



1120 Professional Boulevard • Evansville, Indiana 47714  
Phone (812) 471-7086 • Fax (812) 471-3381

328 N. 2nd Street, Suite 101 • Vincennes, Indiana 47591  
Phone (812) 882-8252 • Fax (812) 895-5636

June 1, 2008

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

Re: Request to renew USNRC Materials License

Dear Sir/Madam:

This is a formal request to renew USNRC Materials License #13-32112-01 (*Open MRI, LLC d/b/a Advanced Diagnostic Imaging*) located at 1120 Professional Boulevard Evansville, IN 47714. It is our intention to continue to use radioactive materials (for which we are licensed), and the existing equipment located at this facility as submitted with this application request.

Please contact our Radiation Safety Officer Mr. William K. Breeden, III, M.S., DABR at 317/223-0322 for further clarification if you desire.

Thank you in advance for completing a review of this documentation.

Sincerely,

**John R. Bies, M.D.**

**President**

***Open MRI, LLC, d/b/a Advanced Diagnostic Imaging***

Cc: William K. Breeden, M.S., DABR, RSO  
NRC Correspondence File

RECEIVED JUN 2 6 2008

**APPROVED BY OMB: NO. 3150-0120** **EXPIRES: 10/31/2008**  
 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

C. RENEWAL OF LICENSE NUMBER **13-32112-01**

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

**Open MRI, LLC, dba Advanced Diagnostic Imaging**  
**1120 Professional Boulevard**  
**Evansville, IN 47714**

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

**1120 Professional Boulevard**  
**Evansville, IN 47714**

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

**William K. Breeden**

TELEPHONE NUMBER

**(317) 223-3022**

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

**See attachment**

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

**See Attachment**

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

**See attachment**

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9. FACILITIES AND EQUIPMENT.

**See attachment**

10. RADIATION SAFETY PROGRAM.

**See attachment**

11. WASTE MANAGEMENT.

**See attachment**

12. LICENSE 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: **John R. Bies, M.D., President**

SIGNATURE: 

DATE: **06/01/2008**

**FOR NRC USE ONLY**

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

APPROVED BY: \_\_\_\_\_ DATE: \_\_\_\_\_

OPEN MRI, LLC, D/B/A ADVANCED DIAGNOSTIC IMAGING  
USNRC APPLICATION RENEWAL REQUEST  
JUNE 1, 2008

**3. ADDRESS WHERE LICENSED MATERIAL WILL BE USE OR STORED:**

1120 Professional Boulevard  
Evansville, IN 47714

**5. & 6. RADIOACTIVE MATERIAL AND USE**

<u>Radioactive Material</u>	<u>Chem &amp; PhysForm</u>	<u>Max.Posse Activity Limit</u>	<u>Purpose</u>
10 CFR 35.190	Any	As Needed	Uptake , Dilution, and Excretion Studies
10 CFR 35.290	Any(excluding Generators and Xe-133 gas)	As Needed	Imaging and Localization Studies
10 CFR 35.390	Any(excluding I-131 Thyroid carcinoma therapy)	As Needed	Radionuclide Therapy and imaging procedures for which a written directive is required

**7. RADIATION SAFETY PROGRAM RESPONSIBILITY**

<u>Authorized Users</u>	<u>Materials</u>
John R. Bies, M.D.	10 CFR 35.190, 10 CFR 35.290 (excluding generators and xenon-133 gas), and 10 CFR 35.390 (excluding I-131 thyroid carcinoma therapy).
Jeffery R. Miller, M.D.	10 CFR 35.190, 10 CFR 35.290 (excluding generators and xenon-133 gas).
Tina M. Molis, M.D.	10 CFR 35.190, 10 CFR 35.290 (excluding generators and xenon-133 gas).

**Training and experience for the above named individuals can be identified as follows:**

John R. Bies, M.D. currently appears on USNRC Materials License number 13-32112-01 amendment no: 8 with an expiration date of 9/30/08 as an authorized user for the materials identified above (copy enclosed).

Jeffery R. Miller, M.D. currently appears on USNRC Materials License number 13-03226-04 amendment no: 26 with an expiration date of 2/28/2015 as an authorized user for the materials identified above (copy enclosed). An amendment request to add this individual is currently pending under previous documentation submitted.

OPEN MRI, LLC, D/B/A ADVANCED DIAGNOSTIC IMAGING  
USNRC APPLICATION RENEWAL REQUEST  
JUNE 1, 2008

Tina M. Molis, M.D. currently does not appear on a USNRC Materials License. An amendment request to add this individual is currently pending under previous documentation submitted. ( A copy of the material submitted has been enclosed if needed).

**Radiation Safety Officer**

William K. Breeden, III, MS, DABR

The above named individual appears on USNRC Materials License number 13-32112-01 amendment no: 8 with an expiration date of 9/30/08 as a radiation safety officer (copy enclosed). Mr. Breeden has experience with the radiation safety aspects of the byproduct material use for which he has RSO responsibilities (10 CFR 35.50 (c) and 35.24 (g), and has sufficient time, authority, organizational freedom, resources and management prerogative to perform the duties.

