



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE

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 6<sup>th</sup> 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 the 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](mailto: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-DRC  
Denver, CO 80225  
 Contact Name: Lou Novak  
 Telephone: 303-236-9866 Fax: \_\_\_\_\_  
 E-mail: \_\_\_\_\_

Send to:  
 Eckert & Ziegler  
 Analytics  
 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 280015B**

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<sup>Te</sup> or 865-285-3003 (direct), or via email at [tgesty@philotechnics.com](mailto:tgesty@philotechnics.com).

Sincerely,

*Philotechnics, Ltd.*

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.

Manifest Number

2284-T-160460

Date Received

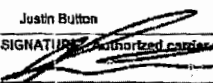
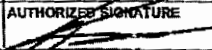
01/29/2016

Thank you for your business.

Sincerely,

Shipping and Receiving

cc: Manifest File  
Shipping and Receiving file

<b>FORM 540</b> <b>UNIFORM LOW-LEVEL RADIOACTIVE WASTE MANIFEST SHIPPING PAPER</b>		<b>Energy Solutions/Bear Creek</b>		<b>5. SHIPPER - NAME AND FACILITY</b> Philotechnics @ FDA USDA 14 Lakeside Lane Denver, CO 80212		<b>SHIPMENT ID NUMBER</b> 1807-102715EN X <b>COLLECTOR</b> PROCESSOR		<b>7. FORM 540 AND 540A</b> FORM 541 AND 541A FORM 542 AND 542A ADDITIONAL INFORMATION		PAGE 1 OF 1 PAGE(S) 1 PAGE(S) 1 PAGE(S) NONE PAGE(S)		<b>8. MANIFEST NUMBER</b> (Use this number on all continuation pages) 1807-102715EN					
<b>1. EMERGENCY TELEPHONE NUMBER (Include Area Code)</b> 800-424-8300				<b>USER PERMIT NUMBER</b> T-TN024-L15		<b>SHIPMENT NUMBER</b> 1807-102715EN		X <b>GENERATOR TYPE</b> (Specify) O		<b>9. CONSIGNEE - Name and Facility Address</b> Energy Solutions/Bear Creek Operated By Energy Solutions 1550 Bear Creek Road Oak Ridge, TN 37830		<b>CONTACT</b> Donnie Brackett <b>TELEPHONE NUMBER (Include Area Code)</b> (865) 220-1620					
<b>ORGANIZATION</b> CHEMTREC #17253				<b>CONTACT</b> Erik Marquosen		<b>TELEPHONE NUMBER (Include Area Code)</b> (840) 783-0881		<b>EPA I.D. NUMBER</b> TNR000030544		<b>SHIPPING DATE</b> 10/27/2015		<b>DATE</b> 10-27-15					
<b>2. IS THIS AN "EXCLUSIVE USE" SHIPMENT?</b> <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		<b>3. TOTAL NUMBER OF PACKAGES IDENTIFIED ON THIS MANIFEST</b> 1		<b>6. CARRIER - Name and Address</b> Philotechnics, Ltd 201 Recovery Blvd. Oak Ridge, TN 37830		<b>Truck #:</b>  <b>Trailer #:</b>  		<b>SIGNATURE - Authorized carrier/owner acknowledging waste receipt</b> 		<b>10. CERTIFICATION</b> 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 in proper condition for transportation and disposal in accordance with the requirements of 10 CFR Parts 20 and 61, or equivalent state regulation.		<b>DATE</b> 1/29/16					
<b>4. DOES EPA REGULATED WASTE REQUIRING A MANIFEST ACCOMPANY THIS SHIPMENT?</b> <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If "Yes", provide Manifest Number		<b>EPA MANIFEST NUMBER</b> N/A		<b>CONTACT</b> Justin Bilton		<b>TELEPHONE NUMBER (Include Area Code)</b> (865) 466-4812		<b>DATE</b> 10-27-15		<b>AUTHORIZED SIGNATURE</b> 		<b>TITLE</b> Manager					
<b>11. U.S. DEPARTMENT OF TRANSPORTATION DESCRIPTION</b> (Including proper shipping name, hazard class, UN ID number, and any additional information)		<b>12. DOT LABEL "RADIOACTIVE"</b>		<b>13. TRANSPORT INDEX</b>		<b>14. PHYSICAL AND CHEMICAL FORM</b>		<b>15. INDIVIDUAL RADIONUCLIDES</b>		<b>16. TOTAL PACKAGE ACTIVITY</b> MBq : mCi		<b>17. LSA/SCO CLASS</b>		<b>18. TOTAL WEIGHT OR VOLUME</b> (Use appropriate units)		<b>19. IDENTIFICATION NUMBER OF PACKAGE</b>	
NON-DOT REGULATED MATERIALS AQUEOUS LIQUID 1-5 GAL POLY DRUM		NA		NA		LIQUID/OXIDES		H-3		0.0018500000 (0.0000500000)		NA		0.68 m³ 10.00000 lb		15-001413 (1)	
<b>FOR CONSIGNEE USE ONLY</b> Tennessee "License For Delivery" No. _____ South Carolina Transport Permit No. _____ US Ecology Generator No. _____ US Ecology Permit No. _____						<b>20. Generator Certification Statement</b> A) Radioactive Materials. 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 revisions of the site Material Acceptance Criteria. B) Hazardous Materials. Generator hereby certifies that this material does not contain a hazardous waste as defined in 40 CFR 261. 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 all Radioactive Material Licenses. D) INFECTIOUS SUBSTANCE. Generator hereby certifies that this material does not contain an infectious substance as defined in 40 CFR 172.134. _____ Print Name <span style="margin-left: 150px;">ON FILE</span> <span style="margin-left: 150px;">Date</span>											