

## **Med – Share, Inc.**

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26222 Telegraph Rd., Suite 100, Southfield, MI 48033  
Tel. (248) 827-7200 Fax. (248) 827-2641

**August 6, 2014**

### **United States Nuclear Regulatory Commission**

Region III, Materials Licensing  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

RE: Amendment to NRC License No. 21-26098-01  
Med-Share Inc.

Dear Sir/Madam:

The purpose of this letter is to clarify our current NRC license conditions to reflect the following.

#### **Mobile Nuclear Medicine Imaging Service**

We provide Nuclear Medicine service to a number of clients (medical facilities) which are unable to provide this service, in addition to locations already listed on our license. All services will be supplied within the facility. We will, if necessary, supply only the imaging portion of the service within a trailer / truck.

Some patient doses will be delivered to these locations by way of courier (technologist) employed by Med-Share Inc. Additionally a unit dose pharmacy may deliver radio-pharmaceuticals to these mobile locations. The doses will only be delivered when our personnel are on location at these temporary job sites. (The unit dose supplier will not leave radioactive material without a Med-Share employee onsite and will only transfer control of radioactive material to a Med-Share Inc. employee).

All waste and used syringes will be returned to a location of use currently listed on our license. Upon approval of this amendment we will notify the unit dose supplier in writing of these requirements.

#### **Temporary Job Sites**

The exact location of the services supplied will vary from site to site. All services will be supplied within the facility itself. We may, if necessary, supply only the imaging portion of the service within a trailer / truck. All radioactive materials will be kept in shielded containers until immediately prior to its use. It is not conceivable that any member of the public would receive exposures that would exceed the limits as required in 10 CFR part 20. All radioactive materials will be removed from the site at the end of each day of use.

**Administrative Requirements**

We will obtain a letter signed by the management of each client's for services which are rendered that authorizes the use of radioactive material at the client's address of use.

We will make available for the client's review the required NRC documents and records kept under this license. In addition, we will allow the client to observe our licensed activities at any time.

**Technical Requirements.**

We will only transport radioactive material that are unit dose syringes containing prepared radiopharmaceuticals or sealed sources required for gamma camera and dose calibrator quality control.

All radioactive materials and associated waste that are brought to each client's location will be removed at the end of each day of use. We will perform area surveys with a GM survey meter and perform wipe tests for removable contamination to ensure that all radio-pharmaceuticals, byproduct materials and associated waste have been removed.

We will secure or keep under constant surveillance and immediate control all byproduct when in transit or at the address of use.

Dose calibrators will be tested for proper function prior to daily use. This test will consist of a constancy check using a Cs-137 source for each commonly used settings.

Survey instruments will also be tested for proper function prior to each use with a dedicated Cs-137 check source. Meters will be calibrated annually as required by our existing license conditions.

All vehicles that are used in the transportation of radioactive materials will be supplied with a GM survey meter. This meter may be used to perform area surveys to ensure that all radio-pharmaceuticals, byproduct materials and associated waste have been removed from the clients address. This meter may also be used for emergent situations.

We will keep a record of the above surveys as required for a period of three years.

**Postings**

All areas of use that require posting will be posted as required in 10 CFR part 19.

**Emergency Procedures**

We have enclosed a copy of the emergency procedures for your review. We will have a copy of these procedures clearly visible in the truck at all times when radioactive material is being transported.

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The RSO or her delegate will be available by either phone and / or beeper at all times whenever services are being provided. Maximum response time is approximately 1 hour to any client location.

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### **Transportation of Radioactive Materials**

All radioactive material will be shipped in accordance with DOT regulations during transport to each imaging location. We have enclosed a copy of our radioactive material shipping paper and the policies associated with the above procedures. All packages will be secured within the transport vehicle through tie-downs or braces in such a manner to prevent movement of the containers during normal transportation.

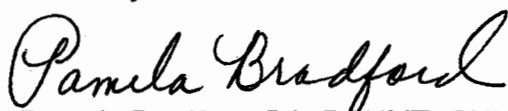
Unit dose syringes are packaged inside the lead syringe holders (either 1/8" or 1/4" lead thickness) and packaged inside U.S. Government approved Type A containers. The containers surpassed tests including drop, compression and penetration. Documentation of these tests and further description of the containers are on file with the unit dose pharmacy.