**MATERIALS LICENSE**

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p style="text-align: center;">Licensee</p> <p>1. Open MRI, LLC d/b/a Advanced Diagnostic Imaging</p> <p>2. 1120 Professional Boulevard Evansville, IN 47714</p>	<p>In accordance with the <b>letter received April 4, 2006,</b></p> <p>3. License number 13-32112-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date <b>September 30, 2008</b></p> <hr/> <p>5. Docket No. 030-34799 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p> <p>C. Any byproduct material permitted by 10 CFR 35.300</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any (excluding generators)</p> <p>C. Any (excluding iodine-131 for thyroid carcinoma therapy)</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. One curie</p>
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9. Authorized Use:
- A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
  - B. Any imaging and localization study permitted by 10 CFR 35.200 (excluding generators).
  - C. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300 (excluding iodine-131 for thyroid carcinoma therapy).

CONDITIONS

- 10. Licensed material shall be used only at the licensee's facilities located at 1120 Professional Boulevard, Evansville, Indiana.
- 11. The Radiation Safety Officer for this license is William K. Breeden III, M.S.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
13-32112-01

Docket or Reference Number  
030-34799

Amendment No. 8

12. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for medical use as indicated:

Authorized Users

Material and Use

James F. Rold, M.D.

10 CFR 35.100, 35.200 (excluding generators), and 35.300  
(excluding iodine-131 for thyroid carcinoma therapy).

John R. Bies, M.D.

10 CFR 35.100, 35.200 (excluding generators), and 35.300  
(excluding iodine-131 for thyroid carcinoma therapy).

13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
14. In addition to the possession limits in item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated July 11, 1998, with attachments; and
- B. Letters dated September 11, 1998, November 23, 1998 (excluding Quality Management Program), February 8, 1999 (excluding Quality Management Program), June 14, 2004, and June 21, 2004.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date JUN 19 2006

By   
Loren J. Hueter  
Materials Licensing Branch  
Region III

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

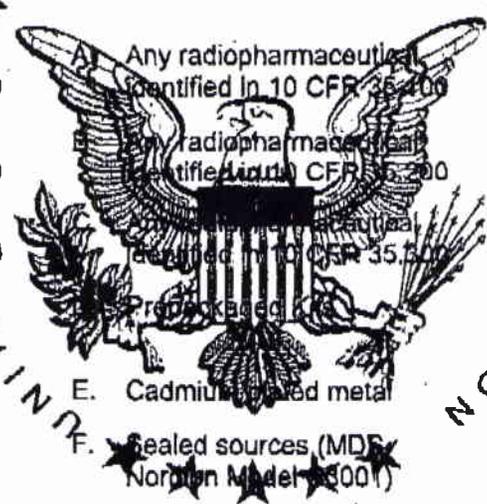
PAGE 1 OF 5 PAGES  
 Amendment No. 26

**MATERIALS LICENSE**

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee  1. St. Mary's Medical Center  2. 3700 Washington Avenue Evansville, IN 47750	In accordance with application dated November 29, 2004,  3. License number 13-03226-04 is renewed in its entirety to read as follows:  4. Expiration date February 28, 2015  Docket No. 030-20812 Reference No.
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6. Byproduct, source, and/or special nuclear material  A. Any byproduct material identified in 10 CFR 35.100 B. Any byproduct material identified in 10 CFR 35.200 C. Any byproduct material identified in 10 CFR 35.300 D. Any byproduct material identified in 10 CFR 31. E. Depleted Uranium F. Cesium-137  G. Iridium-192	7. Chemical and/or physical form  A. Any radiopharmaceutical identified in 10 CFR 35.100 B. Any radiopharmaceutical identified in 10 CFR 35.200 C. Any radiopharmaceutical identified in 10 CFR 35.300 D. Depleted Uranium E. Cadmium plated metal F. Sealed sources (MDS Norton Model 5001)  G. Sealed sources (Omnitron International Model SL-777V, Varian Medical Systems Model SL-777V, Varian Medical Systems Model VS2000)	8. Maximum amount that licensee may possess at any one time under this license  A. As needed B. As needed C. As needed (not to exceed 10 curies of I-131) D. As needed E. 999 kilograms F. No single source to exceed the maximum activity specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State G. 2 sources, 1 source not to exceed 13 curies and 1 source not to exceed 11 curies)
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NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
13-03226-04

Docket or Reference Number  
030-20812

Amendment No. 26

9. Authorized Use:

- A. Medical use described in 10 CFR 35.100.
- B. Medical use described in 10 CFR 35.200.
- C. Medical use described in 10 CFR 35.300.
- D. In vitro studies.
- E. Shielding in a linear accelerator.
- F. For the irradiation of materials, including blood, blood products, cells and tissues, in an MDS Nordion, Gammacell 3000 Elan, Model I self-shielded irradiator device, in accordance with the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and which has been distributed in accordance with a Commission or Agreement State specific license authorizing distribution to persons specifically authorized by a Commission or Agreement State license to receive, possess, and use the device.
- G. One source to be used in a Varian HDR brachytherapy device for interstitial, intraluminal, and intracavitary applications in humans, physics calibrations and Quality Assurance checks. The source activity may not exceed 11 Ci at the time of installation. One source in its shipping container for source replacement.



