WESTERN CONNECTICUT HEALTH NETWORK

DANBURY HOSPITAL

Br. 1

24 Hospital Ave
Danbury, CT 06810
203.739.7000
DanburyHospital.org

December 9, 2015

Ms. Penny Lanzisera
Senior Health Physicist
U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

Licensee: Danbury Hospital
License Number: 06-08544-01 03001274

Dear Ms. Lanzisera,

Enclosed is our request to add Dr. Joseph Zikria as an Authorized User for uses defined by 35.100 and 35.200, as well as for the use of Yttrium-90 SIR-spheres for treatment of liver tumors.

Enclosed are the following supportive documents:

- America Board of Radiology Diagnostic Radiology Certificate letter confirming Board certification as well as AU-eligible designation
- Form 313A(AUD)
- Documentation of completion of *in-vitro* training provided by Sirtex.
- Copy of case log from fellowship at Yale showing 19 SIRT cases done under supervision.

You currently have our request for renewal of our NRC license. We are requesting that you keep these two requests separate, and that you place this request for adding Dr. Zikria as an AU ahead of the request for renewal. The reason we are requesting this is to allow for better continuation of patient care. We are assuming that this would be a relatively straightforward amendment and therefore take much less time than the license renewal request.

Once Dr. Zikria is added to our license for these uses, he will perform the three proctored cases as required, and documentation will be sent in within 30 days of completion of those cases.

Please contact Ruth Shanley, 203-739-7182 (ruth.shanley@wchn.org) if there are any questions about this request. Thank you!

Sincerely,

James Haynes
Vice President of Operations
Norwalk Hospital/Western Connecticut Health Network

NRC FORM 313 (10-2015)
10 CFR 30, 32, 33, 34 35, 36, 37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 **EXPIRES: 12/31/2015**

Estimated burden per response to comply with this mandatory collection request: 4.3 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. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

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. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

MATERIALS SAFETY LICENSING BRANCH
DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS
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:

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:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

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:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

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 _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*

Danbury Hospital
24 Hospital Avenue
Danbury, CT 06810

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

24 Hospital Avenue
Danbury, CT 06810

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Ruth Shanley

BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER
(203) 739-7182	

BUSINESS EMAIL ADDRESS

ruth.shanley@wchn.org

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. maiximum 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 (Fees required only for new applications, with few exceptions*) *(See 10 CFR 170 and Section 170.31)* FEE CATEGORY _____ AMOUNT ENCLOSED $ _____

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, 37, 39, AND 40, AND THAT ALL INFORMATION CONTANED 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 C RIMINAL 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	SIGNATURE	DATE
Vladimir Monastyrenko, Ph.D. Radiation Safety Officer	Vladimir Monastyrenko	12/8/2015

FOR NRC USE ONLY

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

THE AMERICAN BOARD OF RADIOLOGY
EXCELLENCE · PROFESSIONALISM · PUBLIC TRUST · EST. 1934

5441 E. Williams Circle · Tucson, Arizona 85711-7412
Phone (520) 790-2900 · Fax (520) 790-3200 · www.theabr.org

ABR ID: [redacted]

Joseph F Zikria, MD
[redacted]

Dear Dr. Zikria:

I am pleased to inform you that you passed the Certifying Examination held on October 1-2, 2015. The American Board of Radiology hereby grants you a Certificate in Diagnostic Radiology.

In addition, because you completed the appropriate training for Authorized User (AU) eligibility and passed the NRC-related portions of the Core and Certifying examinations, you will receive the AU-eligible designation on your certificate.

All new diplomates are enrolled in Continuous Certification, a process that links the ongoing validity of certificates to meeting the requirements of Maintenance of Certification (MOC). Certificates no longer have "valid-through" dates but instead have the date of initial certification accompanied by the statement that "ongoing validity of this certificate is contingent upon meeting the requirements of Maintenance of Certification." Further information regarding the MOC process will be provided to you in a separate communication.

You may now use the ABR's registered certification mark, DABR (Diplomate, American Board of Radiology), following your name and degree. More information can be found on the policies page of the ABR website, http://www.theabr.org/all-policies.

Our printer will send your certificate to the above address in approximately four months. If you have an address change, you must update your address using the myABR portal by December 1, 2015. Your name will appear on the certificate as it is shown above. If you wish to have your name displayed differently on your certificate, please email information@theabr.org with your requested change by December 1, 2015. Please be sure to title the email "Certificate Name Change." Legal name changes cannot be made via the myABR portal as they require supporting documentation, which can be emailed to information@theabr.org.

