



January 8, 2020

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

**RE: Amendment to NRC License No. 13-18879-01
Elkhart General Hospital**

Dear Ms. Gryglak:

This is in response to your request for more information regarding our request to remove 35.400 materials at Elkhart General Hospital. We used I-125 and Pd-103 sources when our brachytherapy program was active. I-125 was last used on September 2, 2015 and Pd-103 was last used on April 24, 2006. Leftover extra seeds were returned to the manufacturer following the patient implant procedures. Attached are records from the final return shipments of I-125 and Pd-103.

Thank you for your help with this amendment request. Please let me know if you have further questions.

Sincerely,

Daniel J. Archambeault, M.S.
Radiation Safety Officer
Elkhart General Hospital

C R Bard Inc

09/08/15

Elkhart General Hospital
600 East Blvd
Elkhart IN 46514

Email: lwang@egh.org

Dear Larry Wang,

This is verification that the radioactive **I125** seeds you returned have been received for storage and decay. We have assigned an Inventory Control Number for your convenience.

Inventory Control Number	Number of Seeds	Date Checked
RRP #I-15-641	3	September 8, 2015

Please contact Billie Clark @ 770-784-6444 or billie.clark@crbard.com with any questions.

Regards,



Madalyn Harford
Health Physics Tech

License Number IL-02062-01
Edward A. Zdunek
Radiation Safety Officer
Bard Brachytherapy Inc.
295 E. Lies Road
Carol Stream, IL 60188

E-MAILED
BSC 9-8-15

Product Return

Fax

Facility: ELKHART GENERAL HOSPITAL
 City, State: ELKHART, INDIANA
 To: Customer Service
 Contact Phone: 574-523-7857
 Fax: 888-383-3839
 Bard Contact: LARRY WANG
 Phone: 800-977-6733
 Fax Date: 9-4-15
 Re: I125 Seed Return
 Pages: 1

The following BrachySource® Seed Implants are being returned:

Quantity: 3

Return shipment Date: 9-4-2015 Tracking # 8066 3991 9606

Total Contained Activity on Shipment Date: 0.93 mCi

Order Number (if known)	Quantity of Seeds (A)	Apparent activity on original reference date	Apparent activity on return shipment date (B)	Apparent : contained activity correction factor (C)	Contained activity on return shipment date (A) x (B) x (C)
433117750	3		0.309 mCi	1.7	1.58
				1.7	
				1.7	
				1.7	
				1.7	
TOTAL					1.58

Comments:

I-15-641
MH 9/8/15
A5

☒ STORAGE & DECAY
☐ CREDIT
☐ COMPLAINT



806639919606

Ship date
Fri 9/04/2015

Actual delivery
Tues 9/08/2015 10:08 am

ELK US

IL US

Delivered

Signed for by: F DELIPORE

Stay connected wherever you are. Track while you travel.

Travel History

Date/Time	Activity	Location
- 9/08/2015 - Tuesday		
10:08 am	Delivered	IL
7:57 am	On FedEx vehicle for delivery	SCHAUMBURG, IL
7:52 am	At local FedEx facility	SCHAUMBURG, IL
- 9/05/2015 - Saturday		
6:37 pm	At destination sort facility	CHICAGO, IL
3:00 pm	Departed FedEx location	INDIANAPOLIS, IN
1:31 am	Arrived at FedEx location	INDIANAPOLIS, IN
- 9/04/2015 - Friday		
3:52 pm	Picked up	SOUTH BEND, IN

Shipment Facts

Tracking number	806639919606	Service	FedEx Standard Overnight
Weight	2 lbs / 0.91 kgs	Dimensions	6x4x7 in.
Signature services	Direct signature required	Delivered To	Shipping/Receiving
Total pieces	1	Total shipment weight	2 lbs / 0.91 kgs
Packaging	Your Packaging	Special handling section	Deliver Weekday, Direct Signature Required



- Additional Information

About FedEx

Service Information

Service Guide

Mobile Solutions

Healthcare Solutions

Aerospace Solutions

Careers
- Customer Support

Contact Us

Frequently Asked Questions

Send us an email

Write to us

Call FedEx Customer Service at 1.800.GoFedEx 1.800.463.3339

FedEx
Tracking
Number

8066 3991 9606

Form
ID No.

0200

Sender's Copy

1 From Please print and press hard.

Date 9-4-2015

Sender's FedEx
Account Number

SENDER'S FEDEX ACCOUNT NUMBER ONLY

s LARRY WANG Phone (574) 523-7857

Company ELKHART GENERAL HOSPITAL

Address 600 EAST BLVD

City ELKHART

State IN ZIP 46514

Dept./Floor/Suite/Room

2 Your Internal Billing Reference

First 24 characters will appear on invoice.