- 10. A. Licensed materials in Subitem Nos. 6.A. through 6.E. shall be used only at the licensee's facilities located at 3700 Washington Avenue, Evansville, Indiana, and at St. Mary's Breast Center, 711 St. Mary's Drive, Evansville, Indiana.
- B. Licensed materials in Subitem Nos. 6.F. shall be used only at the licensee's facilities located at 3700 Washington Avenue, Evansville, Indiana.
- C. Licensed materials in Subitem 6.C. may be used at St. Mary's Radiation Oncology Center, 3801 Bellemeade Avenue, Evansville, Indiana, in accordance with the letter dated October 14, 2000.
- 11. A. The Radiation Safety Officer for this license is Saiyid M. Shah, Ph.D.
- B. High Dose Rate Brachytherapy Physicist: Zhongshan (John) Zhang, M.S.
- 12. Licensed material is only authorized for use by, or under the supervision of:
  - A. Individuals permitted to work as an authorized user and authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.

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U.S. NUCLEAR REGULATORY COMMISSION

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**MATERIALS LICENSE  
 SUPPLEMENTARY SHEET**

License Number  
 13-03226-04

Docket or Reference Number  
 030-20812

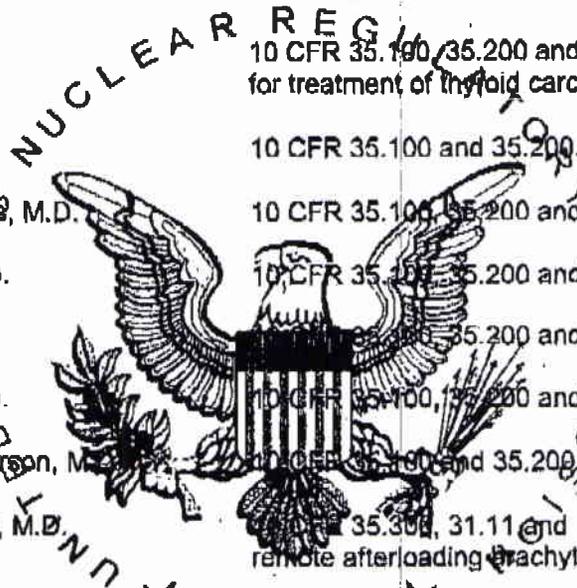
Amendment No. 26

B. The following individuals are authorized users for the materials and uses indicated:

Authorized Users

Material and Use

Alvin Korba, M.D.	10 CFR 35.300
Aly A. Razek, M.D.	10 CFR 35.300
Shannon S. Lamb, M.D.	10 CFR 35.300
Steven Becker, M.D.	10 CFR 35.100, 35.200 and 35.300 (excluding iodine-131 for treatment of thyroid carcinoma).
Keith Phillips, M.D.	10 CFR 35.100 and 35.200.
Thomas E. Schultheis, M.D.	10 CFR 35.100, 35.200 and 35.300.
Ralph A. Sellers, M.D.	10 CFR 35.100, 35.200 and 35.300.
Robert A. Vogt, M.D.	10 CFR 35.100, 35.200 and 35.300.
Killol J. Thakore, M.D.	10 CFR 35.100, 35.200 and 35.300.
Caryn Cockerill Anderson, M.D.	10 CFR 35.100 and 35.200.
Michael James Miller, M.D.	10 CFR 35.300, 31.11 and iridium-192 in a high dose rate remote afterloading brachytherapy device.
Helen E. Sponseller, M.D.	10 CFR 35.100, 35.200 and 35.300.
Robert Woodburn III, M.D.	10 CFR 35.300 and iridium-192 in a high dose rate remote afterloading brachytherapy device.
James M. Esser, M.D.	10 CFR 35.100, 35.200 and 35.300.
Jeffrey B. Hemmerlein, M.D.	10 CFR 35.100 and 35.200.
James D. McDaniel, M.D.	10 CFR 35.100 and 35.200.
Jeffrey R. Miller, M.D.	10 CFR 35.100 and 35.200.
Gary W. Kerber, M.D.	10 CFR 35.100 and 35.200



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U.S. NUCLEAR REGULATORY COMMISSION

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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
13-03226-04

Docket or Reference Number  
030-20812

Amendment No. 26

13. Licensed material in Subitem No. 6.F. shall be used by, or under the supervision of, individuals who have received the training described in the letters dated April 19, 2000, and June 27, 2000. The licensee shall maintain records of individuals designated as users for 3 years following the last use of licensed material by the individual.
14. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
15. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State.
- B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State, prior to the transfer, a sealed source received from another person shall not be placed in use until tested and the test results received.
- C. Sealed sources need not be leak tested if they are in storage and are not being used. However, when they are removed from storage and transferred to another person, and have not been tested within the required intervals, they shall be tested before use or transfer. No sealed source shall be stored for a period longer than 10 years without being tested for leakage and/or contamination.
- D. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Regional Office referenced in Appendix D of 10 CFR Part 20. The report shall specify the source involved, the test results, and corrective action taken.
- E. Tests for leakage and/or contamination, limited to leak test sample collection, shall be performed by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
16. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.
17. The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sealed sources and/or devices received and possessed under the license.