Your name and demographic information will also be included in a directory published by the American Board of Medical Specialties. It is your responsibility to notify other local, state, or national organizations of your certification.

Personally, and on behalf of the Board of Trustees of the American Board of Radiology, I wish to congratulate you for this distinguished achievement.

Best regards,

Valerie P. Jackson, MD
Executive Director

PERSONAL INFORMATION WAS REMOVED BY NRC. NO COPY OF THIS INFORMATION WAS RETAINED BY THE NRC.

NRC FORM 313A (AUD)
(10-2015)

U.S. NUCLEAR REGULATORY COMMISSION

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: (12/31/2015)

Name of Proposed Authorized User	State or Territory Where Licensed
Joseph Zikria	Connecticut

Requested Authorization(s) *(check all that apply)*

- [x] 35.100 Uptake, dilution, and excretion studies
- [x] 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.

- [x] **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 *(not required for 35.590)*			
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 Joseph Zikria (Name of Proposed Authorized User) has satisfactorily completed the requirements in 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 _____ (Name of Proposed Authorized User) has satisfactorily completed the 60 hours of training and 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 Joseph Zikria (Name of Proposed Authorized User) has satisfactorily completed the requirements in 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 _____ (Name of Proposed Authorized User) has satisfactorily completed the 700 hours of training 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
Anna S. Mah, MD		203-739-7938	12/8/15

License/Permit Number/Facility Name

06-08544-01 Danbury Hospital

SIRTeX

SIRTEX MEDICAL INC.
300 Unicorn Park Drive
Woburn. MA 018[illegible]
Tel: +1 (781) 721 3800
Fax: +1 (781) 721 3880

Ref: 104US07

November 5. 2015

Dr. Joseph Zikria
Interventional Radiologist
Danbury Hospital
24 Hospital Ave
Danbury, CT 06810

Dear Dr. Zikria,

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

This letter certifies that on November 5. 2015 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 by-product material;
f) Using procedures to control and to contain spilled by-product 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 or manufacturer's representative oversee your first three (3) patient treatments at a minimum.

® 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,

Adam Paster
Regional Sales Manager

Procedure Log for Zikria, Joseph **Dates:** _____

Code	Procedure Type	Number of Procedures	Number of Patient Encounters (listed against highest level procedure)	If not tech succ	Number of Complications (listed against highest level procedure)
****	**Vascular Diagnosis**	*****	*****	****	*****
01	CTA	24	24	0	0
02	MRA	0	0	0	0
03	Noninvasive vascular lab (duplex, color flow, PVRs, etc.) *(also give subcategories below)*	0	0	0	0
04	****Vascular ultrasound (arterial or venous)	0	0	0	0
05	*****PVRs	0	0	0	0
06	Cardiac imaging	0	0	0	0
07	Arteriography (all: peripheral, renal, mesen, carotid, etc.) *(also give subcategories below)*	196	0	0	0
08	****Thoracic aortography	3	0	0	0
09	****Selective carotid arteriography	6	0	0	0
10	****Selective upper extremity arteriography	4	2	0	0
11	****Abdominal aortography (includes abdominal and pelvis)	30	0	0	0
12	****Pelvic arteriography (when not also performing abdominal aortogram)	29	1	0	0
13	****Abd aorta and/or pelvis with nonselective lower extremity arteriography	8	2	0	0
14	****Selective lower extremity arteriography	29	5	0	0
15	****Selective renal arteriography	6	0	0	0
16	****Selective visceral arteriography	68	6	0	0
17	****Pulmonary arteriography	22	1	0	0
18	Venography (all) *(also give subcategories below)*	150	0	0	0
19	****Extremity venography	29	3	0	0
20	****Selective thoracic central venography, including superior vena cavography	7	2	0	0
21	****Inferior vena cavography	75	1	0	0
22	****Visceral venography other than inferior vena cava	35	0	0	0
23	****Venous sampling	4	4	0	0
24	Dialysis access evaluations (hemodialysis arteriovenous shunt angiography)	27	6	0	0
25	Carotid artery imaging (Noninvasive) *(this is redundant to first 3: CTA, MRA, & US)*	0	0	0	0
26	Lymphography	1	1	0	0
****	**Total Noninvasive Vascular Diagnosis**	**24**	**24**	**0**	**0**
	Total Invasive Vascular Diagnosis	**552**	**7**	**0**	**0**
****	**Total All Vascular Diagnosis (Noninvasive & Invasive)**	**576**	**31**	**0**	**0**
****	**Vascular Intervention**	****	****	****	*****
31	Venous access (all: tunneled, nontunneled, ports)	235	215	0	0
32	IVC filter placement, retrieval	53	53	0	0
33	Venous ablation (varicose veins) *(also give subcategories below)*	7	0	0	0

