



FOOD AND DRUG ADMINISTRATION
109 Holton Street
Winchester, Massachusetts

Mr. Dennis Lawyer
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

Date: March 3, 2016

Docket No. 03004675
License No. 20-08361-01
Control No. 583771 *lmj*

Subject: DEPARTMENT OF HEALTH AND HUMAN SERVICES, REQUEST FOR LICENSE AMENDMENT.

Dear Mr. Lawyer::

This Memorandum is in reply to your communication with myself Ed Baratta, RSO. The closeout of our Denver Facility was previously forwarded to you under separate cover. I trust this new information is satisfactory.

For the Facility located at the Building 20-Denver Federal Center, West 6th Avenue and Kipling Street, Lakewood, Colorado. The only Cesium-137 material was a General Licensed device (from the Liquid Spectrophotometry) and was transferred back to e Manufacturer as shown in the attached. The source was only 30 microcuries and thus did not require leak testing.

The only use of the Carbon-14 at the Facility was the use of the material that was exempt distributed and thus did not require the use of a specific License. Thus there was no specifically Licensed Carbon-14 material at the Facility.

Should you have any questions regarding this Amendment, please contact:

Edmond J. Baratta, Radiation Safety Officer @ 781-756-9742, Cell Phone: 781-799-7838 and/or edmond.baratta@fda.hhs.gov

Sincerely,

Edmond J. Baratta
Radiation Safety Officer,

3/3/2016

X Edmond Baratta

Edmond J. Baratta
Radiation Safety Officer
Signed by: Edmond Baratta -A

589945

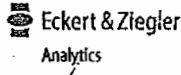
REC'D IN LAT 3-7-16

NMSS/RGNI MATERIALS-002

RETURN PACKING LIST

B

From: U.S. FDA
6th Ave & Kipling St. Bldg. 20 - DFC
Denver, CO 80225
 Contact Name: Lou Novak
 Telephone: 303-236-9866 Fax _____
 E-mail: _____

Send to:

 1380 Seaboard Ind. Blvd.
 Atlanta, GA 30318 US
 Tel: 404-352-8677
 Fax: 404-352-2837
 Email: analytics@ezag.com

PO# - 1597547 - 249
RETURN #RA - UWE 2800A15B

STOP: This packing list must be affixed to the outside and a copy placed inside of the package. Each returned source to EZA must be on a one-to-one exchange basis only. For additional returns, please contact EZA customer service for more information.

Nuclide	Nominal Activity	Product Code	Capsule Description
Cs-137	30 microCi	CDRB	Plastic Capsule in EZN Packaging

If source is damaged, broken, or leaking, describe under this section and submit a copy of last leak test. Keep a copy of this for your records. It may be requested by your regulatory agency.

Describe leakage if applicable: None

I acknowledge that the above information is true to the best of my knowledge.

Contact Signature: Lou Novak

For EZA Use only.

EZA has received the radioactive source(s) listed above, except as noted below:

Receivers Name _____ Receipt Date: _____

Sources not received: _____ n/a



February 5, 2016

AET Environmental
14 Lakeside Lane
Denver, CO 80212

Subject: Shipment Receipt Acknowledgement

RE: FDA USDA

Dear Sir or Madam:

In accordance with the requirements of 10 CFR 20, Appendix G, Section III, C.1., the attached signed manifest copy is provided to you as notice of receipt and acceptance of the radioactive waste materials at the designated processing facility as specified on the manifest.

This letter is acknowledgement of receipt only. Any manifest discrepancies found during unloading or processing will be reported at a later date.

Please contact me if you have any questions or require additional information. I can be reached at 888-RADWAS^{Te} or 865-285-3003 (direct), or via email at tgesty@philotechnics.com.

Sincerely,

Philotechnics, Ltd.

A handwritten signature in cursive script that reads "Tracie Gesty".

Tracie Gesty



Friday, January 29, 2016

Meghan Turvey
Philotechnics, Ltd/Oak Ridge, TN
201 Renovare Blvd
Oak Ridge, TN 37830

Dear Ms. Turvey:

The attached signed shipping manifest copies are your notice of receipt of the radioactive waste materials shipment specified on the manifest number below.

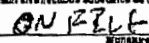
<u>Manifest Number</u>	<u>Date Received</u>
2284-T-160460	01/29/2016

Thank you for your business.

