



BOZEMAN HEALTH

RECEIVED  
JUL 27 2016

**Carol L. Hill**, Licensing Assistant  
United States Nuclear Regulatory Commission  
Region IV  
Medical Licensing Section  
1600 East Lamar Boulevard  
Arlington, Texas 76011-4511

July 21, 2016

**DNMS**

**PUBLIC**

- ☐ Immediate Release  
☒ Normal Release

**NON-PUBLIC**

- ☐ A.3 Sensitive-Security Related  
☐ A.7 Sensitive Internal  
☐ Other: \_\_\_\_\_

Reviewer: mtc Date: 7/29/16

SUBJECT: Addition of AU for NRC License 25-10994-04

Dear Ms. Hill,

This letter is to request a license amendment for the addition of a new Authorized User:

**Dr. Ryan C Kirwan MD** for 10 CFR 35 parts 100, 200 and 300 including I-131

This physician is a Board Certified by the American Board of Radiology in Diagnostic Radiology (AU Eligible) in June 2009 (Attached). We have also included documentation of his recent continuing education.

Also please add:

**Dr. Sean D Kalagher MD** as an Authorized User for 10 CFR part 35.1000 for Y90 SirSpheres®.

Dr Kalagher is currently on our license for other materials. Dr. Kalagher has experience with this technique and has been trained in our procedures by Dr. Reginald Taylor Handley who is an Authorized User for this material on our license. His training by a member of our primary team included assisting with 3 clinical cases and during these procedures a manufacturer representative was also present. A document attesting to this training is attached.

The above addition to the License was reviewed and approved by the Bozeman Deaconess Radiation Safety Committee during our April 21, 2016 meeting.

Thank you for your attention to this matter. Please contact Kari Cann, MS our Radiation Safety Officer at [Kcann@bozemanhealth.com](mailto:Kcann@bozemanhealth.com) or 406-788-7887 if you have any questions.

Sincerely,

Liz Lewis  
Chief Operating Officer  
Bozeman Health

# The American Board of Radiology

*Organized through the cooperation of the  
American College of Radiology, the American Roentgen Ray Society,  
the American Radium Society, the Radiological Society of North America,  
the Section on Radiology of the American Medical Association,  
the American Society for Radiation Oncology, the Association of  
University Radiologists, and the American Association of Physicists in Medicine*

*Hereby certifies that*

**Ryan Conor Kirwan, MD**

*Has pursued an accepted course of graduate study  
and clinical work, has met certain standards and qualifications and  
has passed the examinations conducted under the authority of*

*The American Board of Radiology*

*On this third day of June, 2009*

*Thereby demonstrating to the satisfaction of the Board  
that he is qualified to practice the specialty of*

