

July 11, 2017

Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

**Re: Licensee: Global Isotopes LLC d/b/a Zevacor Molecular
License Number: 24-32827-01MD (Springfield, MO)**

To Whom It May Concern:

In a letter dated March 23, 2017 (Mail Control Number: 594384), Zevacor Pharma, Inc. ("Zevacor") requested that the NRC amend license number 24-32827-01MD (Springfield, MO; Overland, MO; and Noblesville, IN) in 2 respects: (1) to remove the now-decommissioned Overland, MO facility; and (2) to remove the Noblesville, IN facility from pharmacy operations under license number 24-32827-01MD.

Via email dated June 23, 2017, Mr. Bryan Parker of NRC Region III advised that the March 23, 2017 request should be re-submitted as separate amendment requests specific to each license, with additional documentation to support decommissioning of the Overland, MO facility. Each amendment requested to license number 24-32827-01MD is discussed in further detail below.

Please refer also to our second letter dated July 11, 2017 regarding the Noblesville, IN license (number 13-35179-02). In order to provide continuity of operations for both the Springfield, MO and the Noblesville, IN facilities, Zevacor requests that both license amendments be completed concurrently.

1. Decommissioning of the Overland, MO facility.

The following information is presented in the order described in NUREG-1757, Vol. 1, Rev. 2, Section 8.2.

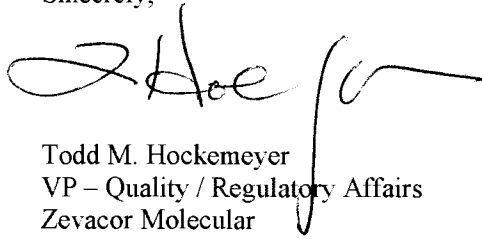
- a. NRC was notified via the March 23, 2017 letter.
- b. Attachment 1 provides documentation of shipment of three licensed sealed sources from the Overland, MO facility to the Noblesville, IN facility.
- c. Attachment 2 provides a final status survey of the Overland, MO facility.
- d. Surveys were completed in accordance with the referenced guidance.
- e. Attachment 3 provides the most recent sealed source leak tests for the three sources.
- f. Decommissioning records have been transferred to Zevacor's Noblesville, IN facility.
- g. Attachment 4 provides NRC Form 314. Please note that section A in Form 314 is left blank, since there is not an option on the form to remove the decommissioned facility from a license that continues to cover another active facility.

2. Removal of the Noblesville, IN facility.

Please refer to our second letter dated July 11, 2017 for a complete description of the changes requested in order to consolidate Noblesville, IN operations under R&D license number 13-35179-02. Concurrent with those changes, please remove all reference to the Noblesville, IN facility from license number 24-32827-01MD.

Please contact me at the phone number or email address below with any questions.

Sincerely,



Todd M. Hockemeyer
VP – Quality / Regulatory Affairs
Zevacor Molecular
(M) +1 317.417.2860
thockemeyer@zevacor.com

Attachments:

1. Sealed Source Shipment Documentation
2. Final Status Survey of Overland, MO facility
3. Sealed Source Leak Tests
4. NRC Form 314

3 April 17

Note to file

St. Louis Zevacor sent their six sealed sources (two rod sources, one disk source, and three vial sources) to Zevacor Decatur on 31 March 17. These sealed sources were entered into inventory (3 vial sources); all six sources were sent to Zevacor Noblesville, Indiana on 3 April 17.

A handwritten signature in black ink, appearing to be the initials 'AL' followed by a horizontal stroke.



Inventory of Sealed Sources

Zevacor Molecular

2300 N Edward St, Suite 100

Decatur, IL 62526

IL-02444-01 exp 02/28/2021

Location: Zevacor Molecular - St. Louis
1968 Innerbelt Business Ctr. Dr.
Overland, MO 63114

Performed By: Scott Chance
Date: 03/31/2017
Time: 14:51

Sealed Source	Activity	Accounted For
Manufacturer: International Isotopes Inc. Product: Co-57 Dose Calibrator Sou Serial Number: BM06057E08234256 Next Leak Test: 07/16/2017	5.570 mCi On: 08/28/2008 Location Stored: Lab	Accounted For Decayed Act.: 0.002 mCi
Manufacturer: International Isotopes Inc. Product: Ba-133 Dose Calibrator So Serial Number: BM06133E13053213 Next Leak Test: 07/16/2017	0.273 mCi On: 02/13/2013 Location Stored: Lab	Accounted For Decayed Act.: 0.208 mCi
Manufacturer: International Isotopes Inc. Product: Cs-137 Dose Calibrator So Serial Number: BM06137E08224118 Next Leak Test: 07/16/2017	0.220 mCi On: 08/14/2008 Location Stored: Lab	Accounted For Decayed Act.: 0.180 mCi

TEST COMMENTS:

Received from St. Louis. Will transfer to Noblesville on 4/3/17.