NRC FORM 313A (AUD) (10-2007)	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008																	
<b>AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION</b> (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]																			
Name of Proposed Authorized User <i>Tina M. Molis, M.D.</i>		State or Territory Where Licensed <i>Indiana</i>																	
Requested Authorization(s) (check all that apply)																			
<input checked="" type="checkbox"/> 35.100 Uptake, dilution, and excretion studies																			
<input checked="" type="checkbox"/> 35.200 Imaging and localization studies																			
<input type="checkbox"/> 35.500 Sealed sources for diagnosis (specify device _____)																			
<b>PART I – TRAINING AND EXPERIENCE</b> (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.																			
<input checked="" type="checkbox"/> <b>1. Board Certification</b>																			
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.																			
<input type="checkbox"/> <b>2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization</b>																			
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.)																			
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:40%;">Description of Experience</th> <th style="width:30%;">Location of Experience/License or Permit Number of Facility</th> <th style="width:10%;">Clock Hours</th> <th style="width:20%;">Dates of Experience*</th> </tr> </thead> <tbody> <tr> <td style="height: 100px; vertical-align: top;">                             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                         </td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	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				<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td colspan="4" style="text-align: center;"><b>Total Hours of Experience:</b></td> </tr> <tr> <td style="width:50%;">Supervising Individual</td> <td colspan="3">License/Permit Number listing supervising individual as an authorized user</td> </tr> </table>			<b>Total Hours of Experience:</b>				Supervising Individual	License/Permit Number listing supervising individual as an authorized user		
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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																			
<b>Total Hours of Experience:</b>																			
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).																			
<input type="checkbox"/> 35.290 <input type="checkbox"/> 35.390 + generator experience in 32.290(c)(1)(ii)(G)																			

NRC FORM 313A (AUD)  
(10-2007)

U.S. NUCLEAR REGULATORY COMMISSION

**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 <i>(not required for 35.590)</i>			
Radiation biology			
<b>Total Hours of Training:</b>			

**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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	

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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects		<input type="checkbox"/> Yes <input type="checkbox"/> 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		<input type="checkbox"/> Yes <input type="checkbox"/> 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 Tina Molis, M.D. has satisfactorily completed the requirements in  
Name of Proposed Authorized User

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 \_\_\_\_\_ has satisfactorily completed the 60 hours of training and  
Name of Proposed Authorized User

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 Tina Molis, M.D. has satisfactorily completed the requirements in  
Name of Proposed Authorized User

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 \_\_\_\_\_ has satisfactorily completed the 700 hours of training  
Name of Proposed Authorized User

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 <u>John R. Bies, M.D.</u>	Signature <u>[Signature]</u>	Telephone Number <u>(812) 471-7086</u>	Date <u>3/19/08</u>
License/Permit Number/Facility Name <u>#13-32112-01 Open MRI, LLC d/b/a Advanced Diagnostic Imaging</u>			

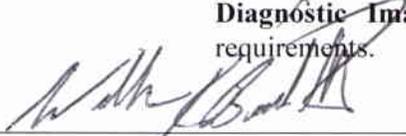
**Radiation Safety Officer Responsibilities [10 CFR 35.24 (e) ]:**

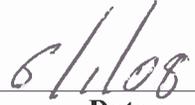
The Radiation Safety Officer (RSO) shall:

1. Investigate overexposures, accidents spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, medical events, and other deviations from the radiation safety practices approved by facility management .
2. Establish, implement, and collect in a centralized location policies and procedures as follows:
  - a. Authorization for the purchase of radioactive material.
  - b. Receipt and opening of packages containing radioactive material.
  - c. Storage of radioactive material.
  - d. Inventory control of radioactive material.
  - e. Safe use of radioactive material.
  - f. Emergency procedures in the event of loss, theft, etc.
  - g. Periodic radiation surveys.
  - h. Checks of radiation survey and other radiation safety instruments.
  - i. Disposal of radioactive material.
  - j. Personnel training of those who work in or frequent areas of radioactive material use or storage.
3. Maintain a record systems to include at least the following:
  - a. All records, reports, written policies and procedures required by regulatory agencies concerning radioactive material.
  - b. A copy of the regulations governing the possession, use and disposal of licensed material, such as Title 10 Code of Federal Regulations.
4. Review the following radiation safety program records, and sign each as directed in 10 CFR 35, if applicable:
  - a. Sealed Source Inventories
  - b. Sealed Source Leak Tests
  - c. Dose Calibrator Calibration Tests
  - d. Medical Event documentation
  - e. Changes in the radiation safety program
  - f. Radiation surveys of sealed source storage.
5. Inform facility management at least annually of the status of the licensed material program.
6. Establish personnel exposure investigational levels as a part of the ALARA program and philosophy.