### **Personnel Training**

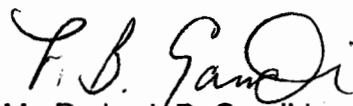
All personnel responsible for the packaging and transport of radioactive material will be trained prior to assuming duties and at least annually thereafter. The in-service shall consist of the proper procedures to follow for: emergency response, recognizing unsafe conditions, response to unsafe conditions and transport conditions pertinent to the transport of these materials. This training will also cover the requirements for HAZMAT 10 CFR part 41. We will document the individuals attending, the topics discussed and the dates.

If you have any questions or require additional information, please contact our physics consultant, James Botti at 734-662-3197 or by email at [jbotti@mpcphysics.com](mailto:jbotti@mpcphysics.com).

Sincerely,



Pamela Bradford, BS, BSNMT, CNMT, NCT  
Radiation Safety Officer



Mr. Prakash B. Gandhi  
Executive Management

## TRANSPORTATION POLICIES

1. Summary of Radioactive Materials Transportation Regulations:

The Department of Transportation (DOT) has regulatory responsibility for safety in the transportation of radioactive materials by all modes of transport in interstate commerce. The Nuclear Regulatory Commission (NRC) also has responsibility for safety in the transport of license byproduct materials. Copies of applicable DOT and NRC regulations (10 CFR 71) are available upon request in the radiopharmacy.

2. Transportation Classifications:

The radiopharmaceuticals transported are categorized as (a) Normal Form Radioactive Materials - n.o.s., (b) Type A Quantity - less than 20 Curies, and (c) Transport Group IV.

3. Shipper's Requirements in the Preparation and Transport of Radioactive Material Packages (R.A.M.):

a. Maximum Radiation Levels at any point on the external surface of any package may not exceed 200 millirems per hour and 10 millirems per hour at 3 feet (i.e. Transportation Index may not exceed 10 mR/hr).

b. Each package must be labeled on two opposite sides with the proper Radioactive Package Label:

LABEL	DOSE RATE	DOSE RATE
	(surface)	(at 3 feet)
"Radioactive - White I"	0.5 mR/hr	0 mR/hr
"Radioactive - Yellow II"	50 mR/hr	1.0 mR/hr
"Radioactive - Yellow III"	200 mR/hr	10 mR/hr

\*requires vehicle placarding

c. The applicable information as required in the blank spaces on the Radioactive Package Label must be inserted by legible printing as follows:

1. **CONTENTS:** Name of the Radionuclide

2. **NUMBER OF CURIES:** Units must be expressed in curies (Ci), millicuries (mCi), or microcuries (uCi)

3. **TRANSPORTATION INDEX (TI):** Dose rate at 3 feet from the external surface of the package must be measured using the GM survey meter and entered on the label.

d. The radioactive packages will be stored at the greatest possible distance from the driver, and at no less than 3 feet from any occupants.

e. When transporting Yellow III packages, drivers will be assigned film badges to be worn during transportation.

- f. The outside of each R.A.M. package must be labeled with the proper shipping name: "TYPE A".
- g. Shipping papers must be included that specify the following information:

**Proper shipping name:** Radioactive Material, n.o.s. Salt/Liquid

**Transport group:** IV

**TYPE A QUANTITY**

This is to certify that the above-mentioned materials are properly classified, described, packages, marked and in proper condition for transportation according to applicable regulations of DOT and NRC.

- h. The outside of each radioactive package must incorporate a security seal which is not readily breakable and which, while intact, is evidence that the package has not been illicitly opened.
- i. The vehicle must remain locked whenever it is left unattended.
- j. Leave deliveries only in secured places that have been previously designated by the customer as a receipt area for radioactive packages.

4. Contamination Control:

- a. After transporting DOT specified activities of radioactive materials, the transport vehicle will be wipe tested in the location of the radioactive packages. The vehicle wipe test shall be counted and recorded. If wipe counts are greater than 2000 dpm/100 cm<sup>2</sup>, the vehicle shall be decontaminated before being returned to service. In this case, results will be recorded in dpm/100 cm<sup>2</sup> or uCi/cm<sup>2</sup>.
- b. Prior to transporting DOT specified activities of radioactive materials, the surface of the packages will be wipe tested and counted. The results will be recorded. If wipe counts are greater than 2000 dpm/100 cm<sup>2</sup>, the dose case, or syringe holder may not be returned to service until being properly decontaminated. In this case, results will be recorded in dpm/100 cm<sup>2</sup> or uCi/100 cm<sup>2</sup>.

5. Shipping Container Description:

Unit dose syringes are packaged inside the lead syringe holders (either 1/8" or 1/4" lead thickness) and packaged inside U.S. Government approved Type A packaging. The transportation containers surpassed all Type A packaging tests including drop, compression and penetration. Documentation of these tests and further description of Type A packaging are on file at the unit dose radiopharmacy.