**Diagnostic Radiology**

**All Eligible**



Certificate No. 56832

*N. Reed* *Secretary*

*Richard I. Morin*  
Secretary-Treasurer

*Hayden*  
President



Valid through 2019

591542

## MULTI-SOCIETY CREDIT REPORT FOR Ryan Kirwan

DATE RANGE: 07/30/2007 TO: 05/31/2016

CREDIT TYPE: ALL

REPORT DATE: 05/23/2016

SPONSOR	PROGRAM	SESSION ID	DESCRIPTION	DATE	TYPE	EARNED
ARRS	Journal Based	714233: Radiography of Sacrum and Coccyx in ED	Radiography of Sacrum and Coccyx in ED	03/30/2016	CAT1	1.00
ARRS	Journal Based	714233: National Mammography Database	National Mammography Database	03/30/2016	CAT1	1.00
ARRS	ARRS Web Lecture	714233: Breast Great Debate: Screening Mammography Controversies	Breast Great Debate: Screening Mammography Controversies	02/17/2016	CAT1	2.00
ARRS	Journal Based	714233: Screening Mammography Practices of Breast Imagers	Screening Mammography Practices of Breast Imagers	02/01/2016	CAT1	1.00
ARRS	Journal Based	714233: MRI of Breast Carcinoma in Augmented Breasts	MRI of Breast Carcinoma in Augmented Breasts	02/01/2016	CAT1	1.00
ARRS	Journal Based	714233: Localization for Lumpectomy	Localization for Lumpectomy	02/01/2016	CAT1	1.00
ARRS	Journal Based	714233: BI-RADS and Management Recommendations for Breast MRI	BI-RADS and Management Recommendations for Breast MRI	01/30/2016	CAT1	1.00
ARRS	Journal Based	714233: Baseline Screening FFDM Versus Digital Breast Tomosynthesis	Baseline Screening FFDM Versus Digital Breast Tomosynthesis	01/30/2016	CAT1	1.00
ARRS	Journal Based	714233: Imaging the Acromioclavicular Joint	Imaging the Acromioclavicular Joint	01/30/2016	CAT1	1.00
ARRS	Journal Based	714233: T2 Relaxation Values of Talar Trochlear Articular Cartilage	T2 Relaxation Values of Talar Trochlear Articular Cartilage	01/29/2016	CAT1	1.00
ARRS	Journal Based	714233: Direct-Conversion Molecular Breast Imaging	Direct-Conversion Molecular Breast Imaging	01/29/2016	CAT1	1.00
ARRS	Journal Based	714233: Complications of Knee Replacement	Complications of Knee Replacement	01/29/2016	CAT1	1.00
ARRS	Journal Based	714233: Clinicoradiologic Mismatch in Closed SCIs in Children and Ad	Clinicoradiologic Mismatch in Closed SCIs in Children and Ad	01/29/2016	CAT1	1.00
ARRS	Journal Based	714233: Characteristics of Probably Benign Lesions at Breast MRI	Characteristics of Probably Benign Lesions at Breast MRI	01/29/2016	CAT1	1.00
ARRS	Journal Based	714233: Skull Vault Lesions	Skull Vault Lesions	01/15/2016	CAT1	1.00
ARRS	Journal Based	714233: Distinguishing Osteomyelitis From Ewing Sarcoma	Distinguishing Osteomyelitis From Ewing Sarcoma	01/15/2016	CAT1	1.00
ARRS	Journal Based	714233: MRI for Lobar Classification of Benign Prostatic Hyperplasia	MRI for Lobar Classification of Benign Prostatic Hyperplasia	01/14/2016	CAT1	1.00
ARRS	Journal Based	714233: Major Hemorrhage After Image-Guided Percutaneous Biopsy	Major Hemorrhage After Image-Guided Percutaneous Biopsy	01/14/2016	CAT1	1.00
ARRS	Journal Based	714233: PET/CT and MRI for Internal Mammary Adenopathy	PET/CT and MRI for Internal Mammary Adenopathy	01/12/2016	CAT1	1.00
ARRS	Journal Based	714233: MRI of Labral and Chondral Lesions of the Hip	MRI of Labral and Chondral Lesions of the Hip	01/12/2016	CAT1	1.00
		714233: Total Ankle				

ARRS	Journal Based	Replacement for Radiologists: Complications	Total Ankle Replacement for Radiologists: Complications	01/11/2016	CAT1	1.00
ARRS	Journal Based	714233: Total Ankle Replacement	Total Ankle Replacement	01/11/2016	CAT1	1.00
ARRS	Journal Based	714233: Architectural Distortion on Mammography	Architectural Distortion on Mammography	01/08/2016	CAT1	1.00
ARRS	Journal Based	714233: Ultrasound of IM Nodes in Patients With Breast Cancer	Ultrasound of IM Nodes in Patients With Breast Cancer	01/08/2016	CAT1	1.00
ARRS	Journal Based	714233: Shear-Wave Elastography for the Diagnosis of Breast Masses	Shear-Wave Elastography for the Diagnosis of Breast Masses	01/04/2016	CAT1	1.00
ARRS	Journal Based	714233: Off Label Use and Digital Breast Tomosynthesis	Off Label Use and Digital Breast Tomosynthesis	01/04/2016	CAT1	1.00
ARRS	Journal Based	714233: Half-Moon Sign on MRI Examination of the Femoral Neck	Half-Moon Sign on MRI Examination of the Femoral Neck	08/14/2015	CAT1	1.00
ARRS	Journal Based	714233: Imaging of Breast Cancer-Related Changes After Surgical Therapy	Imaging of Breast Cancer-Related Changes After Surgical Therapy	09/23/2014	CAT1	1.00
ARRS	Journal Based	714233: Nonpuerperal Mastitis and Subareolar Abscess of the Breast	Nonpuerperal Mastitis and Subareolar Abscess of the Breast	09/23/2014	CAT1	1.00
ARRS	Journal Based	714233: Breast Emergencies: Types, Imaging Features, and Management	Breast Emergencies: Types, Imaging Features, and Management	09/23/2014	CAT1	1.00
ARRS	Journal Based	714233: Incidental Thyroid Nodules Detected at Imaging: Can Diagnostic Workup Be Reduced by Use of the Society of Radiologists in Ultrasound Recommendations and the Three-Tiered System?	Incidental Thyroid Nodules Detected at Imaging: Can Diagnostic Workup Be Reduced by Use of the Society of Radiologists in Ultrasound Recommendations and the Three-Tiered System?	09/23/2014	CAT1	1.00
ARRS	Journal Based	714233: Hip MRI: How Useful Is Intraarticular Contrast Material for Evaluating Surgically Proven Lesions of the Labrum and Articular Cartilage?	Hip MRI: How Useful Is Intraarticular Contrast Material for Evaluating Surgically Proven Lesions of the Labrum and Articular Cartilage?	09/23/2014	CAT1	1.00
ARRS	Journal Based	714233: Sonography of Musculoskeletal Soft-Tissue Masses: Techniques, Pearls, and Pitfalls	Sonography of Musculoskeletal Soft-Tissue Masses: Techniques, Pearls, and Pitfalls	09/23/2014	CAT1	1.00
ARRS	Journal Based	714233: The Pediatric Appendix: Defining Normal	The Pediatric Appendix: Defining Normal	09/23/2014	CAT1	1.00
ARRS	Journal Based	714233: FDG PET/CT of Primary Bone Tumors	FDG PET/CT of Primary Bone Tumors	09/23/2014	CAT1	1.00
ARRS	AJR, December 2008; 191:1631-1639	714233: Primary Breast Cancer in Men: Clinical, Imaging, and Pathologic Findings in 57 Patients	Primary Breast Cancer in Men: Clinical, Imaging, and Pathologic Findings in 57 Patients	09/23/2014	CAT1	1.00
ARRS	AJR, May 2010; 194:1391-1396	714233: Adenoid Cystic Carcinoma of the Breast	Adenoid Cystic Carcinoma of the Breast	09/23/2014	CAT1	1.00
ARRS	Journal Based	714233: Challenges in Mammography; Part I and II:	Challenges in Mammography; Part I and II: Self-Assessment Module	09/23/2014	CAT1	2.00



BOZEMAN HEALTH  
DEACONESS HOSPITAL

## RADIOLOGY DEPARTMENT – NUCLEAR MEDICINE

### DOCUMENTATION OF Y90 EXPERIENCE

The Y90 training policy at Bozeman Deaconess requires: Future primary personnel must receive device-specific, manufacturer-equivalent training from primary personnel already approved by the Radiation Safety Committee, assist in three (3) documented procedures, and be approved by the Radiation Safety Committee before serving as primary personnel during these procedures

This document is intended to document the training and experience for:

**Sean D Kalagher, MD** for Authorized User of 10 CFR 35.1000 uses for Sir Spheres Y90 microspheres

**Reginald Taylor Handley, MD** is the AU preceptor for these procedures and will oversee training

Date of Procedure

Signature of AU Preceptor

Signature of Trainee

7/1/2015

T. Handley MD  
HANDLEY

Sean D Kalagher  
Kalagher

8/13/2015

T. Handley MD

Sean D Kalagher

3/8/2016

T. Handley MD

Sean D Kalagher

Date of Approval by the Radiation Safety Committee:

April 21 2016

Kari L. Cann, MS DABR Radiation Safety Officer

Kari L Cann



Document ID: \_\_\_\_\_  
(Allocated by Sirtex)

## SIR-Spheres® Microspheres Treatment: Proctoring Evaluation Form<sup>(1)</sup>

### Proctored Physicians and Institution Information

Interventional Radiologist (IR): SEAN KALAGHER MD  
 Authorized User (AU): BRENT HERBEL MD  
 Institution: ST. ALEXIUS HOSPITAL, BISMARCK ND  
 Date Proctored: 9-5-12  
 Proctor: RANDALL SMITH MD

/ CASE  
EXPENSES

### 1. Pre-Treatment Evaluation

Evaluation Item	Pass	Deficient <sup>(2)</sup>
1. IR has received and is conversant with the "SIR-Spheres Microspheres Users Manual"	✓	
2. Hospital resources	✓	
a. Hospital has equipment to perform satisfactory visceral angiography	✓	
b. Quality of hepatic angiograms	✓	
i. Power injected	✓	
ii. Anatomy identified, including variant & aberrant vessels	✓	
3. Hospital has appropriate personnel assigned to the treatment team	✓	
a. Medical physicist	✓	
b. Radiation safety officer (RSO)	✓	
c. Radiation oncologist/nuclear medicine or Interventional radiologist (AU)	✓	
d. Nursing staff/patient coordinator	✓	
4. Patient selection & pre-treatment work-up	✓	
a. History & physical examination findings reviewed	✓	
b. Relevant laboratory results reviewed (LFTs/bilirubin, blood exam., etc.)	✓	
c. Triple phase contrast enhanced CT scan of chest/abdo/pelvis reviewed	✓	
d. Hepatic angiograms & variant or aberrant vessels correctly identified	✓	
e. MAA-Tc99 lung shunt study performed & correctly interpreted	✓	
f. Patient selected for treatment is an appropriate candidate	✓	
g. Pre-treatment work up is satisfactory	✓	

Notes: (1) The Proctoring Evaluation Form must be completed by the Proctor following the proctoring of a SIR-Spheres microspheres treatment and forwarded to Sirtex

(2) Please add reason and/or comments below to Section 5

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



Document ID: \_\_\_\_\_  
(Allocated by Sirtex)

2. Dose Preparation: Sign-Off by Sirtex Field personnel

Evaluation Item	Pass	Deficient	Sirtex Sig
1. Nuclear medicine hot lab personnel have the policies and procedures in place to accept and prepare the SIR-Spheres microspheres dose			/
2. Nuclear medicine hot lab personnel can verify and document quantity of SIR-Spheres microspheres activity delivered to the patient			
3. Nuclear medicine hot lab personnel understand radiation safety and decontamination procedures			

3. Treatment Plan

Evaluation Item	Pass	Deficient
1. SIR-Spheres microspheres dose determination is satisfactory		✓
2. Treatment plan is satisfactory (whole liver vs. lobar vs. segmental)	✓	
3. Hepatic arterial implantation site(s) of SIR-Spheres microspheres is satisfactory	✓	
4. Physician(s) involved understand:	✓	
a. Disease process	✓	
b. Their role in the delivery of SIR-Spheres microspheres		+ / -
c. Possible complications and treatment	✓	
d. Treatment planning (whole liver vs. lobar vs. segmental)	✓	
e. Dosimetry calculations		✓
f. Optimal catheter placement, including	✓	
i. Need for embolization of GDA, RG, other variants and aberrants	✓	
ii. Correct positioning of catheter	✓	
iii. Adequate radiation shielding in place	✓	
g. Satisfactory nursing care available during and after procedure	✓	

4. Peri-Procedural Care & Post-Treatment Follow-up

Evaluation Item	Pass	Deficient
1. Peri-procedural care & supportive therapy/medications understood	✓	
2. Post-treatment care & follow-up understood	✓	
3. Post-treatment response assessment and imaging (CT/PET) schedule understood	✓	

5. Comments (attach additional sheets if necessary)

Item #	Comments
3.1, 3.4e	DR KALACHER TRAINED AT UVA WHERE DOSE WAS CALCULATED BY RAD. ONC. WHO ALSO DELIVERED DOSE. (SEE 3.4b). HE PERFORMED WELL TODAY WITH GUIDANCE. GOOD SKILLS.



Document ID: \_\_\_\_\_  
(Allocated by Sirtex)

**6a. Approval for Proctored Cases**

First Proctored Case ☒

If Pre-trained please complete section 6b

Second Proctored Case ☐

Third Proctored Case ☐

Please complete section 6b

**6b. Approval for Future Use of SIR-Spheres Microspheres**

In my opinion, the hospital has the infrastructure in place to receive and to safely treat patients with SIR-Spheres microspheres: YES ☐ NO ☐

In my opinion, the Interventional Radiologist proctored is qualified to implant SIR-Spheres microspheres in cooperation with the Authorized User and does not require additional proctoring:  
YES ☐ NO ☐

In my opinion, the Interventional Radiologist proctored requires at least one additional proctoring session:  
YES ☐ NOT NECESSARY ☐

In my opinion, the Authorized User proctored is qualified to implant SIR-Spheres microspheres in cooperation with the Interventional Radiologist and does not require additional proctoring:  
YES ☐ NO ☐

In my opinion, the Authorized User proctored requires at least one additional proctoring session:  
YES ☐ NOT NECESSARY ☐

**7. Signatures**

Proctor name (print): RANDALL SMITH MD

Proctor Signature: *R. Smith MD* Date: 9-11-12

Proctor: Please fax completed Proctoring Evaluation Form to Sirtex Regional Administrator at the following numbers:

US: +1 (978) 229 9585  
EU: +49 228 1840 735  
AP: +61 2 9964 8410

1 CASE  
EXPENSES (DROVE)

# Express

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JUL 27 2016

DNMS

Carol L. Hill, Licensing Assistant  
United States Nuclear Regulatory Commission - Region IV  
Medical Licensing Section  
1600 East Lamar Boulevard  
Arlington, TX 76011-4511

DNMS

RECEIVED  
JUL 27 2016

931 Highland Boulevard, Suite 3350  
Bozeman, MT 59715

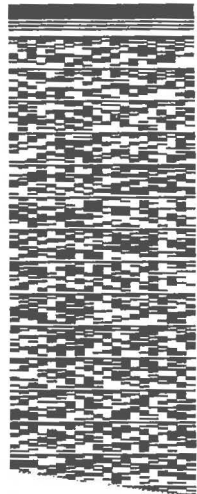
BOZEMAN HEALTH  
DEACONESS HOSPITAL



on top of FedEx Express® shipping label  
FROM: SHIPPING DEPT (400) 542-1701  
BOZEMAN DEACONESS HOSPITAL  
915 HIGHLAND BLVD.  
BOZEMAN MT 59715  
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CBO: 044009570AF2805  
RCHT: 1018  
SHIP DATE: 22 JUL 16

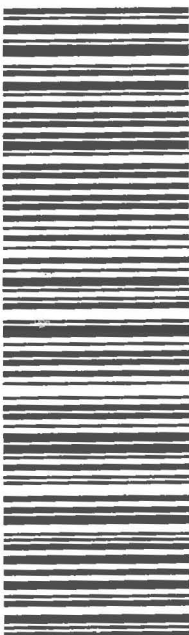
TO CAROL HILL, MED. LICENSING SECTION  
US NUCLEAR REGULATORY COMMISSION-IV  
1600 EAST LAMAR BOULEVARD

ARLINGTON TX 76011  
(817) 200-1590  
DEPT: ADMINISTRATION  
REF: ADMIN



TRK# 6820 2464 5212

9622 0151 0 (000 062 0658) 3 00 6820 2464 5212



US NUCLEAR REGULATORY COM  
1600 E LAMAR BLVD  
ARLINGTON, TX

76011-4511-99

130-4007

ETP:1  
682024645212  
PD:SP:100:Y

76011

(US)

521C1/5CB0/6F03

591542



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Ms. Kari L. Cann, Radiation Safety Officer  
Bozeman Health Deaconess Hospital  
915 Highland Boulevard  
Bozeman, MT 59715

Date

07/28/2016

License Number(s)

25-10994-04

Mail Control Number(s)

591542

Licensing and/or Technical Reviewer or Branch

CHill

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: 07/21/2016

The initial processing, which included an administrative review, has been performed.

☒ Amendment ☐ Termination ☐ New License ☐ Renewal

☐ There were no administrative omissions identified during our initial review.

☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

☐ Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>  
Follow the instructions on the form for submission.

☐ The following administrative omissions have been identified:

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region IV  
U. S. Nuclear Regulatory Commission  
DNMS/NMSB - B  
1600 E. Lamar Boulevard  
Arlington, TX 76011-4511  
(817) 200-1209 or (817) 200-1140

V7/28/16

BETWEEN:

Accounts Receivable/Payable  
and  
Regional Licensing Branches

[ FOR ARPB USE ]  
INFORMATION FROM WBL

Program Code: 02230  
Status Code: Pending Amendment  
Fee Category: 7C  
Exp. Date:  
Fee Comments:  
Decom Fin Assur Req: N

## License Fee Worksheet - License Fee Transmittal

### A. REGION

#### 1. APPLICATION ATTACHED

Applicant/Licensee: Bozeman Health Deaconess Hospital  
Received Date: 07/27/2016  
Docket Number: 3033305  
Mail Control Number: 591542  
License Number: 25-10994-04  
Action Type: Amendment

#### 2. FEE ATTACHED

Amount: \_\_\_\_\_

Check No.: \_\_\_\_\_

#### 3. COMMENTS

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

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

1. Fee Category and Amount: \_\_\_\_\_

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

Amendment: \_\_\_\_\_

Renewal: \_\_\_\_\_

License: \_\_\_\_\_

#### 3. OTHER \_\_\_\_\_

Signed: \_\_\_\_\_

Date: \_\_\_\_\_