7. Approve or disapprove minor changes in radiation safety procedures that are not potentially important to safety with the advice and consent of management.

(1) As Radiation Safety Officer for **Open MRI, LLC dba Advanced Diagnostic Imaging**, I agree to be responsible for implementing the radiation protection program. **Open MRI, LLC dba Advanced Diagnostic Imaging** shall ensure through my authority that radiation safety activities are being performed in accordance with **Open MRI, LLC dba Advanced Diagnostic Imaging's** established approved procedures and regulatory requirements.

  
\_\_\_\_\_  
**William K. Breeden, III, M.S., DABR**  
**Radiation Safety Officer**  
**Open MRI, LLC dba Advanced Diagnostic Imaging**

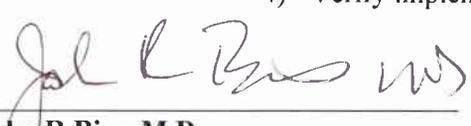
  
\_\_\_\_\_  
**Date**

**Delegation of Authority**

William K. Breeden, III, M.S., DABR, has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radiation. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities.

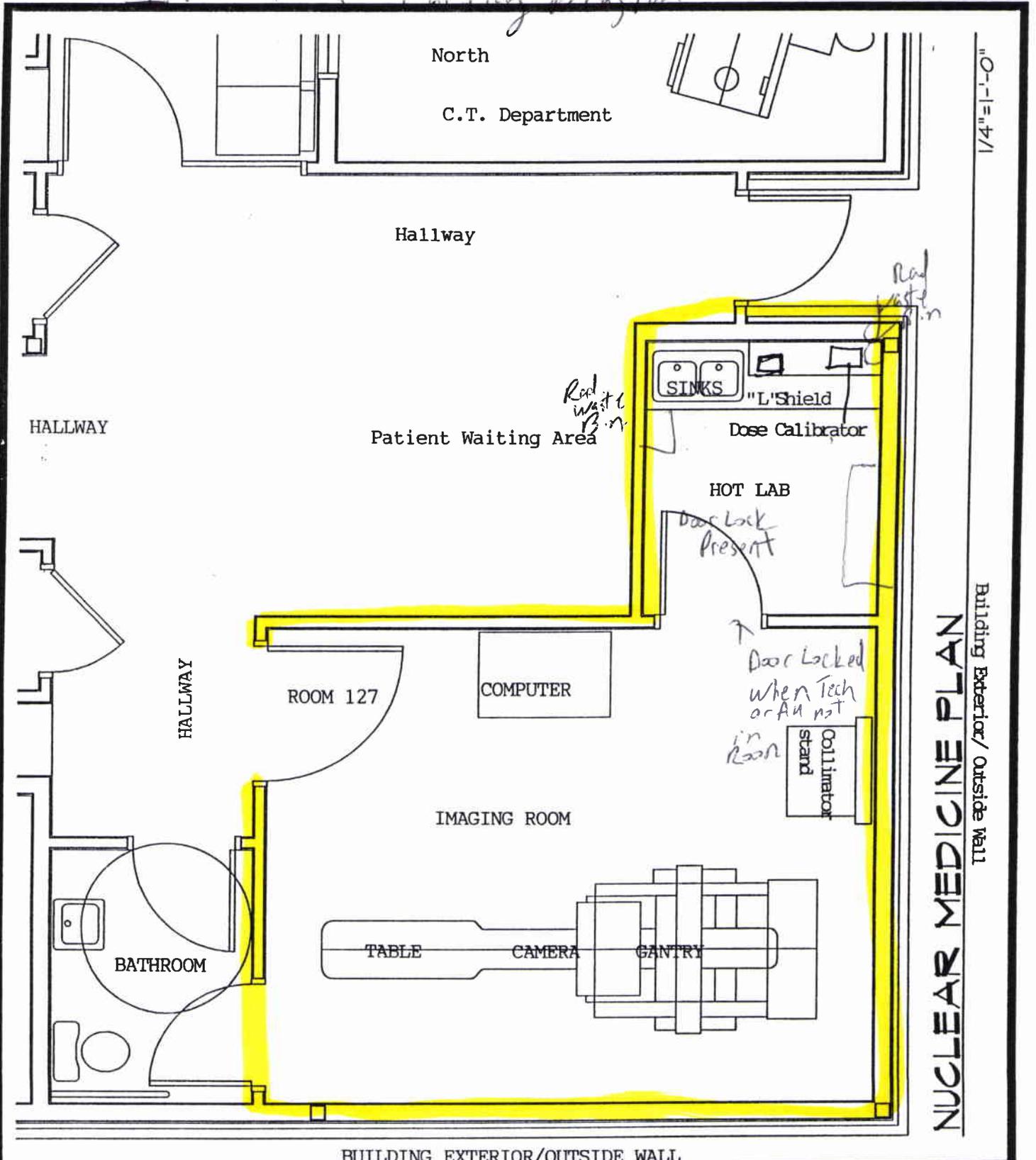
In accordance with 10 CFR 35.2024, "*Records of authority and responsibilities for radiation protection programs*," **Open MRI, LLC dba Advanced Diagnostic Imaging** will provide William K. Breeden, III, (Radiation Safety Officer) with sufficient authority, organizational freedom, time, resources and management prerogative to:

