



10/24/12

United States Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: USNRC Materials License No. 13-02128-03,
Control No: 577617

CARMEL
12188 B North Meridian Street
Carmel, IN 46032
PH: 317 705 4500

To Whom It May Concern:

INDIANAPOLIS
8111 South Emerson Avenue
Indianapolis, IN 46237
PH: 317 865 5000

This is a response regarding the request for additional information to add Dr Rajat Gupta as an Authorized User of Y-90 microspheres, to the Franciscan St Francis Health Indianapolis facility license (Lic No 13-02128-03).

Additional referenced items submitted in this packet include:

MOORESVILLE
1201 Hadley Road
Mooresville, IN 46158
PH: 317 831 1160

- 1) Copy of Dr Gupta's Diagnostic Radiology Residency certificate
- 2) Copy of Dr Gupta's Vascular Interventional Radiology subspecialty certificate
- 3) Signed letter From Dr Fletcher attesting to at least 80 hours of classroom and laboratory training
- 4) Signed manufacturer letter from Sirtex attesting to Authorized User Training and Certification including 3 in-vitro deliveries
- 5) Certificate of completion of 26.25 hours of classroom and laboratory training specific to Y-90

Sincerely,

A handwritten signature in cursive script, appearing to read "Berry L. Stewart".

Berry L. Stewart, M.S.
Radiation Safety Officer
Department of Radiation Oncology
St. Francis Hospital & Health Centers
8111 South Emerson Avenue
Indianapolis, IN 46237

Enclosures:

Cc: USNRC correspondence file

Indiana University

School of Medicine
and
Affiliated Hospitals

Rajat Gupta, MD

has occupied the position of Resident in the
Diagnostic Radiology Program
from July 01, 1999 to June 30, 2003 and has
faithfully and honorably discharged the duties of the position.
In Witness Whereof, the signatures and the Seal have been
affixed below on this 30th day of June 2003.

Rent D. Tan

Training Program Director

Valent S. Juh

Chair of Department



D. G. R. S.

Dean, School of Medicine

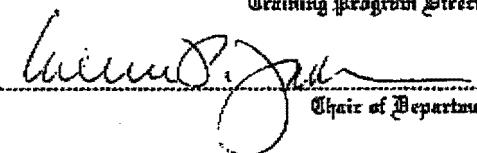
Indiana University

School of Medicine
and
Affiliated Hospitals

Rajat Gupta, MD

has occupied the position of Fellow in the
Diagnostic Radiology-Vascular and Interventional Program
from July 01, 2003 to June 30, 2004 and has
faithfully and honorably discharged the duties of the position.
In Witness Whereof, the signatures and the Seal have been
affixed below on this 30th day of June 2004.


Training Program Director


Chair of Department




Dean, School of Medicine



**DEPARTMENT OF RADIOLOGY
AND IMAGING SCIENCES**

INDIANA UNIVERSITY
School of Medicine

October 5, 2012

To Whom It May Concern:

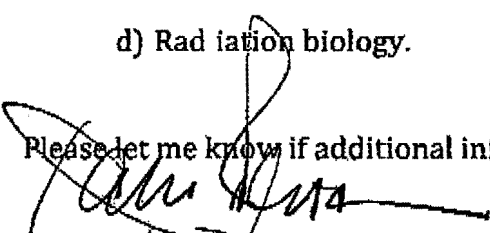
Dr Rajat Gupta has completed 5 months (160 hours per month) of dedicated training in Nuclear Medicine at Indiana University School of Medicine during his diagnostic radiology residency from July 1999 to June 2003.

He is Board Certified in Diagnostic Radiology and Medical Physics by the American Board of Radiology (ABR). He has also completed an ACGME-approved fellowship in Vascular and Interventional Radiology (2003 - 2004).

The residency training in Nuclear Medicine and Radiation Physics at Indiana University specifically included:

- a) Radiation physics and instrumentation;
- b) Radiation protection;
- c) Mathematics pertaining to the use and measurement of radioactivity;
- d) Radiation biology.

Please let me know if additional information is required.


James W. Fletcher, M.D.
Professor of Radiology
Director, Nuclear Medicine/PET
Department of Radiology
Indiana University School of Medicine
University Hospital Room 0655
550 North University Blvd.
Indianapolis, IN 46202

317-944-1800
Fax: 317-944-1806
E-mail: jwfletch@iupui.edu

University Hospital Room 0641 550 N. University Boulevard Indianapolis, IN 46202 (317) 948-2449 fax (317) 948-2803
Indiana University-Purdue University Indianapolis



June 18, 2003

SCHOOL OF MEDICINE

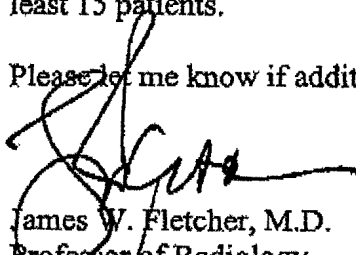
TO WHOM IT MAY CONCERN

Re: Training and Experience of Rajat Gupta M.D.