Sincerely,

Shipping and Receiving

cc: Manifest File
Shipping and Receiving file

FORM 540		Energy Solutions/Bear Creek		5. SHIPPER - NAME AND FACILITY		SHIPMENT ID NUMBER		7. FORM 540 AND 540A		PAGE 1 OF 1 PAGE(S)		8. MANIFEST NUMBER							
UNIFORM LOW-LEVEL RADIOACTIVE WASTE MANIFEST SHIPPING PAPER				Philotechnics @ FDA USDA 14 Lakeside Lane Denver, CO 80212		1807-102715EN		FORM 541 AND 541A FORM 542 AND 542A ADDITIONAL INFORMATION		1 PAGE(S) 1 PAGE(S) NONE PAGE(S)		(Use this number on all continuation pages) 1807-102715EN							
1. EMERGENCY TELEPHONE NUMBER (Include Area Code) 800-424-6300				USER PERMIT NUMBER T-TN024-L15		SHIPMENT NUMBER 1807-102715EN		X GENERATOR TYPE (Specify) O		9. CONSIGNEE - Name and Facility Address Energy Solutions/Bear Creek Operated By Energy Solutions 1650 Bear Creek Road Oak Ridge, TN 37830									
ORGANIZATION CHEMTREC #17253				CONTACT Erik Marquosen		TELEPHONE NUMBER (Include Area Code) (840) 783-0881		EPA I.D. NUMBER TNR00030544		SIGNATURE - Authorized consignee acknowledging waste receipt <i>[Signature]</i>		CONTACT Donnie Brackett							
2. IS THIS AN "EXCLUSIVE USE" SHIPMENT? [] YES [X] NO				3. TOTAL NUMBER OF PACKAGES IDENTIFIED ON THIS MANIFEST 1		6. CARRIER - Name and Address Philotechnics, Ltd 201 Reycove Blvd. Oak Ridge, TN 37830		Truck #: Trailer #:		DATE 1/29/16		10. CERTIFICATION This is to certify that the herein-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. This also certifies that the materials are classified, packaged, marked, and labeled and in proper condition for transportation and disposal in accordance with the requirements of 10 CFR Parts 20 and 61, or equivalent state regulation							
4. DOES EPA REGULATED WASTE REQUIRING A MANIFEST ACCOMPANY THIS SHIPMENT? [] YES [X] NO If "Yes", provide Manifest Number				EPA MANIFEST NUMBER N/A		CONTACT Justin Bolton		TELEPHONE NUMBER (Include Area Code) (865) 466-4812		SHIPPING DATE 10/27/2015		DATE 10-27-15							
11. U.S. DEPARTMENT OF TRANSPORTATION DESCRIPTION (Including proper shipping name, hazard class, UN ID number, and any additional information)				12. DOT LABEL "RADIOACTIVE"		13. TRANSPORT INDEX		14. PHYSICAL AND CHEMICAL FORM		15. INDIVIDUAL RADIONUCLIDES		16. TOTAL PACKAGE ACTIVITY MBq ; mCi		17. LSA/SCO CLASS		18. TOTAL WEIGHT OR VOLUME (Use appropriate units)		19. IDENTIFICATION NUMBER OF PACKAGE	
NON-DOT REGULATED MATERIALS AQUEOUS LIQUID 1-5 GAL POLY DRUM				NA		NA		LIQUID/OXIDES		H-3		0.0018500000 ; (0.0000500000)		NA		0.68 ft ³ 10.00000 lb		15-001413 (1)	
FOR CONSIGNEE USE ONLY						20. Generator Certification Statement													
Tennessee "License For Delivery" No. _____						A) Radioactive Material: Certification is hereby made that this shipment of (low-level) radioactive waste has been prepared in accordance with a radioactive waste management program which has been approved by the Nuclear Regulatory Commission or an Agreement State regulatory agency and with the current version of the site Material Acceptance Criteria.													
South Carolina Transport Permit No. _____						B) Hazardous Material: Generator hereby certifies that this material does not contain a hazardous waste as defined in 40 CFR 261.													
US Ecology Generator No. _____						C) Data: Generator hereby represents and warrants that all data set forth in this (UNIFORM LOW-LEVEL RADIOACTIVE WASTE) MANIFEST are true and correct in all respects and in accordance with all applicable governmental laws, rules, regulations and site Radioactive Material Licenses.													
US Ecology Permit No. _____						D) INFECTIOUS SUBSTANCE: Generator hereby certifies that this material does not contain an infectious substance as defined in 40 CFR 173.134													
						<div style="text-align: center;">  Print Name: <u>ON KELL</u> Signature: <u>[Signature]</u> Date: _____ </div>													