- 6. Drivers will be instructed in the items specified in 10 CFR 19.12 at the time of initial employment and at least annually thereafter.

**INSTRUCTIONS TO DRIVERS CONCERNING  
RADIATION SAFETY AND DELIVERY PROCEDURES**

1. No delivery cases are to be removed from the Nuclear Pharmacy unless they have been placed in the area designated for pick-up.
  2. All cases placed in the pick-up area have been checked by the Nuclear Pharmacy staff and are safe to handle.
  3. Do not attempt to carry more than three cases by hand at any one time. Either make another trip or use a dolly.
  4. All delivery vehicles containing delivery cases will be locked when unattended.
  5. Delivery cases are only to be left in approved areas which have been designated by the customer. If you cannot gain access to the designated area, call the Radiation Safety Officer. Do not leave the delivery case unattended!
  6. Exposure rates at the surface of the delivery case are minimal, however, it is good practice not to place the cases on the front seat of your vehicle, immediately next to you or another person. You should place the cases in a stable location of the vehicle, no closer than three (3) feet to any person.
  7. In the event a delivery case sustains damage, do not attempt to deliver the case. Call the Radiation Safety Officer at the above number for instructions.
  8. You must read the NRC Form "Notice to Employees". If you have any questions regarding our NRC license, we will make every attempt to provide you with an understandable answer.
  9. In the event of a traffic accident, refer to the Emergency Policy Instructions.
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## **EMERGENCY POLICY:**

### **Procedures to be Followed in the Event of a Serious Traffic Accident**

1. Generally, the radioactive material carried in this vehicle consists of diagnostic nuclear medicine and presents a minimal radiation hazard.
2. A complete list of materials contained in the delivery cases can be found in the envelope attached to the outside of each case.
3. The following individuals should be contacted immediately for instructions if a traffic accident has occurred involving this vehicle such that the vehicle is damaged and/or the driver is injured to the extent that the cases cannot be delivered:

**Pam Bradford (RSO)**

**248-790-4807**

4. Delivery cases are not to be removed from the vehicle.
  5. In the event, a delivery case has been thrown from the vehicle, it should not be moved until instructions have been received from one of the individuals above.
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**INSTRUCTIONS TO RADIO-PHARMACY CONCERNING  
DELIVERY PROCEDURES TO TEMPORARY JOB SITES**

1. Radioactive material may only be transferred to a Med-Share Inc. employee.
  2. If a Med-Share Inc. employee is not on-site all radioactive material must be returned to the unit dose pharmacy.
  3. Do not attempt to deliver radioactive material to a temporary job site that is not occupied by Med-Share Inc. personnel.
  4. Delivery cases are only to be left in approved areas which have been designated by Med-Share Inc. Do not leave the delivery case unattended!
  5. If you cannot gain access to the designated area, call the Radiation Safety Officer, Pam Bradford at 248-790-4807.
  6. In the event a delivery case sustains damage, do not attempt to deliver the case. Call the Radiation Safety Officer at the above number for instructions.
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**Med-Share Nuclear Medicine Radioactive Materials Shipping****NRC License No. 21-26098-01**

**Emergency Numbers:** J. Wood (248) 790-4654 P. Bradford (248) 790-4807  
Main Office (248) 827-7200

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

**From:** Med-Share, Inc.  
22116 N. Telegraph Rd  
Southfield, MI 48034

**To:** Temporary Job  
Site Address

**Activity Shipped:** \_\_\_\_\_ **GBq Tech Signature:** \_\_\_\_\_

<b>Shipping Name</b>	Radioactive Material, n.o.s.	<b>Hazard Class</b>	Radioactive, Class 7
<b>Identification</b>	#UN2915	<b>Radionuclide</b> ➡	99mTc
<b>Physical Form</b>	Liquid	<b>Chemical Form</b>	Inorganic
<b>Label Category</b>	Radioactive, White I	<b>Transport Index</b>	None

**Visual Inspection of Package:** \_\_\_\_\_

Out-going Package Survey Instrument &amp; Surface Wipe Results:


**Survey Results:** 1 meter \_\_\_\_\_ mR/Hr; Surface \_\_\_\_\_ mR/Hr**Wipe Test Results** \_\_\_\_\_ dpmAction Level = 6600 dpm/300cm<sup>2</sup> Above Background**Technologist Signature:** \_\_\_\_\_**Record of Return to Med-Share:** Return this completed form to the Truck Yard with the case.