Rajat Gupta M.D. was a resident in diagnostic radiology at Indiana University School of Medicine, during the period 1 July 1999 through 30 June 2003. He was certified in diagnostic radiology by the American Board of Radiology in June 2003 (copy of certificate enclosed). Accordingly, Dr. Gupta meets the requirements to be named as an authorized-user for uptake, dilution, and excretion studies and for imaging and localization studies in accordance with 10 CFR 35.910 and 10 CFR 35.920 (or comparable agreement-state regulations). A copy of the institutional radioactive materials license, under which Dr. Gupta's training and experience were obtained, is enclosed.

Dr. Gupta's training also incorporated the elements specified in 10 CFR 35.932. He has had supervised clinical experience, under the supervision of the several authorized users on the staff of the Division of Nuclear Medicine at Indiana University Department of Radiology, that includes the use of I-131 for diagnosis of thyroid function and for treatment of hyperthyroidism in at least 15 patients.

Please let me know if additional information is required.


James W. Fletcher, M.D.
Professor of Radiology
Director, Nuclear Medicine/PET
Department of Radiology
Indiana University School of Medicine
University Hospital Room 0655
550 North University Blvd.
Indianapolis, IN 46202

DEPARTMENT OF RADIOLOGY

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School of Medicine
1001 West Tenth Street
Indianapolis, Indiana
46202-2879

317-630-6468
Fax: 317-630-7053
www.indyrad.iupui.edu

317-274-1800
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E-mail: jwfletch@iupui.edu



SIRTEX MEDICAL INC.
300 Unicorn Park Drive
Woburn, MA 01801
Tel: +1 (781) 721 3800
Fax: +1 (781) 721 3880

Ref: 104US07

September 20, 2012

Dr. Raj Gupta
Interventional Radiologist
St. Francis Hospital
8111 South Emerson Ave.
Indianapolis, IN 46237

Dear Dr. Gupta

Re: SIR-Spheres® Microspheres Authorized User Training and Certification

This letter certifies that on September 20, 2012, you successfully completed training in the operation of the delivery system, safety procedures and clinical use of SIR-Spheres yttrium-90 microspheres that are to be injected via the hepatic artery to treat patients with unresectable liver tumors in accordance with the June 2012 NRC guidance. This training included three (3) supervised hands-on *in-vitro* simulated set-up and delivery procedures as well as encompassing the following:

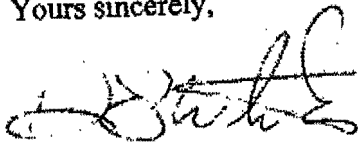
- a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- b) Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters;
- c) Evaluation of each patient for the dose/activity of Y-90 microspheres to be administered to each treatment site;
- d) Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient;
- e) Using administrative controls to prevent a medical event involving the use of byproduct material;
- f) Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures; and
- g) Follow up and review of each patient's case history for Y-90 microspheres

Once your license has been appropriately amended, Sirtex will arrange with you to have a proctor oversee your first three (3) patient treatments at a minimum, including being on site for each case.

® SIR-Spheres is a Registered Trademark of Sirtex SIR-Spheres Pty Ltd

Sirtex would like to thank you for your support in this process.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Derek Webster', written over a horizontal line.

Derek Webster
Regional Sales Manager

cc: Brad Boring
Area Sales Manager



SOCIETY OF INTERVENTIONAL RADIOLOGY

Enhanced care through advanced technology®

The Society of Interventional Radiology Certificate of Completion

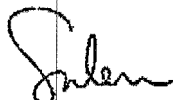
Rajat Gupta, MD

has completed 26 hours of course work and successfully passed a formal examination in the following areas during the Society of Interventional Radiology's Y90: Are you ready course, held February 9-12, 2012, in Scottsdale, Arizona. The course content was based upon the Nuclear Regulatory Commission's Microsphere Brachytherapy Sources and Devices, Licensing Guidance - TheraSphere® and SIR-Spheres® Yttrium-90 Microspheres, revised January 2011 as related to Authorized Use (AU) status for intra-arterial Y90 in the treatment of hepatic malignancies.