OPTIONAL

3 To

Recipient's Name RETURNS

Phone (630) 933-7610

Company BARD

Address 295 E. LIES RD.

We cannot deliver to P.O. boxes or P.O. ZIP codes.

Dept./Floor/Suite/Room

Address

Use this line for the HOLD location address or for continuation of your shipping address.

City Carol Stream State IL ZIP 60188

HOLD Weekday
FedEx location address
REQUIRED. NOT available for
FedEx First Overnight.HOLD Saturday
FedEx location address
REQUIRED. Available ONLY for
FedEx Priority Overnight and
FedEx 2Day to select locations.

Easy new Peel-and-Stick airbill. No pouch needed.

Apply airbill directly to your package. See directions on back.

4 Express Package Service

* To most locations.

NOTE: Service order has changed. Please select carefully.

Next Business Day

☐ FedEx First Overnight
Earliest next business morning delivery to select
locations. Friday shipments will be delivered on
Monday unless SATURDAY Delivery is selected.☐ 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.

2 or 3 Business Days

☐ FedEx 2Day A.M.
Second business morning.
Saturday Delivery NOT available.☐ FedEx 2Day
Second business afternoon. Thursday shipments
will be delivered on Monday unless SATURDAY
Delivery is selected.☒ FedEx Express Saver
Third business day.
Saturday Delivery NOT available.

5 Packaging

* Declared value limit \$500.

☐ FedEx Envelope*☐ FedEx Pak*☐ FedEx
Box☐ FedEx
Tube☒ Other

6 Special Handling and Delivery Signature Options

☐ SATURDAY Delivery
NOT available for FedEx Standard Overnight, FedEx 2Day A.M., or FedEx Express Saver.☐ No Signature Required
Package may be left without
obtaining a signature for delivery.☒ Direct Signature
Someone at recipient'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. For
residential deliveries only. Fee applies.

Does this shipment contain dangerous goods?

One box must be checked.

☐ No ☒ Yes
As per attached
Shipper's Declaration.☐ Yes
Shipper's Declaration
not required.☐ Dry Ice
Dry Ice, 9, UN 1845 _____ x _____ kgDangerous goods (including dry ice) cannot be shipped in FedEx packaging
or placed in a FedEx Express Drop Box.☐ Cargo Aircraft Only

7 Payment Bill to:

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

☐ Sender
Acct. No. in Section
1 will be billed.☒ Recipient☐ Third Party☐ Credit Card☐ Cash/CheckFedEx Acct. No.
Credit Card No.

030046196

Exp.
Date

Total Packages

Total Weight

Total Declared Value†

1

3 lb.

\$.00

†Our liability is limited to US\$100 unless you declare a higher value. See back for details. By using this Airbill you agree to the service conditions on the back of this Airbill and in the current FedEx Service Guide, including terms that limit our liability.

Rev. Date 1/12 • Part #167001 • ©2012 FedEx • PRINTED IN U.S.A. SRS

644

PEEL AND RETAIN THIS COPY BEFORE AFFIXING TO THE PACKAGE. NO POUCH NEEDED.

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

(Provide at least three copies to the airline.)

Shipper **LARRY WANG**
ELKHART GENERAL HOSPITAL
600 EAST BLVD
ELKHART, IN 46514

Air Waybill No.

Page **1** of **1** Pages

Shipper's Reference Number
 (optional)

Consignee

RETURNS

BARD

295 E. Lies Rd.

Carol Stream, IL 60188 US

Two completed and signed copies of this Declaration must be handed to the operator

TRANSPORT DETAILS

This shipment is within the limitations prescribed for:
 (delete non applicable)

Airport of Departure

PASSENGER
AND CARGO
AIRCRAFT

☒ CARGO
AIRCRAFT
ONLY

Airport of Destination:

CHICAGO

WARNING

Failure to comply with all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.

Shipment type: (delete non-applicable)

☒ **NON-RADIOACTIVE**

☐ RADIOACTIVE

NATURE AND QUANTITY OF DANGEROUS GOODS

UN Number or Identification Number, proper shipping name, Class or Division (subsidiary risk), packing group (if required), and all other required information.

UN2910, Radioactive Material, Excepted Package, Limited Quantity
of Material, Class 7, I-125, Metal, Solid, 1 Packages x 34.4 MBq,
DIM: 4.0 x 4.0 x 8.5 cm

Additional Handling Information

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable International and National Governmental Regulations. I declare that all of the applicable air transport requirements have been met.

