

**MIDWEST**  
**BRACHYTHERAPY**  
**SERVICES, INC.**



17295 Chesterfield Airport Rd.  
Chesterfield, MO 63005

November 12, 2010

Licensing Branch  
USNRC Region III  
801 Warrenville Rd.  
Lisle, IL 60532-4351

To whom it may concern:

Please find enclosed a license renewal for a Mobile High Dose Rate Afterloader, Class 2 license.

If you have any questions, please contact me by email at [dkeys@med-phys.com](mailto:dkeys@med-phys.com), or by phone at 636-579-0136.

Sincerely,

David J. Keys, Ph.D.  
President

RECEIVED DEC 01 2010

nrc application111110

NRC FORM 313  
(3-2009)  
10 CFR 30, 32, 33,  
34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 3/31/2012

### APPLICATION FOR MATERIALS LICENSE

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the 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.resource@nrc.gov](mailto:infocollects.resource@nrc.gov), and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

**INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.**

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

OFFICE OF FEDERAL & STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS  
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS  
U.S. NUCLEAR REGULATORY COMMISSION  
WASHINGTON, DC 20555-0001

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

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:

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:

LICENSING ASSISTANCE TEAM  
DIVISION OF NUCLEAR MATERIALS SAFETY  
U.S. NUCLEAR REGULATORY COMMISSION, REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PA 19406-1415

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 24-33280-01

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

**Midwest Brachytherapy Services, Inc.**  
**17295 Chesterfield Airport Rd**  
**Chesterfield, MO 63005**

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

**See Attachment**

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

**David J Keys, PhD**

TELEPHONE NUMBER

**(636) 579-0136**

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 3P AMOUNT ENCLOSED \$ 0.00

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

**David J Keys, PhD President**

SIGNATURE

*David J. Keys, Ph.D.*

DATE

*11/16/10*

#### FOR NRC USE ONLY

| TYPE OF FEE | FEE LOG | FEE CATEGORY | AMOUNT RECEIVED | CHECK NUMBER | COMMENTS |
|-------------|---------|--------------|-----------------|--------------|----------|
|             |         |              | S               |              |          |

APPROVED BY

DATE

### Supporting Documentation

#### Item 3 - Locations of Use

It is to be noted that Radioactive Material will never be present at our Corporate Address. The only time Midwest Brachytherapy Services, Inc. shall possess radioactive material is during transportation from one site to another.

- 1) The following sites are known client sites. Others may be added (with 30 day NRC notification) as services are expanded.

##### Home Base

Address: St Anthony's Medical Center  
10010 Kennerly Rd  
St Louis, MO 63128

NRC license: 24-01041-04

Licensed for HDR patient treatment : Yes

If trained personnel are not available, Midwest Brachytherapy Inc. will not transfer the device to the client.

Source Installation at this site: Yes, primary site

Site 2: Phelps County Regional Medical Center  
1000 West 10<sup>th</sup>  
Rolla, MO 65401

NRC license: 24-18295-01

Licensed for HDR patient treatment : Yes

Source Installation at this site: Yes, if the facility license allows

Trained in HDR techniques and concepts: Yes.

If trained personnel are not available, Midwest Brachytherapy Inc. will not transfer the device to the client.

Source Installation at this site: Yes

Site 3: Scott Radiological Group, Inc.  
1420 Highway 61 South  
Festus, MO 63028

NRC license: 24-32416-01

Licensed for HDR patient treatment : Yes

Source Installation at this site: Yes, if the facility license allows

Trained in HDR techniques and concepts: Yes.



David J. Keys, Ph.D.      RSO  
Authorized Physicist NRC license 24-01041-04

**Item 8 – Training for Individuals entering Restricted areas.**

No MBS employee is likely to receive 100 mrem in a year's time due to the transport of the mobile HDR unit. Annually MBS employees will receive training, in regards to transportation of radioactive material.

**Item 9 – Facility Diagram**

Each client shall submit to the NRC (or Agreement State) facility diagrams showing the site for HDR treatments as part of their NRC or state license. MBS shall determine that appropriate radiation safety surveys have been performed at each client site prior to transferring the device to the client.

**Item 10 – Radiation Safety Program**

**1) Radiation Safety Officer**

David J. Keys, Ph.D. will serve as RSO for Midwest Brachytherapy, Inc. Dr. Keys is named as the RSO for St Anthony's Medical Center, NRC license No24-01041-04.