PASSED

TEST DATA:

Performed by: Scott Chance
 Scott Chance
 Nuclear Pharmacist
 Licensee: Zevacor Molecular
 Registration: IL-02444-01 exp 02/28/2021

**Zevacor Molecular
Shipment Report**

Delivery Date/Time: 04/03/2017 03:23

Container: 200

Actual Shipment Date/Time: 04/03/2017 03:23

Sender:

Zevacor Molecular
2300 N Edward St, Suite 100
Decatur, IL 62526
800-826-2827

Receiver:

Zevacor Molecular - Noblesville Pharmacy
14395 Bergen Boulevard
Noblesville, IN 46060

License: 24-32827-01MD exp: 12/31/2018

BILL OF LADING

RADIOACTIVE MATERIAL, TYPE-A PACKAGE, 7, UN 2915

Serial #	Product	Cal. Date/Time	Total Amount	Quantity	Activity at Time of Shipment	Isotope	Form
BM06133E13053	Ba-133 Dose Calibrator Source	02/13/201 12:00	0.273 mCi	1	0.01 GBq (0.21 mCi)	Ba-133	vial
BM06057E08234	Co-57 Dose Calibrator Source	08/28/200 12:00	5.57 mCi	1	0.00 GBq (0.00 mCi)	Co-57	item
BM08057082102	Co-57 Rod Source	08/12/200 12:00	1.337 uCi	1	0.00 GBq (0.00 mCi)	Co-57	item
210	Cs-137 Disk Source	01/01/200 12:00	1.00 uCi	1	0.00 GBq (0.00 mCi)	Cs-137	item
BM06137E08224	Cs-137 Dose Calibrator Source	08/14/200 12:00	0.22 mCi	1	0.01 GBq (0.18 mCi)	Cs-137	item
BM08137082470	Cs-137 Source	09/09/200 12:00	0.131 uCi	1	0.00 GBq (0.00 mCi)	Cs-137	item

DOT Label: RADIOACTIVE YELLOW II

Total Activity at Shipping: 0.014 GBq

(0.391 mCi)

Trans. Index at 1 Meter: 0.1

This is to certify that the above-named materials are properly classified, described, packaged, marked, and labeled, and are in proper condition for transportation according to the applicable regulations of the Department of Transportation (DOT).

Survey Meter Serial #: 286854
Background (mR/hr): 0.02
Surface Reading (mR/hr): 1.10
One Meter Reading (mR/hr): 0.10
Condition of Container: Good

Wipe Test Instrument Serial #: 311449
Background (CPM): 590
Surface (CPM): 560
Surface (DPM): 0.00
Area (cm²): 300.00

Delivered by:

Date:

Time:

Shipping: Shipped By: Scott Chance



Date: 04/03/2017

Time: 03:23

Emergency Phone Number: 3E services: 800-451-8346 acct 14219

Zevacor Molecular – Overland, Mo.

On July 6, 2017, Ameriphysics performed a final status survey (FSS) of the Zevacor Molecular facility located in Overland, MO. A physical search of the facility for any remaining radioactive material was performed prior to beginning the surveys. No remaining radioactive materials were found. The FSS was designed using the Simplified Survey Procedure as described in NUREG 1757, Volume 1, Figure 8.1.

The only radioactive material used in the facility in dispersible forms was Tc-99m (Half-Life of 6.01 hours) and In-111 (Half-Life of 2.805 days). Although Tc-99m decays to radioactive Tc-99, Tc-99 has a half-life of 2.111×10^5 years.