The Nuclear Medicine Technologist who is checking cases will:

1. File this paper in chronological order in the appropriate file
2. Copy the return case check-out information from this form onto a Mallinckrodt form and put it with the case for return to Mallinckrodt.

**Survey at Surface:** \_\_\_\_\_ mR/Hr**Wipe Test:** \_\_\_\_\_ dpm**Technologist Signature:** \_\_\_\_\_

Packaging Label Requirements:



<u>Surface</u>	<u>One Meter Transport Index</u>	<u>Proper Label</u>
0.5 mR/hr or less	NONE	Radioactive White I
0.51 mR/hr to 50 mR/hr	0.1 mR/hr to 1.0 mR/hr	Radioactive Yellow II
50.1 mR/hr to 200 mR/hr	1.1 mR/hr to 10 mR/hr	Radioactive Yellow III

Med-Share  
DRIVER EMERGENCY PROCEDURE POLICY

In the event of a serious traffic accident:

1. Call 9-1-1 if emergency help is needed; tell dispatch there is radioactive material on the truck.
2. Locate other persons involved in the accident to see if help is needed.
3. Driver should give the shipping papers and emergency response documentation to responding officers.
4. Call the nuclear medicine technologist and RSO
5. Wait for further directions from the RSO or the responding Hazmat team.
6. Drivers should assist emergency response personnel in the emergency response procedures.
7. One of the following individuals must be contacted immediately for instructions if a traffic accident has occurred involving this vehicle such that the vehicle is damaged and / or the driver is injured to the extent that the cases cannot be delivered:
  - a. Pamela Bradford, RSO (248) 790 - 4807
  - b. Jill Wood, Nuclear Manager (248) 790 - 4654
  - c. James Botti, Physicist (734) 662 - 3197
8. Do not remove delivery cases from the vehicle.
9. If a delivery case was thrown from the vehicle, do not move it until instructions have been received from one of the individuals above.
10. The radioactive material carried in this vehicle consists of diagnostic nuclear medicine and presents a minimal radiation hazard.

**SEE REVERSE SIDE FOR DOT EMERGENCY RESPONSE INFORMATION**

## D.O.T. - EMERGENCY RESPONSE INFORMATION

as per 49 CFR 172.602

Radioactive Materials in the following forms are possibly transported by this vehicle.

Physical Form	Contained In	Radionuclides
Liquid	Syringes in Lead holders in Type A2 Normal Form	$^{99m}\text{Tc}$ , or $^{201}\text{Tl}$
Sealed Sources	Lead-Lined Cases	$^{57}\text{Co}$ , & $^{137}\text{Cs}$

### IMMEDIATE HEALTH HAZARD IN ACCIDENT

#### FIRE

If emergency involves a FIRE suppress fire with as little liquid as possible to prevent possible spread.

**Liquids:** Evaporation of aqueous based radioactive material encased in lead could lead to internal radiation exposure due to inhalation - Minimal to Moderate Risk

**Sealed Sources:** Melting of solid radioactive material encased in lead could lead to internal radiation exposure due to inhalation - Moderate to High Risk

If no fire the only hazard could be from liquid leakage or external exposure due to source/lead shield displacement. Check radioactive material shipping container for liquid leaks and contain with absorbent material to prevent spread.

#### EXPLOSION

None

#### FIRST AID

Evaluate if victim has been externally exposed and/or contaminated or internally contaminated to radioactive material by evaluating accident, spills, fire, victim proximity to radioactive material, etc.

Life - saving measures are to be taken without regards to radiation exposure for the victim, once removed from the accident.

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If victim has been externally contaminated with radioactive material, contain exposed area in non-absorbent material to prevent spread of contamination and transport to the hospital.

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#### HANDLING SPILLS

Containment with absorbent material, i.e. sheets, cloth, etc.

**Tran, Frank**

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**From:** Pam Bradford <Pam.Bradford@med-share.com>  
**Sent:** Wednesday, August 13, 2014 10:17 AM  
**To:** Tran, Frank  
**Subject:** License 21 - 26098 - 01 Conditions  
**Attachments:** 8.6.2014 NRC Lic Cond 21.26098.01.pdf

License 21 - 26098 - 01 Conditions

Dear Mr. Tran,

Our physicist wrote a license condition clarification letter and I sent it in on 8/5/2014. He failed to tell me that was a draft, not the final he wanted to send in to the NRC.

What should I do? I would really appreciate some guidance on this one. Should I submit this with a letter of explanation?

I have attached what I was supposed to send to the NRC.

Pamela Bradford, BS, BSNMT, CNMT, NCT  
Accreditation Manager  
Radiation Safety Officer