- 1) Identify radiation safety problems;
- 2) Initiate, recommend, or provide corrective actions;
- 3) Stop unsafe operations; and,
- 4) Verify implementation of corrective actions. |10 CFR 35.24 (g)|

  
\_\_\_\_\_  
**John R Bies, M.D.**  
**President**  
**Open MRI, LLC dba Advanced Diagnostic Imaging**

  
\_\_\_\_\_  
**Date**

ITEM 9 Facility Diagram



Scale: 1/4" = 1'-0"

**Advanced Diagnostic Imaging**

1120 Professional Boulevard  
Evansville, Indiana

**Edmund L. Hafer & Associates, P.C.**

Architecture Engineering Planning Interior Design

Suite 800  
21 Southeast Third Street  
Evansville, Indiana 47708-1433

Project No.

U1-105

Date

7/13/98

Note: Nothing is Above or Below

This Area (Roof, & Slab on Grade)

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Item 9:

**Radiation Monitoring Instruments**

Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations. A description of the instrumentation that will be used to perform the required surveys is identified below.

Capintec Caprac Well Counter with sensitivity of 22 dpm/cm<sup>2</sup>  
Ludlum Model 14C GM Survey Meter (Range: 1-1000 mR/hr)

*Open MRI, LLC, D/B/A Advanced Diagnostic Imaging* reserves the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.

Dose calibrator: Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.

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**Equipment List**

Gamma Scintillation Camera

Siemens Diacam Gamma Camera

Dose Calibrator

Capintec CRC - 15R

Survey Meters

Ludlum Model 14C GM Survey Meter, end window probe -Range (0-2000 mR/r)

Other

Capintec Caprac Well Counter  
Syringe Shields  
Lead-Glass Face Shield  
Lead Lined Waste Container  
Lead Syringe Holders  
Decontamination Kit  
Lead Bricks  
10-15 mCi Co-57 Flood Source  
200-250 uCi Cs-137 Reference Standard Source

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Item 10:

**Occupational Dose**

Either *Open MRI, LLC, D/B/A Advanced Diagnostic Imaging* will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements of listed under "Criteria" in NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About the Medical Use Licensees," dated October 2002.

**Area Surveys**

*Open MRI, LLC, D/B/A Advanced Diagnostic Imaging* has developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.

**Written Procedures for Area Surveys**

1. Areas of radiopharmaceutical prep. & administration may be surveyed daily for ambient radiation exposure rates.
2. Areas of radiopharmaceutical storage and radiopharmaceutical waste storage may be surveyed weekly for ambient radiation exposure rates.
3. Areas of radiopharmaceutical prep, administration or waste storage will be wipe tested weekly for removable contamination.
4. Surveys for ambient exposure rates will be performed with a radiation detection survey instrument able to detect as low as 0.1 mR/hr.
5. Surveys for removable contamination will consist of a series of wipes which will be assayed using a procedure sufficiently sensitive to detect 2000 dpm.
6. The trigger level for exposure rate surveys will be established by the Radiation Safety Officer.
7. Survey results greater than the trigger levels will result in decontamination or shielding procedures necessary to reduce the exposure or contamination levels to ALARA levels on repeat surveys.
8. A record shall be kept of all survey results. These records will be retained for a period of three (3) years. The record will include:
  - a. Location, date, and type of equipment used.
  - b. Initials of the person conducting the survey.
  - c. Drawing of the area surveyed.
  - d. Trigger levels keyed to the location on the drawing.
  - e. Results keyed to the location on the drawing.
  - f. Corrective actions taken in case of contamination or excessive exposure rates and reduced contamination levels after corrective action.
9. The RSO or their designate will review the survey results regularly for conformance to certain action levels.

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10. The method for determining the efficiency factor of each counting instrument used to detect contamination for wipe testing is as follows:

A = Calculated source activity of sample isotope in dpm

B = Measured source counts of sample isotope in cpm

C = Measured background counts in cpm

D = B - C (Net Counts in cpm)

$$\text{Efficiency Factor} = \frac{\text{Calculated Activity in dpm (A)}}{\text{Net Counts in cpm (D)}}$$

$$\text{Wipe Sample-dpm} = (\text{Net Counts of Wipe Sample})(\text{Efficiency Factor})$$

12. The RSO will be notified of all positive wipe test and ambient survey results.

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**Safe Use of Unsealed Licensed Material**

*Open MRI, LLC, D/B/A Advanced Diagnostic Imaging* has developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