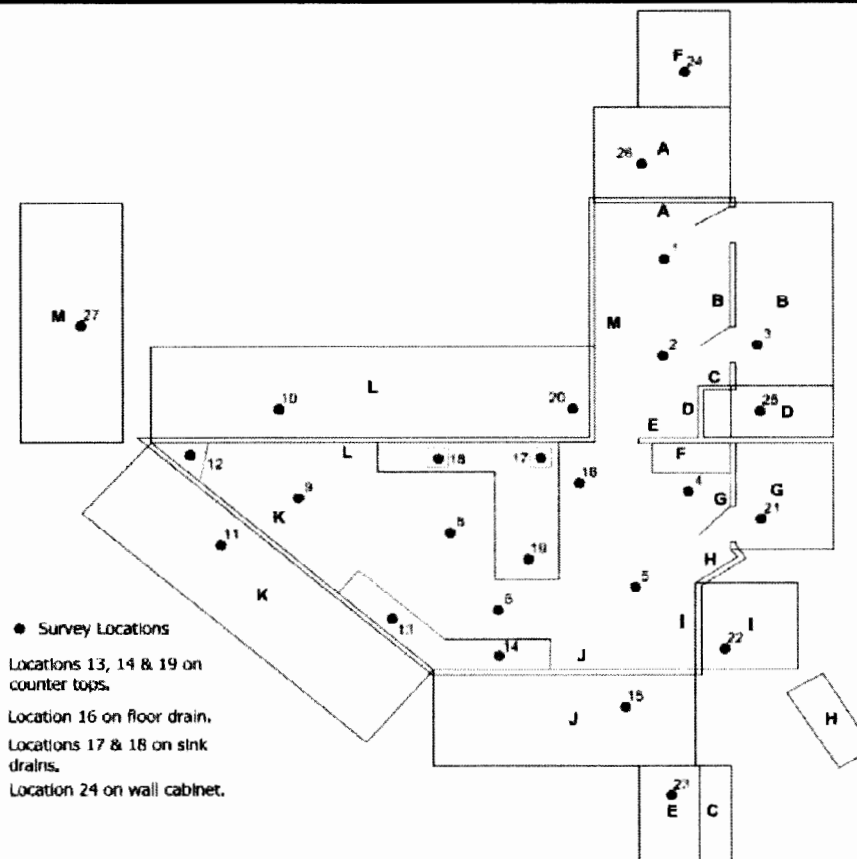
Calculations were performed to determine how much Tc-99 could be present if all remaining atoms of Tc-99m decayed to Tc-99. As a conservative estimate, it was assumed that 1 Ci of Tc-99m remained in the facility. If all Tc-99m atoms decayed and were assumed to be in a single 100 cm^2 area, there would be 7,215 dpm of Tc-99 in that single 100 cm^2 area. This is far less than the Tc-99 default screening value of 1,300,000 dpm/ 100 cm^2 from NUREG-1757, Volume 2, Appendix H, Table H.1.

In-111 would have decayed for approximately 58 half-lives since 1/27/17 (Date of last RAM Use) and is essentially gone.

The FSS consisted of 100% beta scan surveys of accessible surfaces on the floor, walls, and furnishings in the restricted area. No elevated activity exceeding background was detected. Total beta activity and removable beta activity measurements were collected at 27 judgmentally chosen locations. All total beta activity measurements were less than the static beta MDC of 874 dpm/ 100 cm^2 . All removable beta activity measurements were less than the removable beta MDC of 121 dpm/ 100 cm^2 .

Final Status Survey Design Package

Building: Zevacor Molecular - St Louis Survey Unit ID: 1 Page _____ of _____
 Marssim Classification: Simplified Survey Class 2 Class 3
 Room Nos. Included in Survey Unit: Restricted Area