Name/Title of Signatory

LARRY WANG
Sr. Physicist

Place and Date

ELKHART, IN 9-4-15

Signature

Larry Wang

(see warning above)

800-977-6733 (BARD)

Emergency Telephone Number

FOR RADIOACTIVE MATERIAL SHIPMENT ACCEPTABLE FOR PASSENGER AIRCRAFT, THE SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN OR INCIDENT TO RESEARCH, MED ICA L DIAG NOSIS , OR TREATMENT. ADR EUROPEAN TRANSPORT STATEMENT: CARRIAGE IN ACCORDANCE WITH 1.1.4.2.1

BARD

Bard Urological Division,
C.R. Bard, Inc

Elkhart General Hospital
Att: Steven Leung, PHD
600 E Boulevard
Elkhart, , IN 46514

FAX: 574-523-7856

Attention: Steven Leung, PHD

This is a receipt of the radioactive **Pd-103** seeds you returned under the following return authorization number(s).

Return Authorization #	# of Seeds Returned	Date Returned
TS 3320	18	6-12-06

If you have any further questions, please do not hesitate to give us a call at 1-800-977-6733 ext 6937.

Sincerely,

Sherry Gurner



Returned TheraSeed® Pd-103 Device Packing List

RETURN AUTHORIZATION NUMBER: TS 3320

Contact Bard at 1-800-977-6733 prior to returning any TheraSeed® Pd-103 Device!!

Ship to: **Theragenics Corporation®**
5203 Bristol Industrial Way
Buford, GA 30518 U.S.A.
ATTN: Shipping/Receiving
1-770-271-0233

Shipped from: STEVE LEUNG, PhD
Elkhart General Hospital / Rad. Oncology
600 East Blvd.
Elkhart, IN 46514

Seed Qty.

Reason for Return:

18

Unused.

SIGNED: [Signature]

DATE: 6-2-06

PRINTED NAME: STEVE LEUNG

TITLE: MEDICAL PHYSICIST

4
100

FedEx US Airbill
Express

FedEx
Tracking
Number

8569 2450 9340

1 From Please print and press hard.

Date 6-6-06 Sender's FedEx
Account Number

Sender's
Name STEVE LEUNG Phone (574) 523-7857

Company Elkhart General Hospital

Address 600 East Blvd.

City Elkhart State IN ZIP 46514

2 Your Internal Billing Reference
First 24 characters will appear on invoice.

OPTIONAL

3 To

Recipient's
Name Phone (770) 271-0233

Company THERAGENICS CORP

Recipient's
Address 5203 BRISTOL INDUSTRIAL WAY

We cannot deliver to P.O. boxes or P.O. ZIP codes.

Address

To request a package be held at a specific FedEx location, print FedEx address here.

City BUFORD State GA ZIP 30518-1799

0333662982



Schedule a pickup at fedex.com

Simplify your shipping. Manage your account. Access all the tools you need.

fedex.com 1.800.GoFedEx 1.800.463.3339

MUR23

0215

Sender's Copy

4a Express Package Service

☐ 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.*
Saturday Delivery NOT available.

☒ FedEx 2Day
Second business day.* Thursday
shipments will be delivered on Monday
unless SATURDAY Delivery is selected.
FedEx Envelope rate not available. Minimum charge: One-pound rate.

☐ FedEx Express Saver
Third business day.*
Saturday Delivery NOT available.

* To most locations.

4b Express Freight Service

☐ FedEx 1Day Freight*
Next business day.** Friday
shipments will be delivered on Monday
unless SATURDAY Delivery is selected.

☐ 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.

** To most locations.

* Call for Confirmation:

5 Packaging

☐ FedEx
Envelope*

☐ FedEx Pak*
Includes FedEx Small Pak,
FedEx Large Pak, and FedEx Sturdy Pak.

☐ FedEx
Box

☐ FedEx
Tube

☒ Other
* Declared value limit \$500.

6 Special Handling

Include FedEx address in Section 3.

☐ SATURDAY Delivery
NOT Available for
FedEx Standard Overnight,
FedEx First Overnight, FedEx Express
Saver, or FedEx 3Day Freight.

☐ HOLD Weekday
at FedEx Location
NOT Available for
FedEx Priority Overnight and
FedEx 2Day to select locations.

☐ HOLD Saturday
at FedEx Location
Available ONLY for
FedEx Priority Overnight and
FedEx 2Day to select locations.