**Written Procedures for Safe Use of Unsealed Licensed Material**

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Either after each procedure or before leaving the area, monitor your hands and clothing for contamination in a low background area using an appropriate survey instrument.
4. Use syringe shields for reconstitution of radiopharmaceutical kits and administration of radiopharmaceuticals to patients, except when their use is contraindicated (e.g., recessed veins, infants). In these and other exceptional cases, use other protective methods, such as remote delivery of the dose (e.g., use of a butterfly needle).
5. Do not eat, store food, drink, smoke, or apply cosmetics in any area where radioactive material is used or stored.
6. Wear personnel monitoring devices (as prescribed by the RSO) at all times while in areas where radioactive materials are used or stored. Store personnel monitoring devices at the facility in a designated low-background area.
7. Wear extremity personnel monitoring devices when handling radioactive material.
8. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
9. Never pipette by mouth.
10. Wipe test unsealed byproduct material storage, preparation and administration areas weekly for contamination. If necessary, decontaminate or secure the area.
11. Survey with a radiation detection survey meter all areas of licensed material use, including the generator storage (if applicable), kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area. Areas used to prepare and administer therapy quantities of radiopharmaceuticals must be surveyed daily in accordance with 10 CFR 35.70.
12. Store radioactive solutions in shielded containers that are clearly labeled.
13. Always keep flood sources, syringes, waste and other radioactive material in shielded containers.

**Written Procedures for Safe Use of Unsealed Licensed Material (continued)**

14. Radiopharmaceutical multi-dose vials diagnostic and therapy vials must be labeled in accordance with 10 CFR 35.69 and 10 CFR 20.1904.
15. Syringes and unit dosages must be labeled in accordance with 10 CFR 35.69 and 10 CFR 20.1904. Mark the label with the radionuclide, the activity, the date for which the activity is estimated, and the kind of materials (i.e., radiopharmaceutical). If the container is holding less than the quantities of Appendix C to Part 20, the syringe or vial need only to be labeled to identify the radioactive drug (10 CFR 35.69). To avoid mistaking patient dosages, label the syringe with the type of study and the patient's name.
16. For prepared dosages, assay each patient dosage in the dose calibrator (or instrument) before administering it {10 CFR 35.63 (b) (1) or by decay correction {10 CFR 35.63 (b) (2)}}.
17. Do not use a dosage if it does not fall within the prescribed dosage range or if it varies from the prescribed dosage by more than +/- 20% of the prescribed dosage unless approved by the authorized user.
18. When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle.
19. Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering. If the prescribed dosage requires a written directive, the patient's identity must be verified and the administration must be in accordance with the written directive (10 CFR 35.41).
20. Secure all licensed material when not under the constant surveillance and immediate control of an individual authorized under the NRC license (or such individual's designee).

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**Spill Procedures**

***Open MRI, LLC, D/B/A Advanced Diagnostic Imaging*** has developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101.

**Written Procedures for Safe Response to Spills of Licensed Material**

**Minor Spills of Liquids and Solids**

1. NOTIFY: Notify persons in the area that a spill has occurred.
2. PREVENT THE SPREAD OF CONTAMINATION:  
Cover the spill with absorbent paper.
3. CLEAN UP: Wearing gloves and protective clothing such as a lab coat and booties, clean up the spill using absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a "caution radioactive material" labeled bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. SURVEY: Survey the area with a low-range radiation detection survey instrument sufficiently sensitive to detect the radionuclide. Check for removable contamination to ensure contamination levels are below trigger levels. Check the area around the spill, hands, clothing, and shoes for contamination.
5. REPORT: Report the incident to the RSO.

**Major Spills of Liquids and Solids**

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.
2. PREVENT THE SPREAD OF CONTAMINATION: Cover the spill with "caution radioactive material" labeled absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, clearly indicate the boundaries of the spill and limit the movement of all personnel potentially contaminated.
3. SHIELD THE SOURCE (if possible): Do this only if it can be done without further contamination or a significant increase in radiation exposure.
4. CLOSE THE ROOM: Leave the room and lock or otherwise secure the area to prevent entry.
5. NOTIFY: Notify the RSO immediately.
6. PERSONNEL DECONTAMINATION: Decontaminate personnel by removing contaminated clothing and flushing the contaminated skin with lukewarm water and then washing with mild soap. If contamination remains, the RSO may consider inducing perspiration. Then wash the affected area again to remove any contamination that was released by the perspiration.

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**Minimization of Contamination**

It is the understanding of *Open MRI, LLC, D/B/A Advanced Diagnostic Imaging* that the NRC will consider the previously stated criteria has been met if the information provided within this application satisfy the criteria in Sections 8.14, 8.15, 8.20, 8.24, 8.26 and 8.28 on the topics: Facility and Equipment; Facility Diagram; Radiation Protection Program; Safety Program and Waste Management with no further response necessary or required.

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**Leak Testing of Sealed Sources**

*Open MRI, LLC, D/B/A Advanced Diagnostic Imaging* has developed and will implement procedures for leak-testing sealed sources.

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**Written Procedure for Leak Testing of Sealed Sources**

Leak tests will be performed by:

Anyone licensed by the NRC to perform leak testing as a service.

**Written Procedure for Ordering & Receiving Packages**

1. Authorize, through a designee {e.g. The Radiation Safety Officer (RSO)} each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded.
2. Establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:
  - a. Records that identify the authorized user or department, radionuclide, physical and/or chemical form, activity, supplier will be made.
  - b. Confirmation, through the above records, that material received was ordered through proper channels.
3. For deliveries during normal working hours, inform carriers to deliver packages directly to a specified area.
4. For deliveries during off-duty hours, inform security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum for delivery of packages to the department, provided below.