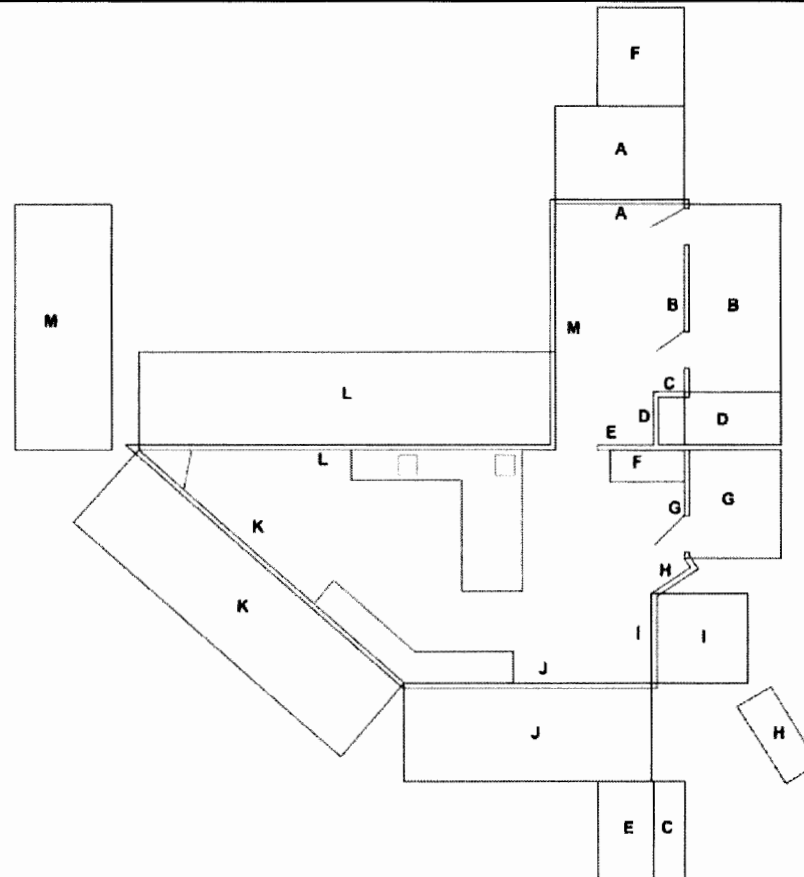


Comments:

Gamma dose rate, static and removable measurements were collected at the numbered locations shown above. Locations were judgmentally selected to ensure at least 1 location per 300 ft² of surface area in accordance with NUREG 1757 Volume 1, Figure 8.1, *Simplified Survey Procedures*. This simplified survey is applicable for facilities meeting the definition of a Decommissioning Group 1.

Final Status Survey Design Package

Building: Zevacor Molecular - St Louis Survey Unit ID: 1 Page _____ of _____
Marssim Classification: Simplified Survey Class 2 Class 3
Room Nos. Included in Survey Unit: Restricted Area



Comments: Scan surveys were performed on all accessible floors, walls, and fixed cabinetry (inside and outside surfaces). No elevated activity exceeding background detected. Scan MDC for 43-93 #PR323025 was 2,511 dpm/100 cm². Scan MDC for 43-93 #PR311222 was 3,042 dpm/100 cm².

Sealed Source Leak Test**Zevacor Molecular Pharmacy**

1968 Innerbelt Business Center Drive

Overland, Missouri, 63114

Lic.# 24-32827-01MD

FACILITY NAME/ADDRESS:

Zevacor Pharmacy
1968 Innerbelt Business Center Drive
Overland, Missouri 63114
314-426-5290

DATE PERFORMED: 01/16/2017 04:46

NEXT DUE DATE: 07/16/2017

INSTRUMENT INFORMATION:

Model Number: 2200
Manufacturer: Ludlum
Serial Number: 251015

Efficiency: 97.63 %
Action Limit: 0.005 uCi

SOURCE INFORMATION:

Nuclide: Tc99m
Source Type: Ba-133 sealed source
Manufacturer: Benchmark

Serial Number: BM06133E13053213
Calibration Amt: 0.273 mCi
Calibration D/T: 02/27/2013 06:00

LEAK TEST DATA:

Measurement	Wipe (CPM)	Background (CPM)	NET (CPM)	NET (DPM)	NET (uCi)	PASS/FAIL
1	35	33	2	2	0.0000009	PASS
2	34	33	1	1	0.0000005	PASS
3	33	33	0	0	0.0000000	PASS
Average	34	33	1	1	0.0000005	PASS

NOTES:

NET (CPM) = Wipe (CPM) - Background (CPM)

NET (DPM) = NET (CPM) / Efficiency

NET (uCi) = NET (DPM) / 2.2×10^6 DPM/uCi

If leak test results are greater than 0.005 uCi of removable contamination, the source is to be removed from use.