Does this shipment contain dangerous goods?
One box must be checked.

☐ No ☐ Yes
As per attached
Shipper's Declaration.

☐ Yes
Shipper's Declaration
not required.

☐ Dry Ice
Dry Ice, 9 UN 1845 _____ x _____ kg

☐ Cargo Aircraft Only

Dangerous goods (including dry ice) cannot be shipped in FedEx packaging.

7 Payment Bill to:

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

☐ Sender
Acct. No. in Section
1 will be billed.

☒ Recipient

☐ Third Party

☐ Credit Card

☐ Cash/Check

FedEx Acct. No.
Credit Card No. 2296-9649-1

Exp.
Date

Total Packages

Total Weight

Total Declared Value†

\$.00

†Our liability is limited to \$100 unless you declare a higher value. See back for details. By using this Airbill you agree to the service conditions on the back of this Airbill and in the current FedEx Service Guide, including terms that limit our liability.

FedEx Use Only

8 NEW Residential Delivery Signature Options If you require a signature, check Direct or Indirect.

☐ No Signature
Required
Package may be left
without obtaining a
signature for delivery.

☒ Direct Signature
Anyone at recipient's
address may sign for
delivery. Fee applies.

☐ Indirect Signature
If no one is available at
recipient's address, anyone
at a neighboring address may
sign for delivery. Fee applies.

519

Rev. Date 11/05-Part #158279-01894-2005 FedEx-PRINTED IN U.S.A.-SRF

PULL AND RETAIN THIS COPY BEFORE AFFIXING TO THE PACKAGE. NO POUCH NEEDED.

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper

Air Waybill No.

Page of Pages

Shipper's Reference Number
(optional) T1360

Consignee SHIPPING & REC
THERAGENICS CORP
5203 BRISTOL INDUSTRIAL WAY
BUFORD GA US 30518

FedEx.

Two completed and signed copies of this Declaration must be handed to the operator.

WARNING

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.

TRANSPORT DETAILS

This shipment is within the limitations prescribed for:
(delete non-applicable)

Airport of Departure

PASSENGER
AND CARGO
AIRCRAFTCARGO
AIRCRAFT
ONLY

Airport of Destination:

ATLANTA

Shipment type: (delete non-applicable)

NON-RADIOACTIVE**RADIOACTIVE****NATURE AND QUANTITY OF DANGEROUS GOODS****Dangerous Goods Identification**

UN ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Pack- ing Group	Quantity and type of packaging	Packing Inst.	Authorization
UN 2915	RADIOACTIVE MATERIAL TYPE A PACKAGE	7		PD-103 SOLID METAL TYPE A PACKAGE X 86 MBQ	TI DIN EE X EE X EE CH	

Additional Handling Information

Emergency Telephone Number 800-424-9300

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.

Name/Title of Signatory

STEVE LEUNG / MEDICAL PHYSICIAN

Place and Date

ELLERIE, IN 6-2-06

Signature

(see warning above)

FOR RADIOACTIVE MATERIAL SHIPMENT ACCEPTABLE FOR PASSENGER AIRCRAFT, THE SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN OR INCIDENT TO RESEARCH, MEDICAL DIAGNOSIS, OR TREATMENT.

Song, Taehoon

From: Gryglak, Magdalena
Sent: Wednesday, January 08, 2020 11:05 AM
To: Pavon, Sandy; Song, Taehoon
Cc: Tomczak, Tammy
Subject: FW: Request to remove 10 CFR 35.400 material, NRC license no. 13-18879-01, Elkhart General Hospital
Attachments: Elkhart General remove 35-400 materials.pdf

Good morning,

Please place the document in ADAMS:

Elkhart General Hospital
030-17305
13-18879-01
CN 617075

Thank you
Magdalena

From: Daniel Archambeault <DArchambeault@beaconhealthsystem.org>
Sent: Wednesday, January 08, 2020 8:34 AM
To: Gryglak, Magdalena <Magdalena.Gryglak@nrc.gov>
Subject: [External_Sender] RE: Request to remove 10 CFR 35.400 material, NRC license no. 13-18879-01, Elkhart General Hospital

Ms. Gryglak,

Attached is a letter answering the questions you had regarding our amendment request.

Thanks for your help. Let me know if you need anything else.

Dan

Daniel J. Archambeault, M.S., DABR, DABMP
Senior Medical Physicist & Radiation Safety Officer
Memorial Hospital of South Bend
Elkhart General Hospital
Phone: (574) 647-7956
Fax: (574) 647-4318
Email: darchambeault@beaconhealthsystem.org