**2) Radiation Safety Committee**

Due to the limited scope of radiation-related activities, there is no need for a Radiation Safety Committee.

**3) Equipment**

- A) Midwest Brachytherapy, Inc. will maintain 2 survey meters. At least one of the survey meters will be able to detect exposure rates from 0.1 mrem/hr to 1 mrem/hr.
- B) Calibration of the survey meters will be performed by a company approved or registered either with the NRC or an Agreement State according to procedures specified in Appendix B of Regulatory Guide 10.8, Revision 2.
- C) Survey meters will be calibrated annually.
- D) Allowed HDR medical devices are:
  - Varian Gammamed 12it (uses Gammamed 212 source)
  - Varian Gammamed Plus (uses Gammamed 232 source)
  - Varian Gammamedplus IX (uses Gammamed 232 source)

**4) Leak Tests/ Inventory of Sealed Sources**

- A) Sources are typically to be returned prior to the 6 month leak test requirement. If necessary, leak tests will be performed according to directions provided by a company approved or registered either with the NRC or an Agreement State
- B) At least semi-annually an inventory of the radioactive material and a radiation survey will be performed about the remote afterloader device.

**5) Ordering and Receipt of Radioactive Material**

- A) The RSO or his designee will order the replacement source for the remote afterloader device. The RSO or his designee will notify the Host site the expected date of arrival of the replacement source .
- B) The Host site will be responsible for the receipt of radioactive material according to their NRC license conditions.

**6) Operational and Safety Checks following HDR Relocation**

- A) Following relocation of an HDR device and prior to turning over control to the client.
  - i) A radiation survey will be performed to demonstrate the integrity of the device.
  - ii) A visual inspection of the device will be performed of the unit.
  - iii) The unit shall be promptly delivered to the client's site for HDR.

It remains the client's responsibility to perform all pretreatment operational functions as required by the client's radioactive material license.

**7) Transportation Safety**

**A) General**

Transportation of the mobile HDR devices is performed by trained and qualified personnel approved by Midwest Brachytherapy Services, Inc. (The applicant) The Applicant will perform the functions of both a shipper (Person offering regulated radioactive material to a carrier) and also a Private Carrier by highway, pursuant to the authority of the license. Applicable DOT requirements of the 49 CFR 170-189 DOT Hazardous Materials Regulations and the 49CFR383-397 Federal Motor Carrier Safety Regulations will be followed.

**B) Packaging**

The mobile HDR devices has been qualified as an authorized DOT 7A Type A package containing 370 mBq (10 Ci) of Ir-192 in the form of an encapsulated sealed source which meets DOT requirements as "special form" radioactive material. The relevant DOT-7A Safety Analysis Report (SARP) for the Remote Afterloading Brachytherapy Units (Varian Medical Systems Gammamed 12it, Varian Medical Systems Gammamedplus, and Varian Medical Systems Gammamedplus IX) will be maintained on file by the applicant as required by 49CFR173.415(a). The certificate for the special form encapsulation of the Gamma Afterloading Sources will be maintained on file as required by 49CFR173.476(a).

**C) Labeling of Package**

The device will be labeled with two labels, one on each of two opposite sides with "Radioactive-White I" labels (or Radioactive-Yellow II), based on the dose rates at the package surface and at one meter (definition of the transport index). Neither of these category of label calls for placarding of the transport vehicle with the RADIOACTIVE placards.

**Marking of Package**

The following required marking will be applied to the exterior of the package:

Proper Shipping name : :Radioactive material, special form, UN 2974"

Identification Number: "UN 2974"  
Hazard Class: "7"  
EPA Reportable Quantity: "RQ"  
(0.37 mBq, 10 Ci.)  
Package Specification: "USA DOT-7A, Type A"  
Gross Weight:  
Consignor's Name: Midwest Brachytherapy Services, Inc., St. Louis, MO or as appropriate  
Consignee's Name: Midwest Brachytherapy Services, Inc., St. Louis, MO or as appropriate  
NOTE: actual addresses will be inserted if different  
24-Hour Emergency Response Telephone Number:

CHEM-TEL, Inc.  
800-255-3924 voice  
813-248-0573 non-emergency number.