In witness whereof, we have hereunto affixed our signatures Society of Interventional Radiology - Fairfax, Virginia, March 1, 2012



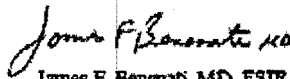
Matthew S. Johnson, MD, FSIR
Y90 Program Coordinator



Riad Salem, MD, MBA, FSIR
Y90 Program Coordinator



Charles W. Nutting, DO, FSIR
Y90 Program Coordinator



James F. Benenati, MD, FSIR
SIR President

Course content of the SIR Y90: Are you ready? Course includes the following topic areas:

Y90 Dosimetry Simplified

Historical Perspective on Liver Cancer

State of the Art: Treatment Strategies

HCC

Metastatic Colon and Rectal Carcinoma
Liver Dominant Metastatic Disease
Hepatobiliary Surgery for Malignancy

Basic Principles of Radiation Physics for Y-90

Fundamentals of Radiation Physics and Instrumentation
Radiation Protection
Mathematics Pertaining to the Use and Measurement of Radioactivity
Brachytherapy

Radiation Biology

Basic Radiation Concepts
Radiation Chemistry
Hepatic Radiation Biology

Y90 Patient Selection and Outcomes - HCC

Diagnosis of HCC and Guidelines
Outcomes of Y90

Y90 Patient Selection and Outcomes -- Metastatic Disease

Colorectal Cancer
Neuroendocrine Tumors
Role of Y90 in Other Primaries

The Initial Clinic Visit

Pretreatment Angio and MAA Shunt Study for Y90

Advanced Angio for Y90

Complex Anomalies
Advanced Coil Embolization Strategies
Mitigating Complications
Cone Beam CT

Mathematical calculations for doses for TheraSphere

Mathematical calculations for doses for SIR-Sphere

Comparing Y90 Devices

AU Requirements

Health Policy and Economics

Professional Coding and Reimbursement Strategies
National Health Policy and Liver Cancer: Where Should Y90 Fit in?

Radiation Safety Issues Treatment and Follow-up

Dosimetry

Advanced Concepts in Y90: Round Table Panel Discussion

Y90 Re-treatment
Segmentectomy/Lobectomy
Adjuvant Chemo Therapy, Metastatic Disease
Sorafenib and Y90, HCC
Re-section Following Y90
Re-distribution
Shunt Over 20 Percent and Portal Thrombosis
Recognizing Radiation Hepatitis
Managing GI Complaints
Nuances of Y90 for Neuroendocrine Cancer
Chemo and Combination Therapy, Metastases

Practice Models: Strategies for Success

AU From an Academic Perspective
AU From a Private Practice Perspective
Unified Multispecialty Practice
Benefits of AU Status
Achieving AU Status

Novel Concepts in Y90

Novel Interventional Approaches to Safe Y90 Delivery
Using Y90 After XRT to the Liver
Moffitt Cancer Center: Experience with Cholangiocarcinoma and Neuroendocrine Tumors
Clinical Trials with Y90: Current Status
Anti-Reflux Catheters

Review of SIR and ASTRO Consensus Guidelines

PHYSICIAN PARTICIPANT CERTIFICATE OF CONTINUING EDUCATION

SIR certifies that

Rajat Gupta, MD

attended the 2012 Y90: Are you ready? Meeting
Thursday, February 09, 2012 - Sunday, February 12, 2012
Scottsdale, Arizona

Rajat Gupta, MD received a total of
26.25 AMA PRA Category 1 Credit(s) $\frac{1}{2}$

The Society of Interventional Radiology is accredited by the
Accreditation Council for Continuing Medical Education (ACCME) to provide Continuing Medical Education for physicians.

The Society of Interventional Radiology designates this
educational activity for a maximum of 26.25 AMA PRA Category 1 Credit(s) $\frac{1}{2}$.

Physicians should only claim credit commensurate with the extent of their participation in the activity

Date of Completion: February 12, 2012

Jennifer L. Rowley

Jennifer Rowley
Senior Manager of Professional
Education and Certification

*Note: If the recipient of this CME Certificate is not a physician (MD or DO), this certificate is null and void.
SIR can only provide AMA PRA Category 1 Credit(s) $\frac{1}{2}$ CME Certificates to physicians.*

Society of Interventional Radiology | 3975 Fair Ridge Drive, Suite 400 North | Fairfax, VA 22033
Tel: 703.691.1805 | Fax: 703.691.1855 | E-mail: CME@SIRweb.org | www.SIRweb.org

CertificateNumber: 321265C_U49_A3587_O1_T1



8111 S. Emerson Ave., Indianapolis, IN 46237
1201 Hadley Road, Mooresville, IN 46158
12188-B North Meridian St., Carmel, IN 46032

To: NRC c/o SARA FORSTER

Company: SEB NRC

Fax: (630) 515-1078

Date: 10/23/12

Pages to follow: 10

From: RAS GUPTA, MD,

Dept.: BERRY STEWART, RSO

Fax: (317) _____

Phone: (317) _____

☐ This fax contains Personal Health Information (PHI)

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Message:

c/o SARA FORSTER

TOTAL PAGES INCLUDING THIS COVER LETTER

10

11 pages inclusive of cover

THANK YOU,
RAS GUPTA

IMPORTANT! Confidentiality Notice

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