

OSTEOPATHIC CARDIOLOGY ASSOCIATES
William A. Esper, D.O., F.A.C.O.I Kevin J. Mikielski, D.O.
4002 Schaper Avenue
Erie, PA 16508
(814) 866-2311

May 25, 2007

RM582

Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

03037180

Re. License No. 37-31143-01

To whom it may concern,

Please amend our license to name James V. Talano, M.D. as an authorized user.
Documentation of his training and experience is enclosed.

If you have any questions, please contact us or our consultant, David Close at 440-350-1242.

Sincerely,



William A. Esper, D.O.
Owner

2007 JUN 11 PM 1:00
RECEIVED
REGION I

140646

NMSS/RGN1 MATERIALS-002



American Radiology Services, Inc.

Centralized Scheduling
(239) 947-9329 • 1-888-AMERRAD

- ☐ Banyan Medical Center
1350 Tamiami Trail N.
Naples, FL 34102
Fax (239) 263-8189
- ☐ 9500 Bonita Beach Road, Suite 110
Bonita Springs, Florida 34135
Fax 239-444-1926

May 4, 2007

Dear Colleague,

I am an Authorized User listed on the Radioactive Materials License of: *American Radiology*
License # *3374-1*

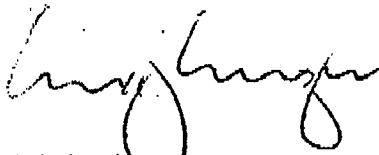
This communication is to confirm that James V. Talano, MD has successfully completed all training requirements set forth by the Nuclear Regulatory Commission section §35.290, paragraph c (1) from January 1st 2005 to May 1st 2007. I attest he has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under the NRC guidelines 35.200.

Dr. Talano has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. This training and experience included a minimum of the following:

- A. 1) 80 hours of classroom and laboratory training in the following areas:
- a) Radiation physics and instrumentation;
 - b) Radiation protection;
 - c) Mathematics pertaining to the use and measurement of radioactivity;
 - d) Chemistry of byproduct material for medical use;
 - e) Radiation biology
 - f) Generator Elution
- 2) Work experience, under the supervision of authorized user(s) (Mark Marzano, MD) which meet the requirements in §§ 35.290, involving:
- a) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - b) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - c) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

- d) Calculating, measuring, and safely preparing patient or human research subject dosages;
- e) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
- f) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
- g) Administering dosages of radioactive drugs to patients or human research subjects; and
- h) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radiomuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs

I am pleased to attest that Dr James V. Talano has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under the NRC regulations CFR 35.290.



Mark Marzano, MD
Director
American Radiology
Naples, FL



RADIOACTIVE MATERIALS LICENSE

Pursuant to Chapter 404, Florida Statutes, and Chapter 64E-5, Florida Administrative Code (F.A.C.), and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to receive, acquire, possess and transfer the radioactive material(s) designated below and to use such radioactive material(s) for the purposes and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the state of Florida Department of Health now or hereafter in effect and to any conditions specified below.

Licensee		3. License Number: 3374-1
1. Name: AMERICAN RADIOLOGY SERVICES, INC.	is hereby amended in its entirety, with reference to correspondence dated November 23, 2004 and January 17, 2005.	
2. Address: 671 Goodlette Road, Suite 200 Naples, FL 34102	Expiry Date: 5/31/2007	Category: 5C

- A. Any radioactive material described in section 64E-5.626, F.A.C. As necessary
- B. Any radioactive material described in section 64E-5.627, F.A.C., except gases, aerosols and generators. As necessary
- C. Technetium 99m C. Aerosol C. As necessary

- A. Any medical use described in section 64E-5.626, F.A.C.
- B. Any medical use described in section 64E-5.627, F.A.C., except gases, aerosols and generators.



C. To be used for pulmonary function studies as described in section 64E-5.627, F.A.C.

10. The authorized place of use is the licensee's facility located at the address in Item 2.

11. Failure to comply with the provisions of this license is a felony of the third degree pursuant to section 404.161, Florida Statutes. Also, violations may warrant an administrative fine of up to \$1,000.00 per violation per day pursuant to section 404.162, Florida Statutes.

12. A. The following individuals are authorized for the materials and uses as indicated:

64E-5.626 and 64E-5.627

Mark J. Marzani, M.D. ←

64E-5.626 and 64E-5.627 (X-ray generators)

Charles E. Newton, M.D.

B. The radiation

C. Radiologic facilities shall not use, store, administer radioactive materials or perform brachytherapy unless the licensee is under the direct supervision of an authorized user shall hold a valid certificate as required by section 64E-5.629, F.A.C.

13. Radioactive material transported for use in a facility shall be packaged, prepared for shipment, and transported in accordance with the rules of Federal Regulations and Chapter 64E-5, F.A.C.

14. Sealed sources containing licensed materials shall not be opened.

15. The licensee shall not authorize release from confinement for medical care any patient administered a radiopharmaceutical until:

A. The dose rate is less than 5 millirem (50 microsieverts) per hour at a distance of 1 meter; or

B. The amount of radioactive material in the patient is less than 30 millicuries.

16. The licensee shall implement the quality management program (QMP) as stated in Condition 17 and section 64E-5.611, F.A.C.

17. A. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, 8, and 9 of this license in accordance with statements, representations and procedures contained in the licensee's application dated February 16, 2002, signed by Mark J. Marzano, M.D., President, and correspondence dated:

May 13, 2002 (revised facility diagram), and
January 17, 2005 (delegation of authority – Mark Smith, Radiation Safety Officer) and
(new use location), all signed by Mark J. Marzano, M.D., President.

- B. The licensee shall comply with all applicable requirements of Chapter 64E-5, Florida Administrative Code, and the regulations shall supersede the licensee's statements in applications or correspondence if the statements are more restrictive than the regulations.



Bureau of Radiation Control

Issuance Date: JAN 26 2005

Willie R. Burgess
Willie R. Burgess
Environmental Specialist
4052 Bald Cypress Way – Bin C21
Tallahassee, FL 32399-1741
(850) 245-4545

A party whose substantial interest is affected by this order may petition for an administrative hearing pursuant to sections 120.609 and 120.67, Florida Statutes. Such proceedings are governed by Rule 28-105, Florida Administrative Code. A petition for administrative hearing must be in writing and must be received by the Agency Clerk for the Department, within twenty-one (21) days from the receipt of this order. The address of the Agency Clerk is: Agency Clerk, 4052 Bald Cypress Way, BIN # A02, Tallahassee, Florida 32399-1703. The Agency Clerk's facsimile number is 850-410-1449. A copy of the petition should also be sent to: Bureau Chief, Bureau of Radiation Control, 4052 Bald Cypress Way, BIN # C21, Tallahassee, FL 32399-1741. The Bureau Chief's facsimile number is 850-487-0436. Mediation is not available as an alternative remedy. Your failure to submit a petition for hearing within 21 days from receipt of this order will constitute a waiver of your right to an administrative hearing, and this order shall become a "final order." Should this order become a final order, a party who is adversely affected by it is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings may be commenced by filing one copy of a Notice of Appeal with the Agency Clerk of the Department of Health and a second copy, accompanied by the filing fees required by law, with the Court of Appeal in the appropriate District Court. The notice must be filed within 30 days of rendition of the final order.

This is to acknowledge the receipt of your letter/application dated

5/25/2007, and to inform you that the initial processing which includes an administrative review has been performed.

☒ ATTEND. 37-31143-01
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 140646.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.