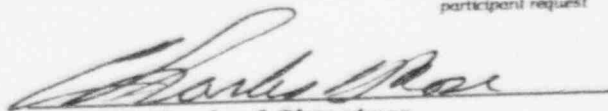
- 50 Didactic Instructional Hours (DIH)  
(In compliance with 10CFR35)
- 5 Continuing Education Units (CEU)
- 50 Continuing Medical Education (CME)
- 50 Technical/Professional Credit specified by the  
American Pharmaceutical Association and the  
American Association of Health Physicists\*

\*additional documentation will be provided to Regulatory Agencies upon participant request



17 June 1992

**Date Class Commenced**

  
**Authorized Signature**

078015

**Affidavit of Competency**

## INSTITUTE FOR NUCLEAR MEDICAL EDUCATION

5785 Arapahoe, Suite D, Boulder, CO 80303 800-548-4024

Certified as an Approved Educational Institution by the Department of Higher Education, State of Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education.



# NUCLEAR MEDICAL EDUCATION PROGRAM

## Affidavit of Academic Completion and Competency

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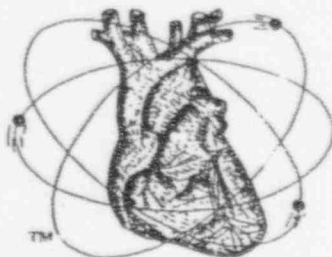
THOMAS P. DAVIS, M.D.,

*has successfully completed the didactic program*

### MEDICAL RADIATION INSTRUMENTATION

*and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.*

*This program provides the following levels of accomplishment:*



- 50 Didactic Instructional Hours (I\*H)  
(In compliance with 10CFR35)
- 5 Continuing Education Units (CEU)
- 50 Continuing Medical Education (CME)
- 50 Technical/Professional Credit specified by the  
American Pharmaceutical Association and the  
American Association of Health Physicists\*

\*Additional documentation will be provided to Regulatory Agencies upon participant request

11 NOVEMBER 1992

Date Class Commenced

189383

Authorized Signature

Affidavit of Competency

## INSTITUTE FOR NUCLEAR MEDICAL EDUCATION

5785 Arapahoe, Suite D, Boulder, CO 80303 800-548-4024

Certified as an Approved Educational Institution by the Department of Higher Education, State of Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education.

# NUCLEAR MEDICAL EDUCATION PROGRAM

## Affidavit of Academic Completion and Competency

*This document is to attest that*

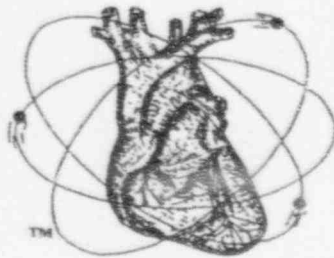
THOMAS P. DAVIS, M.D.

*has successfully completed the didactic program*

### PRINCIPLES OF RADIATION PHYSICS

*and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.*

*This program provides the following levels of accomplishment:*



- 50 Didactic Instructional Hours (DIH)  
(In compliance with 10CFR35)
- 5 Continuing Education Units (CEU)
- 50 Continuing Medical Education (CME)
- 50 Technical/Professional Credit specified by the  
American Pharmaceutical Association and the  
American Association of Health Physicists\*

\*Additional documentation will be provided to Regulatory Agencies upon participant request