Procedure Log for Zikria, Joseph **Dates:** _____

Code	Procedure Type	Number of Procedures	Number of Patient Encounters (listed against highest level procedure)	If not tech succ	Number of Complications (listed against highest level procedure)
34	****Thermal ablation (e.g. GSV laser or radiofrequency ablation)	2	2	0	0
35	****Chemical sclerotherapy	5	3	0	0
36	****Phlebectomy	0	0	0	0
37	Dialysis access intervention *(also give subcategories below)*	42	0	0	0
38	****Angioplasty	23	9	0	0
39	****Stenting	9	4	0	0
40	****Thrombolysis and mechanical thrombectomy	18	11	0	0
41	TIPS & TIPS evaluation/revision	24	24	2	0
42	Angioplasty/stents/covered stents: arterial (peripheral, renal, mesenteric)	36	19	0	0
43	Angioplasty/stents/covered stents: venous (all - not dialysis)	18	9	1	0
44	Carotid stenting	5	5	0	0
45	Thrombolytic therapy (all except dialysis), thrombectomy	28	23	0	0
46	Aortic endografting (thoracic and/or abdominal)	2	2	0	0
47	Embolization, emergency: (trauma, GI bleed, bronchial bleed, other)	20	16	0	0
48	Embolization, elective: (uterine fibroids, PAVMs, peripheral AVMs, varicoceles, etc.)	38	31	0	0
49	Chemoembolization (TACE)	22	22	0	0
50	Radioembolization (selective internal radiotherapy)	19	19	0	0
51	Other	3	3	0	0
****	**Total Vascular Intervention**	**510**	**441**	**1**	**0**
****	**Nonvascular Intervention**	****	****	****	*****
61	Biopsy *(also give subcategories below)*	81	1	0	0
62	****Image-guided focal mass biopsy	61	53	0	0
63	****Transcatheter biopsy (e.g. transvenous liver, endobiliary)	20	20	0	0
64	Abscess drainage & tube checks	127	114	0	0
65	Paracentesis, thoracentesis	20	15	0	0
66	Chest tube placement *(also give subcategories below)*	8	1	0	0
67	****Nontunneled	8	7	0	0
68	****Tunneled pleural catheter	0	0	0	0
69	Pleurodesis	0	0	0	0
70	Peritoneal catheter (not infection) and related procedures (e.g. tunneled peritoneal catheter	4	4	0	0
71	Biliary procedures: PTC, biliary drainage, biliary stents; tube checks	26	24	0	0
72	Nephroureteric procedures: Nephrostomy, nephroureterostomy; tube checks	67	64	0	0
73	Gastrostomy, gastrojejunostomy; tube checks	38	38	0	0
74	Cholecystostomy; tube checks	16	16	0	0

Procedure Log for Zikria, Joseph **Dates:** _____

Code	Procedure Type	Number of Procedures	Number of Patient Encounters (listed against highest level procedure)	If not tech succ	Number of Complications (listed against highest level procedure)
75	Aspiration, drainage, sclerosis (cyst, lymphocele); tube checks	9	7	0	0
76	Stents, miscellaneous nonvascular: (esophageal, tracheobronchial, duodenal, colonic)	0	0	0	0
77	Transplant interventions, miscellaneous	1	1	0	0
78	Tumor ablation (RFA, laser, microwave, cryo, ethanol, other)	21	15	0	0
79	Pain management	4	4	0	0
80	Fallopian tube recanalization	0	0	0	0
81	Other	2	2	0	0
****	**Total Nonvascular Intervention**	**420**	**302**	**0**	**0**
****	**Clinical and Related Nonprocedural Activities**	****	****	****	*****
91	Hospital inpatient care: (admission, H&P, orders, management/visit, discharge)	****	0	****	0
92	Inpatient consults	****	0	****	0
93	Outpatient visits, new patient referrals	****	46	****	0
94	Outpatient visits, postintervention follow-up	****	32	****	0
****	**Total Clinical and Related Activities**	****	**78**	****	**0**
****	**Total Invasive Diagnosis & Intervention**	**1482**	**750**	**1**	**0**
****	**Total All Diagnosis & Intervention**	**1506**	**774**	**1**	**0**

This is to acknowledge the receipt of your letter/application dated 12/8/2015, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (06-08544-01)

[X] 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** 589638.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader