

Estimated burden per response to comply with this mandatory collection request: 4.4 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 Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@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.

APPLICATION FOR MATERIALS 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:

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
 475 ALLENDALE ROAD
 KING OF PRUSSIA, PA 19406-1415

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
 612 E. LAMAR BOULEVARD, SUITE 400
 ARLINGTON, TX 76011-4125

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 21-00258-06
- C. RENEWAL OF LICENSE NUMBER

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

Allegiance Health
205 N East Avenue
Jackson, MI 49201

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

205 N East Avenue, Jackson, MI 49201
AND 1102 E Michigan Avenue, Jackson, MI 49201

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Anas Orfali

TELEPHONE NUMBER

(517) 780-7299

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. LICENSE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY N/A 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.

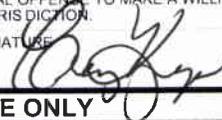
THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND 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

Terry Keys, Executive Director NMS/Imaging Service

SIGNATURE



DATE

2/6/09

FOR NRC USE ONLY

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

Item 7. Authorized Users Names.	Requested Uses	Experience/Training
Please add to the list of Authorized Users: Charlie Pan, M.D.	35.400	Dr. Pan is certified by the American Board of Radiology in the field of Radiation Oncology. Dr. Pan is also named as an Authorized User for 35.400 uses on the University of Michigan NRC Broad Scope License # 21-00215-04. Please find attached enclosed documentation.

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 Therapeutic Radiology and Oncology, the Association of
University Radiologists, and American Association of Physicists in Medicine*

Hereby certifies that

Charlie Chen-Chih Pan, MD

*Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examination conducted under the authority of
The American Board of Radiology*

On this seventh day of June, 2005

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

Radiation Oncology



Steven A. Glick, M.D.
President

Richard T. Hoopes, MD
Secretary-Treasurer

R.P. Hatten, MD
Executive Director

№ 52574

Valid Through 20

Form RSS-102R
Revision: 12/03

**UNIVERSITY OF MICHIGAN
ROUTINE USE OF RADIOACTIVE MATERIAL IN OR ON HUMANS
(NON-INVESTIGATIONAL / ROUTINE CLINICAL)**

Purpose of this Application
(Check One)

- NEW APPLICATION
- RENEWAL APPLICATION *w/ Amendments*
- AMENDMENT TO EXISTING APPLICATION

RECEIVED

1. Department / Unit Submitting Application Radiation Oncology

Room / Building B2C490 / UH

Campus Zip 0010

MAY 03 2007

Phone Number 936-4309

Fax Number 936-7859

Occupational Safety &
Environmental Health
RADIATION SAFETY SERVICE

2. Individual to Contact Regarding Application Bruce Curran

Room / Building B2C432 / UH

Campus Zip 0010

Phone Number 615-7075

Fax Number 936-7859

3. Physical Locations of Radioactive Material Use.

Room	Building	Intended Use
A8403, A8404, A8411, A8412 (Shielded patient rooms, 8 th floor)	Univ. Hosp.	Low Dose Rate Brachytherapy (Cs-137, Ir-125, Ir-192)
OR2233, OR2215, OR2205, 2302 (Operating rooms, Recovery Room)	Kellogg Eye Center (2 nd Floor)	Eye Plaques (I-125)
B2C303 - Source Room/Hot Lab	Univ. Hosp.	Storage/Preparation/Calibration
B2C413 - 600CD linac room/HDR B2C525 - EX2 linac room/HDR	Univ. Hosp.	HDR afterloader Brachy treatments (Ir-192)
UH ORS (1G407 - 1G429)	Univ. Hosp.	Permanent Implantation of Brachy seeds for Lung Resections or Prostate Implants (I-125 Pd-103)
B2C422, 428 - Sim 1, 2	Univ. Hosp.	LDR Source Localization
<i>IR Rooms 1, 2, 3, 4, 5, 6 (Bi Level)</i>	<i>University Hospital</i>	<i>P-90 Theraspheres PM</i>
<i>4562A, 4562B, 4562G</i>	<i>Cardiovascular Center</i>	<i>P-90 Theraspheres. PM</i>

4. Authorized User Physicians: (List all authorized user physicians who will independently use or directly supervise the use of radioactive material under this authorization. Typically, senior staff physicians.)

Attach documentation demonstrating compliance with the training and experience requirements of 10 CFR 35 Subparts B, and D through J (ex: board certification, etc)

UM		Affiliate	
Ben-Josef, Edgar	Sandler, Howard	Chan, June	McLaughlin, Patrick William
Eisbruch, Avraham	Tsien, Christina	DeBiase, David	Moni, Janaki
Hayman, James	Pan, Charlie		Soriano, Julie
Jagsi, Reshma	Hamstra, Daniel	Freedman, Laura	
Lawrence, Theodore	<i>Jolly, SHKOT</i>		
Pierce, Lori	<i>(APPROVED 11/11/06)</i>	Kong, Feng-ming	
Ray, Michael (left 3/1/2007)	<i>MTC</i>		

5. Additional Users: (List all physicians who will be using radioactive material under the supervision of one or more of the authorized user physicians listed above under this authorization. Typically, fellows, residents and other physicians-in training).

Attach documentation demonstrating compliance with the training and experience requirements specified in 10 CFR 35 Subparts B, and D through J (ex: board certification, etc.)

UM Residents		Associated Physicians	
2003-7	2005-9	Kellogg Eye Center	RadOnc Fellows
Feng, Mary	Contessa, Joseph	Vine, Andrew	Gluck, Iris
Lin, Alexander	Oh, Kevin		Popovtzer, Aron
Lopez, Carlos		Thoracic Surgery	Kretzler, Annette
2004-8	2006-10	Chang, Andrew	
Soto, Daniel	Feng, Felix	Lau, Christine	
Spaulding, Aaron	Correa, Candace	Orringer, Mark	
Lee, Irwin		Pickens, Allan	

6. Ancillary Personnel: (List all individuals other than physicians who will handle radioactive material under this authorization. Normally, this would include medical or clinical physicists, authorized nuclear pharmacists, nuclear medicine technologists, staff nurses, etc.).

Attach documentation demonstrating compliance with the training and experience requirements specified in 10 CFR 35 Subparts B, and D through J (if applicable).

Medical Physicists			
UH-Based		Argus-Based	Affiliates
Balter, James	Litzenberg, Dale	Antonuk, Larry	Narayana, Vrinda
Curran, Bruce	Moran, Jean	El-Mohri, Youcef	Graves Ditman, Maria
Fraass, Benedick	Roberts, Don	Roberson, Peter	
Hadley, Scott	JEE, KYONG-WOOK (KW)	Jee, Ken	
Lam, Kwok	(APPROVED #1/19/08)	TenHaken, Randall	
Prisciandaro, Joann			

Medical Physics Residents		
2005-7	2006-8	2007-9
Christou, Christina	Smith, Chadd	Gopal, Anant
Shtraus, Natan		

Dosimetrists

UH-Based	Argus-Based
Archer, Paul	Marsh, Robin
Burger, Pamela	Tatro, Daniel
Jarema, David	
Marsh, Lon	
Yanke, Bethany	
Wilkerson, Joel	

7. Approval is requested for the following routine clinical uses of radioactive material (as described in 10 CFR 35) by or under the supervision of the authorized user physicians listed in Item 4 above.

(Check All That Apply)

	10 CFR 35 Classification	Maximum Possession Limit (mCi)
<input checked="" type="checkbox"/>	35.100 Use of Radiopharmaceuticals for Uptake, Dilution and Excretion Studies for which a Written Directive is NOT Required <i>For use for calibration of dose calibrator</i>	100 mCi
<input type="checkbox"/>	35.200 Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies for which a Written Directive is NOT Required	
<input type="checkbox"/>	35.300 Use of Radiopharmaceuticals Requiring a Written Directive	
<input checked="" type="checkbox"/>	35.400 Use of Sources for <u>Manual</u> Brachytherapy Specify radionuclide(s) and intended use(s): Cs-137 sealed sources in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer. Ir-192 sealed sources in seeds encased in nylon ribbon for interstitial treatment of cancer. I-125 sealed sources for ophthalmologic treatment of cancer sealed sources in seeds for interstitial treatment of cancer sealed sources in seeds encased in nylon ribbon for permanent implantation Pd-103 sealed sources in seeds for interstitial treatment of cancer Sealed sources in seeds for permanent implantation	4000 mCi 2000 mCi 2500 mCi 2500 mCi
<input type="checkbox"/>	35.500 Use of Sealed Sources for Diagnosis Specify radionuclide(s) and intended use(s):	
<input checked="" type="checkbox"/>	35.600 Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit Specify radionuclide(s) and intended use(s): Ir-192 sealed source seed in Varian Gammamed HDR afterloader unit for treatment of cancer.	30 Ci
<input checked="" type="checkbox"/>	35.1000 Other Medical Uses of Radioactive Material Not Specifically Addressed Above (ex: GlioSite, Guidant Galileo, IVB, Y-90 TheraSpheres, Novoste Beta Cath, Cordis Check Mate, Liquid Brachytherapy, etc.) <i>Y-90 TheraSpheres PAP 3/27/05</i>	600 mCi

NOTE 1: Radiopharmaceuticals in 35.100/35.200/35.300 require a FDA-approved IND or a FDA-accepted NDA.

NOTE 2: For 35.400/35.600, radionuclides must be (a) approved in the Sealed Source and Device Registry or (b) used in research in accordance with an active IDE application accepted by the FDA.

NOTE 3: For 35.500, only sealed sources approved by the Sealed Source and Device Registry shall be used.

8. Approval is also requested for the following radioactive material not listed in #7 above.

RADIONUCLIDE	CHEMICAL AND / OR PHYSICAL FORM	MAXIMUM ACTIVITY (mCi)	DESCRIPTION OF USE
Strontium-90 Cesium-137 <i>mp 5/1/08 TC-99m</i>	All Sealed Sources <i>calibration vial</i>	10 mCi 500 mCi <i>100 mCi</i>	Constancy/calibration sources

9 - 21. ADDITIONAL INFORMATION SUBMITTED IN SUPPORT OF THIS APPLICATION

For the following items, check the appropriate sections and submit a detailed description of all requested information. Begin each item on a separate sheet. Identify the item number and date of the application at the top of each page.

NOTE: You may incorporate sections of the NRC "Consolidated Guidance About Materials Licenses - Program Specific Guidance About Medical Use Licenses" (NUREG-1556 / Vol. 9 / Final Report) or the "Manual of Nuclear Medicine Procedures" by reference. In such cases, do NOT duplicate information from these documents; but clearly identify the document and the specific section you will incorporate into this application. Do NOT reference old applications.

If this is an 'amendment' to an existing RSS-102R application, complete only those parts that are applicable to the amendment and indicate "N/A" in the remaining sections.

9. Available Radiation Safety Monitoring & Measuring Instrumentation (List Survey Meters & Counting Equipment)

10. Calibration of Instruments (10 CFR 35 / Subpart C or U-M Broad Scope License Criteria)

Procedures Adopted by Reference or Procedures Attached

11. Dose Calibrator (10 CFR 35.60) **N/A**

Procedures Adopted by Reference or Procedures Attached

12. Radiological Safety Procedures

Describe the general procedures, radiological safety protocols, and ALARA program to be implemented when handling or working around radioactive materials. In addition, describe the precautions to be used to prevent the spread of radioactive contamination and/or reduce the unnecessary exposure to radiation.

Procedures Adopted by Reference or Procedures Attached

13. Radiological Emergency Notifications

Describe the procedures to be implemented for notifying Radiation Safety Service / OSEH in the event of a radioactive contamination incident, unnecessary exposure, or other radiological concerns.

Procedures Adopted by Reference or Procedures Attached

14. Medical Event Notification Procedures (10 CFR 35.310, 35.410, or 35.3045)

Describe the procedures that will be used for ensuring timely notification of the RSS/OSEH Radiation Safety Officer if a patient dies or has a medical emergency while undergoing a radiopharmaceutical or an implant therapy, or in the event of 'medical event' (35.3045).

Procedures Adopted by Reference or Procedures Attached

15. Facilities and Equipment

Attach Description(s) and Diagram(s)

16. Procedures for Ordering and Receiving Radioactive Material (Attach Description or Procedures)

17. Procedure for Safely Opening Packages Containing Radioactive Material (10 CFR 20.1906)

Procedures Adopted by Reference or Procedures Attached

18. Radioactive Waste Disposal

Describe the procedures and precautions to be implemented to ensure the proper disposal of radioactive wastes: hold-for-decay (survey & properly discard), return to manufacturer, disposal through OSEH Haz Mat, etc.

Procedures Adopted by Reference or Procedures Attached

19. Therapeutic Uses of Radiopharmaceuticals (ex: MIBG, GliaSite, etc.) **N/A**

Procedures Adopted by Reference or Procedures Attached

20. Therapeutic Uses of Sealed Sources (Brachytherapy, Eye Plaques, Guidant Galileo, Y-90 TheraSpheres, HDR, etc.)

Procedures Adopted by Reference or Procedures Attached

21. Release of Individuals Containing Radiopharmaceuticals or Radioactive Implants (10 CFR 35.75)

Describe the procedures and radiological safety protocols to be implemented for the release of individuals containing radiopharmaceuticals or radioactive implants. (ex: NRC Regulatory Guide 8.39 or NUREG-1556 / Vol. 9 / Appendix U)

Procedures Adopted by Reference or Procedures Attached

22. Use of Radioactive Gases **N/A**

Describe the procedures, radiological safety precautions, and ALARA program to be implemented when using radioactive gases (ex: Xe-133, Tc-99m aerosols, etc)

Procedures Adopted by Reference or Procedures Attached

23. Use of Radioactive Material Specified in Item 8 above.

Describe the procedures, radiological safety precautions, and ALARA program to be implemented when using the radioactive materials specified in Item 8.

Procedures Adopted by Reference or Procedures Attached

24. Recordkeeping Requirements (10 CFR 35 / Subpart L)

Briefly describe what and how records will be maintained in accordance with 10 CFR 35 / Subpart L.

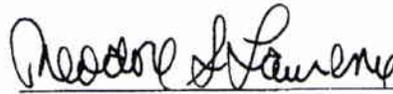
[NOTE: Refer to NUREG-1556, Volume 9, Appendix X for recordkeeping guidance]

Department or Unit Submitting This Application
(Type)

Radiation Oncology

Department / Unit Head: Theodore S. Lawrence, MD, PhD
(Type / Print)

Title: Professor and Chair


(Signature)

Date: May 1, 2007

REMINDER: Be sure that all enclosures or attachments referenced in this application are attached and properly identified.

RADIATION SAFETY SERVICE / OSEH

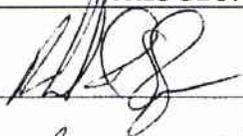
**OCCUPATIONAL SAFETY & ENVIRONMENTAL HEALTH
1239 KIPKE DRIVE (1010)**

PHONE: (734) 764-4420

FAX: (734) 763-1185

WEBSITE: <http://www.umich.edu/~oseh>

THIS SECTION FOR RSS USE ONLY

HEALTH PHYSICS REVIEW BY  DATE 11/13/07

DEPARTMENT / UNIT Radiation Safety Service / OSEA

HEALTH PHYSICS RECOMMENDATIONS: see attached HP Rev. rev. 11/13/07

PERSONNEL DOSIMETRY

BIOASSAY

ENVIRONMENTAL MONITORING

RESTRICTED AREA MONITORING

OTHER:

SIGNATURE OF APPROVAL BY THE RADIATION POLICY COMMITTEE _____ DATE _____

SIGNATURE OF APPROVAL FOR THE RADIOACTIVE DRUG RESEARCH COMMITTEE AND THE SUBCOMMITTEE FOR THE HUMAN USE OF RADIOISOTOPES _____ DATE _____

EXPIRATION DATE: _____

UNIVERSITY OF MICHIGAN – DEPARTMENT OF RADIATION ONCOLOGY
RSS-102R RENEWAL (May 2007)

ITEM 4: AUTHORIZED USER PHYSICIANS

**RSS-101A and/or NRC-313A forms are enclosed for all Radiation
Oncology Authorized User Physicians.**

Changes since previous renewal:

Additions:

Hamstra, Daniel	(Previous UM Resident)
Jagsi, Reshma	(Previously at Harvard)
Pan, Charlie	(Previous UM Resident)
Freedman, Laura	(Providence Hospital Radiation Oncologist)

Removals:

Ray, Michael
Sullivan, Molly
Ajlouni, Elizabeth
Kucway, Roger

UNIVERSITY OF MICHIGAN – DEPARTMENT OF RADIATION ONCOLOGY
RSS-102R RENEWAL (May 2007)

ITEM 5: ADDITIONAL USER PHYSICIANS

RSS-101A and/or NRC-313A forms are enclosed for all Radiation Oncology Additional User Physicians.

Changes since previous renewal:

Additions:

Contessa, Joseph	(Radiation Oncology Resident)
Oh, Kevin	(Radiation Oncology Resident)
Soto, Daniel	(Radiation Oncology Resident)
Spaulding, Aaron	(Radiation Oncology Resident)
Lee, Irwin	(Radiation Oncology Resident)
Feng, Felix	(Radiation Oncology Resident)
Correa, Candace	(Radiation Oncology Resident)
Gluck, Iris	(Radiation Oncology Fellow)
Popovtzer, Aron	(Radiation Oncology Fellow)
Kretzler, Annette	(Radiation Oncology Fellow)
Chang, Andrew	(Thoracic Surgeon)
Lau, Christine	(Thoracic Surgeon)
Orringer, Mark	(Thoracic Surgeon)
Pickens, Allan	(Thoracic Surgeon)

Removals:

Fernando, Shanelli
Hamstra, Daniel
Herman, Joseph
Meirovitz, Amichay
Saito, Naoyuki
Ben-David, Merav

HEALTH PHYSICS REVIEW

AUTHORIZED USER: Radiation Oncology

REVIEW COMMITTEE: RPC

TYPE OF APPLICATION: Renewal w/ amendments

APPLICATION NUMBER: 07-051

**EXPIRATION DATE
(IF AMENDMENT)**

1. IF PERSONNEL MONITORING IS REQUIRED, SPECIFY TYPE AND FREQUENCY. HAVE ALL MEMBERS OF THE APPLICANT'S STAFF WHO REQUIRE MONITORING BEEN IDENTIFIED?

Radiation monitoring dosimeters are required. Individuals handling > 5 mCi of high energy beta or gamma emitters also require extremity monitoring. Separate sets of dosimeters will be supplied to those individuals involved in Y-90 TheraSpheres administrations so these doses can be tracked separately.

2. IF BIOASSAY IS REQUIRED, SPECIFY TYPE AND FREQUENCY. HAVE ALL MEMBERS OF THE APPLICANT'S STAFF WHO REQUIRE BIOASSAY BEEN IDENTIFIED?

Bioassays are not required unless requested by RSS.

3. DESCRIBE ANY SPECIAL MONITORING THAT SHOULD BE CONDUCTED (BREATHING ZONE AIR SAMPLING, STACK EFFLUENT MONITORING, ETC.). SPECIFY FREQUENCY, LOCATION(S) WHERE SAMPLING SHOULD BE CONDUCTED, AND ISOTOPE(S) FOR WHICH SAMPLES SHOULD BE ANALYZED.

Effluent monitoring is not required.

4. LIST TYPE(S) OF RADIOACTIVE WASTE LIKELY TO BE GENERATED UNDER THIS AUTHORIZATION, INCLUDING AN ESTIMATE OF VOLUME.

Radioactive waste generation is minimal. Transient sealed sources are disposed either via UM OSEH-HazMat or sent back to the manufacturer. Sealed sources are occasionally taken out of service. Disposal is via UM OSEH-HazMat.

Y-90 TheraSpheres waste is collected in an OSEH-supplied waste container and called in for pick-up shortly after each procedure.

5. EVALUATE THE APPLICANT'S PROCEDURES FOR HANDLING RADIOACTIVE MATERIAL.

Radiation Oncology wishes to renew the RSS-102R on file with RSS. Major revisions include adding permanent implants (either Pd-103 and/or I-125) for interstitial treatment of tumors and Y-90 TheraSphere therapy treatments for liver tumors. Permanent implants utilizing either Pd-103 or I-125 for prostate treatment or other interstitial use is not currently planned in the near future, but is being added to the RSS-102R at this time. RSS anticipates being notified by Radiation Oncology well in advance of any planned use. An experimental lung brachytherapy was performed only once in 2006 (with RDRC/SHUR approval), but has not be repeated since. There are no substantive changes in eye plaque, traditional brachytherapy, or HDR use or protocols from the 2004 RSS-102R renewal.

Y-90 TheraSphere use is the most significant addition to this RSS-102R renewal for Radiation Oncology. Use of TheraSpheres is in accordance 10 CFR 35.1000.

Background information: Y-90 TheraSpheres is a pure beta emitter used to treat individuals who have liver cancer and it is meant to extend their life expectancy. It has been granted a Humanitarian Device Exemption. Some traditional chemotherapy treatments for liver cancer use a similar technique without radioisotopes. Unit dose Y-90 TheraSphere stocks will be obtained from MDS Nordion and will be shipped to RSS via normal protocol. Six dose vials are available ranging from 81 mCi up to 540 mCi. Each milligram of solution contains 22,000- 73,000 microspheres. The general appearance of the Y-90 TheraSpheres stock is that of very fine sand particles in solution. Once shaken, it can take up to several minutes for the glass TheraSpheres to settle out, but they do settle out of solution. The idea is to have these individual microspheres get stuck and stay embedded in the fine vascular structure of the liver tumor to deliver the desired localized radiation dose.

Patients must first qualify for the treatment based on prior Nuclear Medicine testing, namely Tc-99m MAA. Once it is determined the patient is a candidate, plans for possible dates of treatment are set. Since fluoroscopy is needed for proper catheter placement into the

liver, Y-90 TheraSpheres must be administered in one of nine possible Interventional Radiology suites (either at UMH or CVC). Since these areas are high volume patient areas, the shut-down of such areas for any radioactive contamination will have a high impact on patient flow in the area. Thus, extreme care must be taken to ensure that ANY contamination or leakage is contained. All possible areas of leakage must have absorbent material placed under and around them. All individuals must be surveyed upon exiting the room.

Those individuals immediately involved in TheraSpheres administration must attend 'Theraspheres University' at Northwestern University as required by MDS Nordion. This training was conducted in late January 2008. Participants observe an actual procedure being conducted and delivered by the Theraspheres Administration Accessory kit (see Diagram 2 in Y-90 Theraspheres Section). In addition, MDS Nordion representatives are on-site to present a refresher a few days before the actual treatment. This refresher is done for the first few patients until faculty and staff is familiar with the procedure and protocol. The AU Physician for Theraspheres administration will be Charlie Pan, M.D. and Venkat Krishnamurthy, M.D., is the primary Interventional Radiology contact. Radiation Oncology Physics Group, namely Pete Roberson, Ph.D., and Joann Prisciandaro, Ph.D.

The dose is well shielded at all times, with the exception of the brief time during actual dose administration when the TheraSpheres are pushed through the series to tubes and stopcocks with saline.

Once the procedure is complete, everyone involved will be thoroughly surveyed with a pancake G-M before being allowed to leave the room. The patient will be surveyed to ensure dose rates are low (as to be expected with a pure beta emitter). All associated waste will be collected and placed in the OSEH-supplied container and will be picked up ASAP by OSEH HazMat.

6. FOR NEW APPLICANT'S: EVALUATE APPLICANT'S TRAINING AND EXPERIENCE.

N/A

7. LIST ANY RECOMMENDED SPECIAL CONDITIONS OF USE THAT SHOULD BE MADE PART OF THIS AUTHORIZATION.

- 1) All safety precautions required by Radiation Safety Service and MDS Nordion regarding Y-90 TheraSpheres administration must be strictly followed.
- 2) RSS must be contacted well in advance of any planned prostate treatments to ensure that NRC licensing requirements have been addressed by the RSO.

8. LIST ANY PREWORK CONDITIONS OF USE THAT SHOULD BE MADE PART OF THIS AUTHORIZATION.

N/A

9. DESCRIBE FACILITIES AND ASSOCIATED LABORATORY CLASSIFICATIONS.

LOCATION (e.g. Room / Bldg)	INTENDED USE	LAB CLASSIFICATION
8402 University Hospital	Low Dose Rate Brachytherapy	A
8404 University Hospital	Low Dose Rate Brachytherapy	A
8411 University Hospital	Low Dose Rate Brachytherapy	A
8412 University Hospital	Low Dose Rate Brachytherapy	A
OR 2244 Kellogg Eye Center	Eye Plaques	A
OR 2215 Kellogg Eye Center	Eye Plaques	A
OR 2205 Kellogg Eye Center	Eye Plaques	A

2302 Kellogg Eye Center	Eye Plaques	A
B2C303 University Hospital	Source Room / Hot Lab	A
B2C413 University Hospital	HDR Afterloader Brachy treatments	A
B2C525 University Hospital	HDR Afterloader Brachy treatments	A
Operating Rooms – University Hospital	Permanent implantation of Brachy seeds (Lung or Prostate)	A
B2C422 University Hospital	LDR Source Localization	A
B2C428 University Hospital	LDR Source Localization	A
Interventional Radiology Suite University Hospital (B1 level – Rooms 1,2,3,4,5,6)	Y-90 TheraSpheres	A
Interventional Radiation Suite Cardiovascular Center (CVC) (Level 4 - Rooms 7,8, 9)	Y-90 TheraSpheres	A

APPLICATION NUMBER 07-051	EXPIRATION DATE <i>Timely Renewal</i>
HEALTH PHYSICS REVIEW COMPLETED BY Richard D. Dugan <i>[Signature]</i>	DATE March 31, 2008
TEMPORARY APPROVAL REQUEST <input checked="" type="checkbox"/> <i>Y-90 Theraspheres</i> <i>Mark L. Driscoll</i>	<i>04/09/08</i> DATE
SIGNATURE FOR TEMPORARY APPROVAL/RADIATION SAFETY OFFICER <i>Immanuel Nicholas (m)</i>	<i>4/21/08</i> DATE
SIGNATURE OF APPROVAL BY RADIATION POLICY COMMITTEE <i>(RDRS/SHUR chair)</i>	

FILENAME:

Nicolaas Bohnen, MD, PhD

STATEMENT OF TRAINING AND EXPERIENCE

(Please Print or Type)

Name: PAN CHARLIE C UM ID#: 2577 5975
 Last First Middle
 Birthdate: August 13, 1973 Sex: M Uniqname: Cpan
 Work Phone: (734) 936-4300 Work Address: 1500 E Medical Center Dr.
 Job Title: House Officer Ann Arbor, MI 48109
 Department: Radiation Oncology Authorized User: Theodore Lawrence M.D. Ph.D.

Please complete this form to the best of your knowledge. Check the appropriate response and elaborate on "YES" answers in the space provided.

- YES NO HAVE YOU:
- Attended the University of Michigan – Radiation Safety Orientation Course required by the Nuclear Regulatory Commission (10 CFR 19.12). Date attended: July 2003
 - Had formal training or college level courses in the radiological areas listed below? If yes, list course title, instructional location, and approximate date and duration in space provided.
 - Principles/Practices of Radiation Protection: Radiation Physics, UoM, August 2000 - May 2000, Aug 2001 - May 2001
Radiation Biology, UoM, Aug-Dec 2000, Aug-Dec 2002
 - Biological Effects of Radiation: "
 - Radioactivity Measurements, Monitoring or Radiation Instrumentation Use: "
 - Mathematics/Calculations Basic to the Use and Measurements of Radioactivity: "
 - Atomic/Nuclear Structure, Radiochemistry, Nuclear Engineering, Nuclear Physics, etc.: "
 - Attended Seminars, conferences or training sessions relative to radiation, radioactive material or radiological safety: _____
 - Handled radioactive materials or operated radiation-producing devices (X-ray, etc.). Indicate radioisotope(s) or equipment used, activity handled (uCi or mCi), location and purpose of use:
LINAC, Cs-137 (LDR), Ir-192, I-125, Pd-103 (Prostate Brachytherapy)
Varian 6-100, 1800, 2100 C, 2100 CB, 2100 EP; Standard GE X-ray Sim, CT Sim

Charlie P
Signature

May 14, 2004
Date

Please return to: **Radiation Safety Service**
1239 Kipke Drive / CSSB 1010

Or Fax to: (734) 763-1185

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LISLE, IL 60532-4352

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