7 NOVEMBER 1992  
Date Class Commenced

189372

Authorized Signature

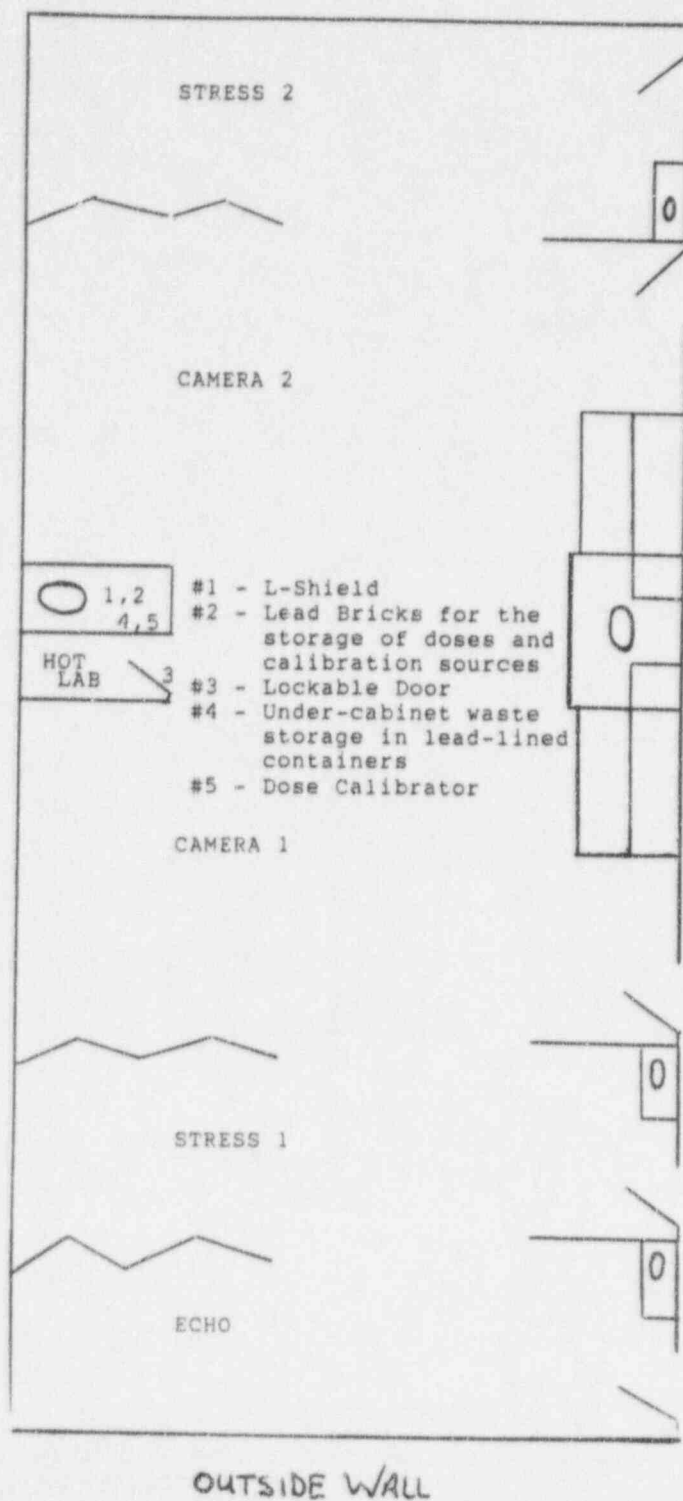
Affidavit of Competency

## INSTITUTE FOR NUCLEAR MEDICAL EDUCATION

5785 Arapahoe, Suite D, Boulder, CO 80303 800-548-4024

Certified as an Approved Educational Institution by the Department of Higher Education, State of Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education.

OUTSIDE WALL



HALLWAY

**DIVISION OF ACCOUNTING AND FINANCE  
REQUEST FOR REFUND TO EMPLOYEE/VENDOR**

THE EMPLOYEE/VENDOR IDENTIFIED BELOW HAS OVERPAID THE NUCLEAR REGULATORY  
COMMISSION FOR GOODS AND/OR SERVICES PROVIDED AND IS DUE A REFUND

EMPLOYEE/VENDOR/PAYEE CODE: \_\_\_\_\_

NAME: Eastlake Cardiovascular Assoc., P.C.

ADDRESS: Attn: George B. Ghafari, M.D.

ADDRESS: 25940 Kelly Suite 4

CITY: Rossville STATE: IN ZIP: 48066

TRANS CODE: PX

TRANS TYPE: FE FUND: X5280 JOB CODE: \_\_\_\_\_ AMOUNT: \$960<sup>00</sup>

TRANS TYPE: IR FUND: R1435 JOB CODE: INTR AMOUNT: \_\_\_\_\_

TRANS TYPE: IR FUND: R1099 JOB CODE: ADCH AMOUNT: \_\_\_\_\_

TRANS TYPE: IR FUND: R1099 JOB CODE: FINE AMOUNT: \_\_\_\_\_

TOTAL REFUND AMOUNT: \$960<sup>00</sup>

COMMENTS: Lic # 26393-01/CK 7625/yr  
3/11/97 rest

(Limit comments to 40 characters, including spaces)

PREPARED BY: Shirley Crutchfield DATE: March 20, 1997

AUTHORIZED BY: Sandra Kimberly DATE: 3/20/97

ORIGINAL INV. NO: \_\_\_\_\_ DATE PAID: \_\_\_\_\_ AMOUNT: \_\_\_\_\_

REFUND ENTERED INTO COLLECT BY: \_\_\_\_\_

REFUND DETERMINED BY: \_\_\_\_\_ DATE: \_\_\_\_\_

Mar 8 III  
CK 7625 STA 3/11/97 \$1400  
AND 7C \$440  
304421

PLEASE ATTACH APPROPRIATE SUPPORTING DOCUMENTATION



APR 04 1997

Georges B. Ghafari, M.D.  
Radiation Safety Officer  
Eastlake Cardiovascular Associates  
25990 Kelly Road, Suite 4  
Roseville, MI 48066

Dear Dr. Ghafari:

This refers to your letter dated March 11, 1997, and to our telephone conversation with your consultant, Frederick Urban, on March 24, 1997.