PASSED

TEST COMMENTS: PASSED

TEST DATA:

Performed by:


STEVEN ALVEY
Pharmacist

Licensee: Zevacor Molecular Pharmacy

Registration: Lic.# 24-32827-01MD

Prepared by: STEVEN ALVEY

Printed: 3/28/2017 9:32:58 AM Sealed Source Leak Test ID: 14

Page: 1

Sealed Source Leak Test**Zevacor Molecular Pharmacy**

1968 Innerbelt Business Center Drive

Overland, Missouri, 63114

Lic.# 24-32827-01MD

FACILITY NAME/ADDRESS:

Zevacor Pharmacy
1968 Innerbelt Business Center Drive
Overland, Missouri 63114
314-426-5290

DATE PERFORMED: 01/16/2017 04:46

NEXT DUE DATE: 07/16/2017

INSTRUMENT INFORMATION:

Model Number: 2200
Manufacturer: Ludlum
Serial Number: 251015

Efficiency: 98.26 %

Action Limit: 0.005 uCi

SOURCE INFORMATION:

Nuclide: Cs-137
Source Type: CS 137 REF VIAL
Manufacturer: Radqual

Serial Number: bm06137e08224118

Calibration Amt: 220.00 uCi

Calibration D/T: 08/14/2008 00:00

LEAK TEST DATA:

Measurement	Wipe (CPM)	Background (CPM)	NET (CPM)	NET (DPM)	NET (uCi)	PASS/FAIL
1	35	33	2	2	0.0000009	PASS
2	36	33	3	3	0.0000014	PASS
3	34	33	1	1	0.0000005	PASS
Average	35	33	2	2	0.0000009	PASS

NOTES:

NET (CPM) = Wipe (CPM) - Background (CPM)

NET (DPM) = NET (CPM) / Efficiency

NET (uCi) = NET (DPM) / 2.2×10^6 DPM/uCi

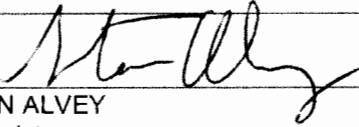
If leak test results are greater than 0.005 uCi of removable contamination, the source is to be removed from use.

PASSED

TEST COMMENTS: PASSED

TEST DATA:

Performed by:


STEVEN ALVEY
Pharmacist

Licensee: Zevacor Molecular Pharmacy

Registration: Lic.# 24-32827-01MD

Prepared by: STEVEN ALVEY

Printed: 3/28/2017 9:32:51 AM Sealed Source Leak Test ID: 15

Page: 1

Sealed Source Leak Test**Zevacor Molecular Pharmacy**

1968 Innerbelt Business Center Drive

Overland, Missouri, 63114

Lic.# 24-32827-01MD

FACILITY NAME/ADDRESS:

Zevacor Pharmacy
1968 Innerbelt Business Center Drive
Overland, Missouri 63114
314-426-5290

DATE PERFORMED: 01/16/2017 04:46

NEXT DUE DATE: 07/16/2017

INSTRUMENT INFORMATION:

Model Number: 2200
Manufacturer: Ludlum
Serial Number: 251015

Efficiency: 97.63 %

Action Limit: 0.005 uCi

SOURCE INFORMATION:

Nuclide: Co-57
Source Type: CO-57 E-VIAL
Manufacturer: Radqual

Serial Number: bm06057e08234256

Calibration Amt: 5.57 mCi

Calibration D/T: 08/28/2008 00:00

LEAK TEST DATA:

Measurement	Wipe (CPM)	Background (CPM)	NET (CPM)	NET (DPM)	NET (uCi)	PASS/FAIL
1	34	33	1	1	0.0000005	PASS
2	33	33	0	0	0.0000000	PASS
3	33	33	0	0	0.0000000	PASS
Average	33	33	0	0	0.0000000	PASS

NOTES:

NET (CPM) = Wipe (CPM) - Background (CPM)

NET (DPM) = NET (CPM) / Efficiency

NET (uCi) = NET (DPM) / 2.2×10^6 DPM/uCi

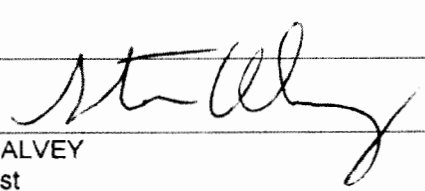
If leak test results are greater than 0.005 uCi of removable contamination, the source is to be removed from use.

PASSED

TEST COMMENTS: PASSED

TEST DATA:

Performed by:


 STEVEN ALVEY
Pharmacist

Licensee: Zevacor Molecular Pharmacy

Registration: Lic.# 24-32827-01MD

Prepared by: STEVEN ALVEY

Printed: 3/28/2017 9:33:04 AM

Sealed Source Leak Test ID: 13

Page: 1



CERTIFICATE OF DISPOSITION OF MATERIALS

Estimated burden per response to comply with this mandatory collection request: 30 minutes. This submittal is used by NRC as part of the basis for its determination that the facility is released for unrestricted use. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NE08-10202, (3150-0028), 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.

