



Harper University Hospital
Detroit Medical Center / Wayne State University

December 19, 2012

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Branch
2443 Warrenville Road
Suite 210
Lisle, IL 60532

Re: Amendment to 21-04127-02
Control Number 577497

Dear Madam or Sir:

We wish to amend our Materials License 21-04127-02 as follows:

ADD - AUTHORIZED USE AND POSSESSION

<u>Byproduct Material</u>	<u>Form or Manf / Model #</u>	<u>Max. Quantity</u>	<u>Authorized Use</u>
Radium-223	Chloride Aqueous Injectable Solution	5 mCi	Radiopharmaceutical Therapy – Written Directive Required

We wish to add Radium-223 Chloride ($^{223}\text{RaCl}_2$) as a sterile aqueous solution for intravenous injection for treatment of patients with late-stage castration-resistant prostate cancer with bone metastases. We wish to participate in a clinical trial of this radiopharmaceutical know as "Alpharadin" as supplied by Bayer HealthCare AG under a company sponsored IND #067521. This is a resubmission of this request previously forwarded to NRC dated 4/24/12 and given control number 577497.

- We confirm that all aspects of our "Radiation Protection Program", to include receipt, use and disposal will be applied to this clinical usage.
- We confirm that all aspects of our "Written Directive Program", to include "Patient Release" will be applied to this radiopharmaceutical usage.
- The manufacturer will supply radiation safety training to include questions & answers specific to this product, to technical and physician staff prior to first patient use.
- The manufacturer will initially proctor at least the first three (3) clinical cases for authorized users as a "Preceptor" for this specific radiopharmaceutical.
- Dose calibrators will be calibrated with NIST traceable standards prior to first patient use.

RECEIVED JAN 16 2013

If you have any questions regarding this request, please contact Thomas M. Kumpuris,
M.S. FACR of Medical Physics Consultants, Inc. 800-321-2207 or
tkumpuris@mpcphysics.com.

Sincerely,

Samuel Libon RD-MSA NE-BC
COO 12/21/12
Executive Management

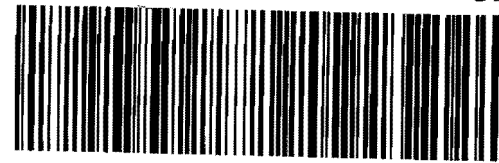
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PRIORITY OVERNIGHT

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ExpressFedEx
Tracking
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Date

FedEx
Tracking Number

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Sender's
Name

HARPER RADIOLOGY DEPT Phone 313 745-8401

Company

66148DMC/DETROIT MEDICAL CTR

Address

3790 JOHN R ST

Dept./Floor/Suite/Room

City

DETROIT

State MI

ZIP 48201-2018

2 Your Internal Billing Reference

3 To

Recipient's
Name

US Nuclear Regulatory Commission - Region III

Phone

Company

Materials Licensing Branch

Address

2443 Warrenville Rd

Address

Suite # 210

City

Lisle

State IL

ZIP 60532



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Recipient's Copy

4a Express Package Service

* To meet deadlines.

Packages up to 150 lbs.

☐ FedEx Priority Overnight
Next business morning. * Friday shipments will be delivered on Monday unless SATURDAY Delivery is selected.☐ FedEx Standard Overnight
Next business afternoon. * Saturday Delivery NOT available.☐ FedEx First Overnight
Earliest next business morning delivery to select locations.☐ FedEx 2Day
Second business day. * Thursday shipments will be delivered on Monday unless SATURDAY Delivery is selected.☐ FedEx Express Saver
Third business day. * Saturday Delivery NOT available.

4b Express Freight Service

** To meet deadlines.

Packages over 150 lbs.

☐ FedEx 1Day Freight
Earliest business day. * Friday shipments will be delivered on Monday unless SATURDAY Delivery is selected.☐ FedEx 1Day Freight Booking No.☐ FedEx 2Day Freight
Second business day. * Thursday shipments will be delivered on Monday unless SATURDAY Delivery is selected.☐ FedEx 3Day Freight
Third business day. * Saturday Delivery NOT available.

5 Packaging

* Declare value (not \$100).

☐ FedEx
Envelope*☐ FedEx Pak*
Includes FedEx Small Pak and
FedEx Large Pak.☐ FedEx
Box☐ FedEx
Tube☐ Other

6 Special Handling and Delivery Signature Options

☐ SATURDAY Delivery

NOT available for FedEx Standard Overnight, FedEx Express Saver, or FedEx 2Day Freight.

☐ No Signature Required
Package may be left without
shipper's signature for delivery.☐ Direct Signature
Someone at shipper's address
may sign for delivery. Fee applies.☐ Indirect Signature
If no one is available at recipient's
address, someone at a neighboring
address may sign for delivery. Fee
for residential deliveries only. Fee applies.

Does this shipment contain dangerous goods?

One box must be selected.

☐ No☐ Yes
As per attached
Shipper's Declaration.☐ Shipper's Declaration
not required.☐ Dry Ice
Dry Ice, 9, JAN 1995☐ Cargo Aircraft Only

7 Payment Bill to:

Enter FedEx Acct. No. or Credit Card No. below.

Obtain recip.
Acct. No.☐ Sender
Acct. No. in Section
7a below.☐ Recipient☐ Third Party☐ Credit Card☐ Cash/Check

Total Packages

Total Weight

Credit Card Auth.

*Our liability is limited to \$100 unless you declare a higher value. See the current FedEx Service Guide for details.

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