

REGIONAL CARDIOLOGY ASSOCIATES, P.L.C.

Radwan Alkiek, M.D., F.A.C.C.
Omar Bakr, M.D., F.A.C.C.
Hameem Changezi, M.D., F.A.C.C., F.S.C.A.I.
Gail F. Dawson, M.D., M.S., F.A.A.E.P.
David Dobies, M.D., F.A.C.C., F.S.C.A.I.
Vuong DuThinh, M.D., Ph.D., F.A.C.P., F.A.C.C.
Imad Issawi, M.D., F.A.C.C., F.S.C.A.I.
James Kure, M.D., F.A.C.C.
Paul Lafia, M.D., F.A.C.C.
Jeffrey Ledis, D.O., F.A.C.C.
Ramesh Misra, M.D., F.A.C.C., F.S.C.A.I.
Abdufatah Osman, M.D., F.A.C.C., F.S.C.A.I.
Gary Weber, D.O., F.A.C.C.

August 1, 2008

Nuclear Regulatory Commission
Region III
Materials Licensing Branch
2443 Warrenville Road, Ste 210
Lisle, IL 60532-4352

RE: (#21-32298-01) Add New Authorized User

We would like to request an amendment to our license – to add new Authorized User to our license at Regional Cardiology Associates, PLC, 3399 Pollock Road, Grand Blanc, MI 48439

The appropriate Form 313d – preceptor statement, CV, Board Certificate, are attached.

If there are any further questions, please contact our nuclear medical physicist, Laura T. Smith, MS, DABR at (586) 716-8885.

Thank you,



Imad Issawi, M.D., F.A.C.C., F.S.C.A.I.
Radiation Safety Officer
Authorized User

RECEIVED AUG 07 2008

Grand Blanc

3399 Pollock
Grand Blanc, MI 48439-8070
Phone: 810-603-0170
Fax: 810-603-2370

Clarkston

5625 Water Tower Place
Suite 270
Clarkston, MI 48346
Phone: 248-620-4270
Fax: 248-620-4272

Lapeer

944 Baldwin Road
Suite B
Lapeer, MI 48446-3089
Phone: 810-603-0170
Fax: 810-245-3833

APPLICATION FOR MATERIALS LICENSE

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:	IF YOU ARE LOCATED IN:
DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001	ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:
ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:	MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, IL 60532-4352
IF YOU ARE LOCATED IN:	
ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:	ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:
LICENSING ASSISTANCE TEAM DIVISION OF NUCLEAR MATERIALS SAFETY U.S. NUCLEAR REGULATORY COMMISSION, REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PA 19406-1415	NUCLEAR MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 612 E. LAMAR BOULEVARD, SUITE 400 ARLINGTON, TX 76011-4125

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) <input type="checkbox"/> A. NEW LICENSE <input checked="" type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER 21-32298-01 <input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER	2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code) Regional Cardiology Associates 3399 Pollock Rd Grand Blanc, MI 48439
3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED Regional Cardiology Associates 3399 Pollock Rd Grand Blanc, MI 48439	4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION Laura T. Smith - MS - Physicist TELEPHONE NUMBER (586) 215-5947

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. LICENSE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY AMOUNT ENCLOSED \$ 0.00

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 Imad Issawi, MD, FACR, Radiation Safety Officer	SIGNATURE 	DATE 8/11/08
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FOR NRC/USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED \$	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	

**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

Gail F. Dawson

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

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:

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		Yes No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		Yes No	

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		Yes	
		No	
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

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)

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 Gail F. Dawson 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 Gail F. Dawson 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

Imad Issawi MD

I. Issawi

810-603-0170

8/1/08

License/Permit Number/Facility Name

21-32298-01 Regional Cardiology

Curriculum Vita

Gail F. Dawson, MD MS FAAEP

10140 Halsey
Grand Blanc, MI 48439

PROFESSIONAL TRAINING

Medical school: University of Michigan Medical School
Degree: M.D. with Honors in Embryology, General Surgery,
Orthopedic Surgery, Ob/Gyn, Cardiology, Pediatrics,
Surgical Intensive Care, Emergency Medicine 1982

Internship/residency: St. Joseph Mercy Hospital, Ann Arbor, MI
Dept. of Surgery 1982-1984
McLaren Regional Medical Center, Flint MI
Dept of Internal Medicine 2000-2003

Fellowship Wayne State University, Detroit MI
Division of Cardiology 2004 – 2007

POSTGRADUATE TRAINING Master of Science in Clinical Research Design and Statistical
Analysis, University of Michigan, 4/01

CERTIFICATION Board Certified Cardiology 1/08
Board Certification in Emergency Medicine –BCEM 1998
Board Certification in Internal Medicine – ABIM 2004
Board Certification in Nuclear Cardiology – 10/06
Board Certification in Echocardiography – 7/07
Certification in BCLS, ACLS, PALS, ATLS