D) Vehicle Placarding

Placarding of the highway vehicle is not required since the Radioactive-Yellow III labels are not required on the package

E) Shipping Paper (Manifest) Information

The following elements of required information will be included on the shipping paper documentation"

Proper shipping name: Radioactive material, special form , n.o.s UN 2974"  
Name of nuclide: "Ir-192" or "Iridium 192"  
Activity in package: "370 mBQ (10 Ci)"  
Category of Label applied: "Radioactive-White I" or "Radioactive-yellow II"  
Transport Index Assigned: (probably "0")

NOTE: multiply rad level at 1 meter in mSv/hr by 100  
Exclusive Use Notation "Exclusive Use round down to "0" if measured TI is less than 0.05)

Shipment", add : "Exclusive use being used but not required by DOT regulations, and is being used at shipper's option for security of material in transit per NRC requirements)

NOTE: Accessibility and visibility of shipping documents inside cab of transport vehicle will be in accordance with DOT requirements in 49CFR 177.817(e).

F) Pre-determined Exposure Rates Table

A table showing the calculated exposure rates for an unshielded source as a function of distance shall be available with the radiation safety materials in the transportation van.

G) Emergency Response Procedures

Shipments of the licensed device by the applicant will be unique with respect to providing emergency response information to the first responder. This is because the "first responder" is

very likely to be the trained driver employee of Midwest Brachytherapy, Inc. (Unless incapacitated by the accident). This person will have been trained in the emergency response actions needed to be taken to isolate the area, survey for unusual radiation, and report the incident as required to relevant authorities.

DOT regulations in 49 CFR 172, Subpart G will be followed with respect to required information on shipping documents, 24-hour emergency telephone number and information on the nature and hazards of the material. The information must be present with the shipping documents in the vehicle and at all locations where the material is stored in transit.

The 24-hour emergency telephone number provided by the applicant is that of CHEM-TEL, 800-255-3924. The applicant has registered with CHEM-TEL and maintains up to date and current information on the hazards of the device with that agency.

Shipping paper documents will also include a copy of DOT Emergency Response Guide #164 (Attached) from the DOT Emergency Response Guidebook as well as a copy of the manufacturer's photo of the device.

Also to be included is a current copy of the emergency response guidance from the Conference of Radiation Control Program Directors (CRCPD), attached., entitled "Contacts for Radiological Assistance to First Responders at Transportation Accidents", which contains the name and telephone number points of contact in each state for radiological assistance involving radioactive materials.

All transportation documentation will be updated as appropriate and reviewed annually.

The transport vehicle shall carry a calibrated survey meter located in the cab of the vehicle. This meter shall be used to measure radiation levels of the HDR unit and surrounding vicinity in the event of an accident. The operator of the vehicle will be trained in the proper use of the survey meter and corresponding procedures in the event that a radiation hazard is detected.

Prior to leaving the vehicle unattended, the van operator will engage all door locks and arm the vehicle alarm system. In addition, the locks will be visually inspected to verify they are in the locked position. Note: Vehicle alarm system is equipped with motion sensors that will activate if mechanical checks are performed. Alarm system (including sensors) will be checked monthly to ensure proper functioning.

#### **Suspected Hazard – Limiting Access to the Van:**

In the event that a radiation hazard is suspected the procedure for determining whether such an event is present or not will be as follows:

**Two person team:** One of the team members, the authorized physicist, will perform an area survey with the calibrated survey instrument located in the cab of the vehicle. The second member, the driver, will visually monitor the area and verbally warn any individuals to remain 25 ft away from the vehicle until the survey has been completed and radiation levels ascertained. Upon completion of the survey, if:

- 1) No radiation hazard is present, both van operator and authorized physicist will attend to the accident details.
- 2) A radiation hazard is present, the authorized physicist will take control of the scene and initiate the appropriate emergency procedures (see retrieving and securing a dislodged source).

**One person:** The van operator will visually inspect a 25 foot area immediately around the van. Any individuals within the perimeter will be verbally warned to step outside the perimeter. The operator will perform an area survey with the calibrated survey instrument located in the cab of the vehicle. Upon completion of the survey, if:

- 1) No radiation hazard is present, van operator will attend to the accident details.
- 2) A radiation hazard is present, the van operator will take control of the scene and initiate the appropriate emergency procedures (see retrieving and securing a dislodged source).