**Written Procedure for Safely Opening Packages Containing Radioactive Material**

1. Put on gloves to prevent hand contamination.
2. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop and notify the RSO or designee of the RSO if the RSO is not immediately present.
3. Monitor the external surfaces of a labeled package for radioactive contamination, unless the package contains only radioactive material in the form of a gas or in a special form, as defined in 10 CFR 71.4.
4. Monitor the external surfaces of a labeled package for radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR 71.4 and Table A to 10 CFR Part 71.
5. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels, if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.
6. Remove the packing slip.
7. Open the outer package following the supplier's instructions,
8. Open the inner package and verify that the contents agree with the packing slip.
9. Check the integrity of the final source container. Notify the RSO (or the RSO's designee) of any broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
10. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. An appropriate instrument with sufficient sensitivity will be used to assay the sample. For example, a NaI(Tl) crystal and rate meter, a liquid scintillation counter, or a proportional flow counter may be used for these assays. The detection efficiency will be determined to convert wipe sample counts per minute to disintegrations per minute. Note: a dose calibrator is not sufficiently sensitive for this measurement. Take precautions against the potential spread of contamination.
11. Verify that the material received is the material ordered.
12. Monitor the packing material and the empty packages for contamination with a radiation detection meter before discarding. If contaminated, treat as radioactive waste. If not contaminated, deface all radiation labels before discarding.
13. Make a record of the receipt.

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**MEMORANDUM FOR OFF-HOURS DELIVERY OF RADIOACTIVE MATERIAL**

To: All authorized staff  
From: William K. Breeden, III, M.S., DABR  
Radiation Safety Officer

Subject: Receipt of Packages Containing Radioactive Material

Only authorized radioactive material providers that have received appropriate radiation safety and hot lab security training are allowed access to the secure hot lab within the nuclear medicine department when deliveries occur that arrive outside normal working hours. The door will be unlocked with the package placed in a predetermined designated package receipt location. The door will be re-locked and secure upon delivery.

If the package appears to be damaged, immediately contact one of the individuals identified below as well as the radiopharmaceutical provider.

If you have any questions or concerns regarding this memorandum, please contact the Radiation Safety Officer.

	Cell Number*
Radiation Safety Officer:	William K. Breeden, III, MS, DABR *(317/223-3022)
Authorized User:	John R. Bies, M.D.
Nuclear	(817) 471-7086
Medicine Technologist:	Carol McCollom, CNMT *(270) 577-3711

*\*home telephone numbers intentionally not provided because of The Freedom of Information Act, 5 U.S.C. § 552, As Amended By Public Law No. 104-231, 110 Stat. 3048*

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Item 11.

**Waste Management**

*Open MRI, LLC, D/B/A Advanced Diagnostic Imaging* has developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20 and 10 CFR 35.92.

**Written Procedure for Waste Management**

10 CFR 35.92 describes the requirements for decay-in-storage. Storage should be designed to allow for segregation of wastes with different half-lives (e.g., multiple shielded containers). Containers should have shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location.

If possible, use separate containers for different types of waste (e.g., needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container). Because the waste will be surveyed with all shielding removed, the containers in which the waste will be disposed of must not provide any radiation shielding for the material.

When a container is full, seal it and attach an identification tag that includes the date sealed and the longest lived radionuclide in the container. The container may then be transferred to the decay in storage area.

Prior to disposal as in-house waste, monitor and record the results of monitoring of each container as follows:

1. Use a survey instrument that is appropriate for the type and energy of the radiation being measured;
2. Check the radiation detection survey meter for proper operation and current calibration status;
3. Monitor in a low-level radiation (<0.05 mR/hr) area away from all sources of radioactive material, if possible;
4. Remove any shielding from around the container or generator column;
5. Monitor at contact, all surfaces of each individual container;
6. Remove or deface any radioactive material labels (unless the containers will be managed as biomedical waste after they have been released from the licensee as described in 10 CFR 35.92);
7. Discard as in-house waste only those containers that cannot be distinguished from background radiation. Containers may include trash bags full of waste, generator columns, and biohazard (needle) boxes. Record the disposal date, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal;
8. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred to an authorized byproduct material recipient.

**Written Procedure for Waste Management (continued)**

1. Generators will not be used at this facility.

**Procedure for Return of Licensed Material to Authorized Recipients:**

1. In accordance with 10 CFR 30.41 (a)(5), confirm that persons are authorized to receive byproduct material prior to transfer (e.g., obtain a copy of the transferee's NRC license or Agreement State license that authorizes the byproduct material);
2. Retain the records needed to demonstrate that the package qualifies as a DOT specification 7A container;
3. Assemble the package in accordance with the manufacturer's instructions;
4. Perform the dose rate and removable contamination measurements;
5. Label the package and complete the shipping papers in accordance with the manufacturer's instructions;
2. Retain records of receipts and transfers in accordance with 10 CFR 35.51.