EMPLOYMENT Cardiologist with Regional Cardiology Associates, Grand Blanc, MI
10/07 – present
Staff Physician in Emergency Departments at McLaren,
Hurley, McAuley Health System in Ann Arbor, McPherson
Hospital, St. Joseph Hospital in Flint, Genesys 1984-1999

POSITIONS HELD Member, IRB, Genesys Hospital, Grand Blanc MI 1/08 - present
Medical Director, Plymouth Urgent Care, Plymouth, MI 1985-8
PALS instructor
Board Member, BCEM
Oral Board Examiner, Board Certification in Emer. Med

PROFESSIONAL SOCIETIES Fellow, Amer College Cardiology (by invitation, finalization pending)
Diplomate, Amer Assoc Physician Specialists – AAPS
Diplomate, American Board Internal Medicine – ABIM
Fellow, Amer Acad. Emer. Physicians – FAAEP
Member, American College of Physicians - ACP
Member, Genesee County Medical Society Member, Michigan State
Medical Society
Member, American Medical Women's Association - AMWA
Member, American College of Emergency Physicians - ACEP

RESEARCH/PUBLICATIONS Easy Interpretation of Biostatistics I am the sole author of this book

which presents the science of biostatistics in a concise, easy to understand approach. Publication began 5/08 by Elsevier Publication Co, Philadelphia, PA

“The Concept of Inferential Statistics Made Exceedingly Simple (...Because It Is!) in Genesee County Medical Society Journal, May 1999, p166-7.

Dawson GF, Lampman RM and Santiga JT. Effect of physical training on carbohydrate intolerance and insulin resistance in chemical diabetes. Clinical Research, 28:4 p798A, 1980.

Dawson, GF et al. Characterization of hyaluronic acid formed by normal and rheumatoid cells in cell culture (unpublished) 1978

Dawson GF Handbook of Splinting Techniques. A guide on proper splinting techniques of fractured extremities distributed by Emergency Physicians Medical Group, 1986.

CURRENT RESEARCH

Unusual causes of cardiogenic shock: A case report and review of the literature. Dawson G and Spears R

PRESENTATIONS

“Aortic Valve Replacement in Calcific Aortic Stenosis: When to Operate?” (oral presentation) MSU FAME Community Research Forum, Flint MI 4/02

“Pulmonary Sequestration: New Insights into Pathogenesis” (poster) Michigan Chapter ACP, Traverse City, MI 10/00

COMPETITIONS

“An Unusual Cause of Acute Respiratory Failure, Secondary to an Uncommon Presentation of Coronary Artery Occlusion.” Finalist, Michigan Cardiology Fellows Society Clinical Vignette Oral Competition, Detroit MI 8/01

“An Economic Analysis of Mitral Valve Repair in End Stage Congestive Heart Failure Compared to Medical Therapy.” Semi-finalist, (poster) Michigan Chapter ACC. Traverse City MI, 10/01

AWARDS

“Best Internal Medicine Resident, Post-Graduate Year 2”, McLaren Regional Medical Center, Flint, MI 2000-01

Nominated for Chief Resident in Second year of residency by fellow residents, but could not accept position since timing of contract was not consistent with fiscal year.

I have done basic molecular research, clinical intervention research, given community lectures to seniors and schoolchildren, and presented lectures to physicians and other health professionals on various medical topics. I am familiar with computer applications of Word, Power Point, and Excel. I have worked with SAS (a statistical software program) and Tree-Age (Economic Analysis software program).

I enjoy many types of outdoor activities and sports. Recently I have been competing in mini-triathlons.

Certification Board of Nuclear Cardiology

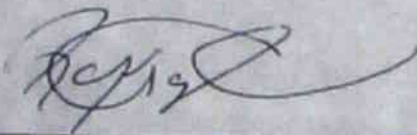
Incorporated 1996

Certifies That

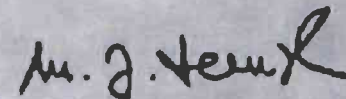
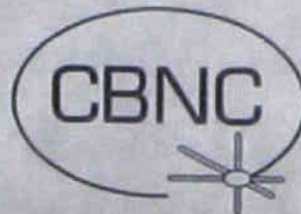
Gail F. Dawson, MD, MS, FAAEP

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD
FOR PHYSICIANS TRAINED IN THE UNITED STATES
AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION,
IS HEREBY DESIGNATED
A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF
NUCLEAR CARDIOLOGY

FOR THE PERIOD 2006 - 2016



President



Secretary



CERTIFICATE NUMBER: 4848

**REGIONAL CARDIOLOGY
ASSOCIATES, P.L.C.**

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Grand Blanc, MI 48439



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