H) Retrieving and Securing a Dislodged Source.

In the unlikely event that the source becomes dislodged creating a radiological hazard, the following procedure will be executed.

The van will be equipped with a shielded source container, a pair of long forceps, a pair of diagonal cutters and a calibrated survey meter.

**Two person team:** The physicist or other trained person will perform a quick survey to record the approximate exposure levels and approximate the time the suspected event began. The operator will initiate the procedure to limit access to van. Once the source has been located, if still attached to the cable and the unit, the physicist shall attempted to manually return it to its "safe" position. If this does not occur, using the forceps, the source should be placed into the shielded container. The physicist or other trained person should again survey the area to confirm that the source is secure. If, for whatever reason, the source cannot be contained, the physicist or other trained person should secure the area while the operator goes to call:

- |                              |                                      |
|------------------------------|--------------------------------------|
| 1) CHEM-TEL                  | 800-255-3924                         |
| 2) MDS Nordion               | 800-826-2258                         |
| 3) MBS –                     | David J. Keys, Ph.D.<br>636-579-0136 |
| 4) NRC Emergency<br>Response | 301-816-5100                         |

The van will be attended by MBS personnel until the appropriate assistance arrives.

**Securing the Area:** The van shall be equipped with signs. Each sign shall read:

"Restricted Area  
Radiation Survey in Progress  
Keep back 25 ft"

And shall be printed large enough to be read at a distance of 25 ft. One sign shall be posted on each side of the vehicle ( front, rear, right and left) and shall remain there until the source has been recovered.

**One person:** The operator will visually inspect an area 25 ft around the van to confirm that there are no other people in the immediate vicinity of the vehicle. The operator shall perform a quick survey to record the approximate exposure levels and approximate the time the suspected event began. Once the source has been located, if still attached to the cable and the unit, the operator shall attempted to manually return it to its "safe" position. If this does not

occur, using the forceps, the source should be placed into the shielded container. The operator should again survey the area to confirm that the source is secure. If, whatever reason the source cannot be contained, the operator should establish a safe perimeter from the van (see **Securing the Area**) and prevent anyone from entering until help arrives. Once help has arrived, the operator should immediately contact:

- |                              |                                      |
|------------------------------|--------------------------------------|
| 1) CHEM-TEL                  | 800-255-3924                         |
| 2) MDS Nordion               | 800-826-2258                         |
| 3) MBS –                     | David J. Keys, Ph.D.<br>636-579-0136 |
| 5) NRC Emergency<br>Response | 301-816-5100                         |

- I) Re-qualification of the unit after an accident and prior to patient delivery:

Under no circumstances shall patient treatments be delivered with an HDR unit that has been involved in an accident until it has been fully checked by an authorized medical physicist or radiation safety officer. In order to verify operational functionality, the medical physicist will setup unit at host site and perform all QA/QC associated with a monthly calibration and the Transportation Protocol. This will include a source calibration, verification film of source positioning, timer functions, and system interlocks. In the event that the unit fails any of these tests, the vendor will be contacted in order to repair and re-certify the unit for patient use. In addition, a copy of the report generated in accordance with 10CFR30.50 will be provided to the clients which use that unit. Once again, after re-certification and prior to patient use, the unit will be tested at the host site by the authorized medical physicist or radiation safety officer.

- J) Hazmat training

Tri-annually (or at a frequency defined by law) all licensed personnel involved with HDR transportation shall receive "hazmat" training in accordance with 49 CFR Part 172.704.

- K) Survey meter availability

At least one survey meter, capable of reading 0.1 mR/hr to 100 mR/hr will be available in the cab of the transportation vehicle.

- L) Vehicle Security

The transportation vehicle will remain secured at all times from unauthorized access when the vehicle is unattended. An alarm system shall be present on the vehicle.

Note: Chem-tel is listed as the initial provider of 24 hour response support. Other companies may be utilized as circumstances arise.

#### **Item 11 Waste Management**

Radioactive material will be returned to the manufacturer according to DOT regulations in a shipping container similar to the one initially shipped with the source.

D. Keys  
Midwest Brachytherapy Services  
17295 Chesterfield Airport Rd  
Chesterfield, MO 63005



Materials Licensing Branch  
USNRC  
2443 Warrenville Rd, Ste 210  
Lisle, IL 60532-4352

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