Enclosed is Amendment No. 02 to your NRC Material License No. 21-26393-01 in accordance with your request. As discussed with Mr. Urban, Drs. Crawford and I have been added as Authorized Users for material and use per 10 CFR 35.200 (limited to cardiovascular clinical procedures), and the new facility in St. Clair Shores has been added as a location of use.

Please be advised that we cannot authorize you to release your old nuclear medicine facility in Roseville for unrestricted use (even by other members of your staff) until we have received and reviewed a copy of the results of your close-out survey. The survey should consist of exposure rate measurements to show that all sources of radioactive material have been removed, and contamination checks of areas where radioactive materials were used or stored. Average radiation levels associated with surface contamination and removable contamination should not exceed those specified in the enclosed decontamination guide. Please submit the following information with your close-out survey:

- A. A diagram of your old facility with survey and wipe test results keyed to specific locations.
- B. The name of the person performing the survey.
- C. The date the survey was performed.
- D. The instrument(s) used for exposure rate measurements and for analysis of the wipes.

302421

E. Background readings.

F. The date that the survey instrument was last calibrated.

Please refer to the close-out survey as additional information to Control Number 302421.

Your license was also updated in accordance with current NRC policy. Specifically: 1) the previous License Condition No. 13 was dropped since it has been superseded by NRC regulations, and 2) a new License Condition (No. 13) was added which restricts the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

Please review the enclosed document carefully and 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 be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC, in writing, within 30 days:
  - a. When an authorized user or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
  - b. When the mailing address listed on the license changes. (No fee is required if the location of byproduct material remains the same.)
3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

4. Request and obtain a license amendment before you:
  - a. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;
  - b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;
  - c. Change Radiation Safety Officers;
  - d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
  - e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
  - f. Change ownership of your organization.
5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

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

G. Ghafari

-4-

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,

Original Signed By  
Michael F. Weber  
Nuclear Materials Licensing Branch

License No. 21-26333-01  
Docket No. 030-32700

Enclosures:

1. Amendment No. 02
2. Decontamination Guidelines

DOCUMENT NAME: M:\03032700.CL7

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII	C							
NAME	MFWeber:brt								
DATE	04/3/97								

OFFICIAL RECORD COPY



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
801 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4351  
630-829-9887 (phone), 630-515-1259 (fax)

CONVERSATION RECORD

TIME

3:00 pm

DATE

3/24/97

NAME OF PERSON(S) CONTACTED

ORGANIZATION

TELEPHONE NO.

Rick Urban, consultant

Eastlake Cardiovascular Assoc., P.C.

216-982-1110

SUBJECT

Amendment request (Control No. 302421)

SUMMARY

I asked about the need for 35.100 and full 35.200 authorizations. I pointed out that the licensee is currently authorized for only 35.200 materials, and that Drs. Ghafari and Davis have experience in cardiovascular procedures only, thus their 35.200 authorizations would be limited to cardiovascular procedures.

Mr. Urban said the request should be for 35.200 only, limited to cardiovascular procedures.

ACTION REQUIRED

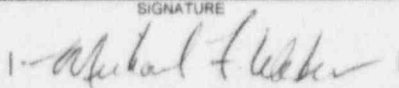
Grant amendment.

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Michael F. Weber



3/24/97



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
801 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4351

March 18, 1997

Georges B. Ghafari, M.D.  
Radiation Safety Officer  
Eastlake Cardiovascular Associates, P.C.  
25990 Kelly Road, Suite 4  
Roseville, MI 48066

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE  
(Letter & Application Dated 03/11/97)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

☐ New License                      ☒ Amendment                      ☐ Renewal  
☐ Termination                      ☐ Auth User (Amendment not required)                      ☐ Other\_\_

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is routine (see 1-3 below, as applicable).

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.
2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.
3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 302421  
License No. 21-26393-01