

**St. Joseph Medical Park
1475 Kisker Rd, Ste 180
St. Charles, MO 63304
(636)442-7300**

January 13, 2009

Materials Licensing Section
U. S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road STE 210
Lisle, Illinois 60532-4352

Lic. No. 24-15159-01

Dear Sir or Madam,

I would like to request the additional authorization for material use under Part 35.600 "Use of a sealed source in a remote afterloader unit" for John M. Bedwinek, M.D. a current authorized user on our license.

Dr. Bedwinek was previously on an Agreement State Licence for use of Ir-192 in a remote afterloading unit in the State of Tennessee. This license is attached. However, due to the date of this license we understand we must provide recentness of training documentation. To this end we have attached form 313A which outlines the course work performed and experience he has completed under the two preceptors which are both authorized users on our material license.

To summarize his recent training; he has taken two didactic courses in HDR. The first course was at the Seattle Prostate Institute and covered HDR for Prostate, Gynecological and Breast Cancer. The second was an online course provided by the manufacturer "Cytyc" of the Mammosite Balloon. He was then proctored by two Authorized users on our license for a total of 5 patients for both Gynecological and Mammosite treatments with our HDR unit. Our physicist Dr. Pohlman (AMP) under the supervision of Dr. Dickerson (AU) provided hands on training on normal operation of the HDR unit, emergency procedures, full calibration measurements, spot checks and use of survey meters at our facility.

In support of this authorization I would also like to provide you a brief summary of Dr. Bedwinek's extensive background and training in Radiation Oncology. He has been a practicing clinician for over thirty years and was board certified in 1975 by the American Board of Radiology and then Re-certified by the ABR in 2001. He also has over 50 publications, 4 of which are on High Dose Rate Brachytherapy. In addition due to his extensive experience and service to the field of Radiation Oncology he has been honored with the title of "Fellow" of the following organizations: American Society for

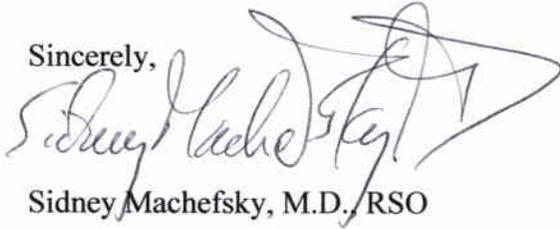
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Therapeutic Radiology and Oncology (ASTRO) the American College of Radiation
Oncology (ACRO) and the American College of Radiology (ACR).

As always we very much appreciate your help with our materials license and if you have
any questions over this information please feel free to call our medical physicist Mark
Pohlman, Ph.D.. His contact numbers are 314-941-1030 or 314-488-5111.

Thank you again for your consideration in this matter.

Sincerely,

A handwritten signature in cursive script, appearing to read "Sidney Machefsky". The signature is written in black ink and is positioned above the printed name.

Sidney Machefsky, M.D., RSO

(5-1997)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

Estimated burden per response to comply with this information collection request: 7 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. Forward comments regarding burden estimate to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0120), Office of Management and Budget, Washington, DC 20503. NRC may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a currently valid OMB control number.

APPLICATION FOR MATERIAL 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:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
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:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

ATLANTA FEDERAL CENTER
U. S. NUCLEAR REGULATORY COMMISSION, REGION II
81 FORSYTH STREET, S.W., SUITE 23T85
ATLANTA, GEORGIA 30303-3415

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING SECTION
U S NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, 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 SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

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 24-15159-01
- C. RENEWAL OF LICENSE NUMBER _____

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

DR. SIDNEY MACHETSKY, RSO
ST. JOSEPH HEALTH CENTER
300 FIRST CAPITAL DR.
ST. CHARLES, MO 63301

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

SSM ST. JOSEPH MEDICAL PARK
1475 KISKER RD.
ST. CHARLES, MO 63304

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

MARK POHLMAN, Ph.D.

TELEPHONE NUMBER
(314) 941-1030

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. LICENSEE FEES (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, 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

DR. SIDNEY MACHETSKY, RSO

SIGNATURE

DATE

6/2/09

FOR NRC USE ONLY

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

**MEDICAL USE TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**

PART I -- TRAINING AND EXPERIENCE

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulation (10 CFR Part 35)

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

John M. Bedwinek, MD – Authorized User – 35.690(b)

2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed

Missouri

3. CERTIFICATION

- a. Provide a copy of the board certification. (Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a); continue if applying under other subparts.)
- b. Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); 35.51(c); 35.290(c)(1)(ii)(G) for AU seeking 35.200 authorization; 35.390(b)(1)(ii)(G); 35.396(d)(1) and 35.396(d)(2); 35.590(c); or 35.690(c).
- c. Provide completed Part II Preceptor Attestation, Items 11a through 11d.
Stop here after completing items 3a, 3b, and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements.

4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO), AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS

- a. Provide a copy of the license or broadscope permit listing the current authorization **and** (b) or (c)
- b. Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c).
- c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).

5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation			
Radiation Protection			
Mathematics Pertaining to the Use and Measurement of Radioactivity			
Radiation Biology			
Chemistry of Byproduct Material for Medical Use			
OTHER			

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6a. WORK OR PRACTICAL EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
Reviewing full calibration measurements and periodic spot-checks	Gregg Dickerson, MD.	SSM St. Joseph Health Center 24-15159-01	2/28-3/5/08
Preparing treatment plans and calculating treatment doses and times	Gregg Dickerson, MD.	SSM St. Joseph Health Center 24-15159-01	2/28-3/5/08
Checking and using survey meters	Gregg Dickerson, MD.	SSM St. Joseph Health Center 24-15159-01	2/28-3/5/08
Using administrative controls to prevent a medical event involving the use of byproduct material	Anna Fu, MD	SSM St. Medical Park 24-15159-01	11/11/08 – 1/6/09
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console	Anna Fu, MD	SSM St. Medical Park 24-15159-01	11/11/08 – 1/6/09
Selecting the proper dose and how it is to be administered	Anna Fu, MD	SSM St. Medical Park 24-15159-01	11/11/08 – 1/6/09
Annual Equipment Operation, Safety Precautions and Emergency Procedures Seminar	Scott McGuire, Field Service Engineer for Nucletron	SSM St. Medical Park 24-15159-01	2/20/2009

6b. SUPERVISED CLINICAL CASE EXPERIENCE (describe experience elements in 6a)

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
Ir-192	HDR remote afterloader	1	Gregg Dickerson, MD	SSM St. Joseph Health Center 24-15159-01	2/28-3/5/08
Ir-192	HDR remote afterloader	1	Anna Fu, MD	SSM St. Joseph Medical Park Center 24-15159-01	11/11-12/18/08
Ir-192	HDR remote afterloader	1	Anna Fu, MD	SSM St. Joseph Medical Park Center 24-15159-01	12/3-12/16/2008
Ir-192	HDR remote afterloader	1	Anna Fu, MD	SSM St. Joseph Medical Park Center 24-15159-01	12/11-12/18/2008
Ir-192	HDR remote afterloader	1	Anna Fu, MD	SSM St. Joseph Medical Park Center 24-15159-01	12/30/08-1/6/2008

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.690(c)

Training Element	Type of Training *	Location and Dates
(B) Preparing treatment plans and calculating treatment doses and times	Didactic - High Dose Rate Brachytherapy for Prostate, Gynecological, and Breast CA	Institute for Medical Studies (IMS) and Seattle Prostate Institute CME course (11 AMA PRA Cat1) February 25-26, 2008
(B) Preparing treatment plans and calculating treatment doses and times	Didactic - Mammosite 5-day Targeted Radiation Therapy Training Program	Online Course for Surgeons, Radiation Oncologists, Medical Physicists through Cytac @ Mammosite.com/physicians

* Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic, or vendor training.

7. FORMAL TRAINING Physicians (for uses under 35.400 and 35.600) and Medical Physicists

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)

8. RADIATION SAFETY OFFICER (RSO) -- ONE-YEAR FULL-TIME EXPERIENCE

YES Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervision of _____ the RSO for License No. _____

N/A

9. MEDICAL PHYSICIST -- ONE-YEAR FULL-TIME TRAINING/WORK EXPERIENCE

YES Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics (35.961) or medical physics (35.51) under the supervision of _____ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51);

N/A

and

YES Completed 1 year of full-time work experience (at location providing radiation therapy services described and for topics identified in item 6a) for (specify use or device) _____ under the supervision of _____ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) _____

N/A

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

10. SUPERVISING INDIVIDUAL -- IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in 10 CFR Part 35, provide the following information for each) :

A. Name of Supervisor

Gregg Dickerson, MD

B. Supervisor is:

Authorized User

Authorized Medical Physicist

Radiation Safety Officer

Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 690

for medical uses in Part 35, Section(s) Iridium-192, permitted by 10 CFR 35.600

D. Address

SSM St. Joseph Health Center
330 First Capitol Dr. Ste, 120
St. Charles, MO 63301

E. Materials License Number

24-15159-01

PART II -- PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet training requirements in 35.590 or Part 35, Subpart J (except 35.980).

I attest the individual named in Item 1:

11a.

has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 35.690(b) as documented in section(s) 6a, 6b of this form.

11b. Select one

meets the requirements in 35.50(e) 35.51(c) 35.390(b)(1)(ii)(G) 35.690(c) for types of use, as documented in section(s) of this form.

11c.

has achieved a level of competency sufficient to independently operate a nuclear pharmacy (for 35.980); **OR**

has achieved a level of competency sufficient to function independently as an authorized User for High dose-rate remote uses (or units); **OR** afterloader

has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee ; **OR**

N/A

11d.

I am an Authorized Nuclear Pharmacist; **OR** I am a Radiation Safety Officer; **OR**

I meet the requirements of 690 section(s) of 10 CFR Part 35

or equivalent Agreement State requirements to be a preceptor AU or AMP

for the following byproduct material uses (or units): High dose-rate remote afterloader

A. Address

SSM St. Joseph Health Center
330 First Capitol Dr. Ste, 120
St. Charles, MO 63301

B. Materials License Number

24-15159-01

C. NAME OF PRECEPTOR (print clearly)

Gregg Dickerson, MD

D. SIGNATURE -- PRECEPTOR

E. DATE

1/24/2009

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

10. SUPERVISING INDIVIDUAL -- IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in 10 CFR Part 35, provide the following information for each) :

A. Name of Supervisor

Anna Fu, MD

B. Supervisor is:

Authorized User

Authorized Medical Physicist

Radiation Safety Officer

Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35. Section(s) 690

for medical uses in Part 35, Section(s) Iridium-192, permitted by 10 CFR 35.600

D. Address

SSM St. Joseph Medical Park
1475 Kisker Rd, Ste. 180
St. Charles, MO 63304

E. Materials License Number

24-15159-01

PART II -- PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet training requirements in 35.590 or Part 35, Subpart J (except 35.980).

I attest the individual named in Item 1:

11a.

has satisfactorily completed the requirements in Part 35. Section(s) and Paragraph(s) 35.690(b) as documented in section(s) 6a, 6b of this form.

11b. Select one

meets the requirements in 35.50(e) 35.51(c) 35.390(b)(1)(ii)(G) 35.690(c) for _____ types of use, as documented in section(s) _____ of this form.

11c.

has achieved a level of competency sufficient to independently operate a nuclear pharmacy (for 35.980); **OR**

has achieved a level of competency sufficient to function independently as an authorized User for High dose-rate remote uses (or units); **OR** afterloader

has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee ; **OR**

N/A

11d.

I am an Authorized Nuclear Pharmacist; **OR** I am a Radiation Safety Officer; **OR**

I meet the requirements of 690 section(s) of 10 CFR Part 35

or equivalent Agreement State requirements to be a preceptor AU or AMP

for the following byproduct material uses (or units): High dose-rate remote afterloader

A. Address

SSM St. Joseph Health Center
1475 Kisker Rd., Ste 180
St. Charles, MO 63304

B. Materials License Number

24-15159-01

C. NAME OF PRECEPTOR (print clearly)

Anna Fu, MD

D. SIGNATURE -- PRECEPTOR

E. DATE

1/28/09

MARK POTEMPA, PhD.
SSM St. JOSEPH Medical Park
1475 KISKEG RD, STE 180
ST. CHARLES, MO 63304



ST LOUIS MO F&DC 631

THU 26 FEB 2009 PM

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, STE 210
LISLE, ILLINOIS, 60532-4352