LICENSEE NAME AND ADDRESS

Global Isotopes, LLC d/b/a Zevacor Molecular
1968 Innerbelt Business Center Drive
Overland, MO 63114

LICENSE NUMBER

24-32827-01MD

DOCKET NUMBER

LICENSE EXPIRATION DATE

12/31/2018

A. LICENSE STATUS (Check the appropriate box)

- This license has expired.
- This license has not yet expired; please terminate it.

B. DISPOSAL OF RADIOACTIVE MATERIAL

(Check the appropriate boxes and complete as necessary. If additional space is needed, provide attachments)

The licensee, or any individual executing this certificate on behalf of the licensee, certifies that:

- 1. No radioactive materials have ever been procured or possessed by the licensee under this license.
- 2. All activities authorized by this license have ceased, and all radioactive materials procured and/or possessed by the licensee under this license number cited above have been disposed of in the following manner.
 - a. Transfer of radioactive materials to the licensee listed below:
Zevacor Noblesville, IN facility; NRC License # 1335179-02 (see attached leak test and shipment documentation)
 - b. Disposal of radioactive materials:
 - 1. Directly by the licensee:
 - 2. By licensed disposal site:
 - 3. By waste contractor:
- c. All radioactive materials have been removed such that any remaining residual radioactivity is within the limits of 10 CFR Part 20, Subpart E, and is ALARA.

C. SURVEYS PERFORMED AND REPORTED

- 1. A radiation survey was conducted by the licensee. The survey confirms:
 - a. the absence of licensed radioactive materials
 - b. that any remaining residual radioactivity is within the limits of 10 CFR 20, Subpart E, and is ALARA.
- 2. A copy of the radiation survey results:
 - a. is attached; or b. is not attached (Provide explanation); or c. was forwarded to NRC on: _____ Date
- 3. A radiation survey is not required as only sealed sources were ever possessed under this license, and
 - a. The results of the latest leak test are attached; and/or
 - b. No leaking sources have ever been identified.

The person to be contacted regarding the information provided on this form:

NAME	TITLE	TELEPHONE (Include Area Code)	E-MAIL ADDRESS
Peter Webner	Senior VP	917-295-2955	pwebner@zevacor.com

Mail all future correspondence regarding this license to:

21000 Atlantic Blvd., Suite 730, Dulles, VA 20166

C. CERTIFYING OFFICIAL I CERTIFY UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT

PRINTED NAME AND TITLE	SIGNATURE	DATE
Peter Webner Senior VP		7-11-17

WARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECT. 18 U.S.C. SECTION 1001 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.

RECEIVED JUL 13 2017

ORIGIN ID:MZZA (317) 578-1251
ZEVACOR MOLECULAR
14395 BERGEN BLVD.
NOBLESVILLE, IN 46060
UNITED STATES US

SHIP DATE: 12JUL17
ACTWGT: 0.50 LB
CAD: 105219914/NET3850

BILL SENDER

TO MATERIALS LICENSING BRANCH
NUCLEAR REGULATORY COMMISSION
2443 WARRENVILLE ROAD
SUITE 210
LISLE IL 60532

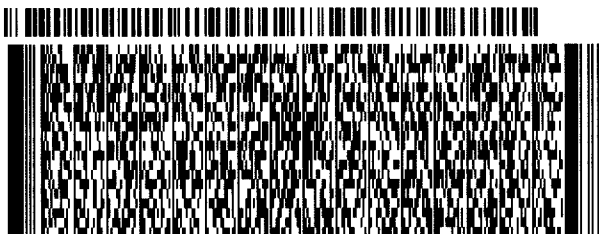
Attn: Bryan Parker

(317) 578-1251
INV
PO

REF:

DEPT:

546J11000255C1



FedEx
Express



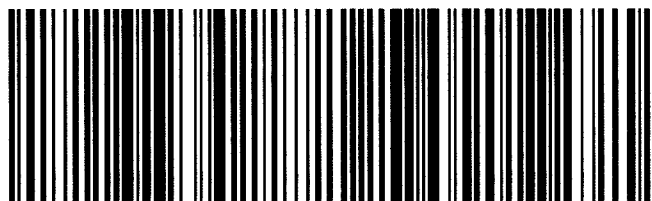
471172446ur

THU - 13 JUL 10:30A
PRIORITY OVERNIGHT

TRK# 7796 1625 5342
0201

NA ENLA

60532
IL-US ORD



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