DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
WO62, Suite 3210
Silver Spring, MD 20993-0002

August 2, 2012

K4
03004544

Licensing Assistance Team
USNRC Region I DNMS
U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Blvd
King of Prussia, PA 19406

Subject: The CDRH response to requested documentation for Termination of License 19-07538-01 Docket No. 03004544, Control No. 577649

Dear Mr. Courtemanche:

CDRH is responding to the four request listed below for additional documentation as stated by NRC in a letter dated June 27, 2012, Control Number 577649:

1. The review of your application determined that it was signed by the Radiation Safety Officer. A person of management authority other than the Radiation Safety Officer should sign the application as the Certifying Official. Please confirm, by your signature, that you are in agreement with the contents of the application dated May 23, 2012, to terminate your license.

   I am signing all final documentation certifying that I am in agreement with the contents of this application

2. You provided liquid scintillation counter results entitled "FDA/CDRH Leak Test Results." Please confirm that a leak test was performed of all sealed sources that were present and previously used at your location. Please state the energy sensitivity of the liquid scintillation counter for the respective isotopes using your counting protocol, eg. Am-241, Pu-239, Co-57, Cd-109, etc.

   Leak test Results are attached for the two 14 millicuries Am-241 sources and the Pu-239 source.

   No data is attached for the additional sealed sources. Number 13D of the Conditions section of the CDRH License states that sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less, or they contain not more than 100 microcuries of beta-and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material. Additionally, number 13E of the CDRH License states that leak test requirements for sealed sources that are in storage and are not being used need not be leak tested.

3. You provided information about the disposal of three Americium-241 sources and one Plutonium-239 source. The FDA/CDRH Leak Test Results Record provides information about a number of other sealed

577649
NMSS/RGN1 MATERIALS-002

sources for which there is no record of their being transferred to or disposed of as waste to an authorized recipient. Please provide a record of the transfer or disposal of those sealed sources in the record but not accounted for in the record provided with your May 23, 2012, application.

See the two attached Bill of Ladings that accounts for all sources except the following:

Petro Shandruk, the CDRH Radiation Safety Officer for this license through September 23, 2010, stated that he transferred one H3 and one C14 Liquid scintillation reference to his possession and disposed of them in May 2010. He also stated that he has no records because both references were exempt quantities as referenced in section 30.18 and do not exceed the applicable quantities set forth in section 30.71, Schedule B

4. On the "FDA/CDRH Leak Test Results" Record, the results of an evaluation of items 17 were contained in a facsimile received November 24, 2010. Dade Moeller & Associates determined the radionuclide and the amount of contamination on the items and indicated that the company was willing to assist you in the disposal of the items. Please provide confirmation in the form of a transfer record that a waste disposal firm accepted the items or that you disposed of the items directly to a radioactive materials landfill.

RSO, Inc of Laurel, Maryland assisted in disposal of the referenced items. See attached documentation for contamination, leak testing, survey, shipping, and disposal

Sincerely,

Steven K. Pollack, Ph.D.
Director
Office of Science and Engineering Laboratories
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue, Building 62, Room 3214
Silver Spring, Maryland 20903-0002
(301)-796-2530 (voice)
(301)-801-4228 (cell)
(301)-796-9959 (fax)

Attachments: NRC form 314, Question2_LeakTests, Question3_BillofLading, Question4a_contaminationLeaktesting, Question4b_WasteDisposal

cc:
Mary D. Walker, CDRH Radiation Safety Officer for NRC License No. 19-07538-01

NRC FORM 314 (05-2012) 10 CFR 30.36(j)(1); 40.42(j)(1); 70.38(j)(1); and 72.54(k)(5)(i)(1)

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0028 EXPIRES: 10/31/2013

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 Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-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.

CERTIFICATE OF DISPOSITION OF MATERIALS

LICENSEE NAME AND ADDRESS	LICENSE NUMBER	DOCKET NUMBER
DHHS-FDA-Center for Devices and Radiological Health DIAM/OSEL WO62, Room 4126 10903 New Hampshire Avenue Silver Spring, MD 20993-0002	19-07538-01	030-04544
	LICENSE EXPIRATION DATE: June 30, 2015	

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:

☐ b. Disposal of radioactive materials:

☐ 1. Directly by the licensee:

☐ 2. By licensed disposal site:

☑ 3. By waste contractor:

RSO, Inc.;5204 Minnick Road;Laurel, Maryland 20725-1450
Phone: 301 953-2482

☐ 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
Mary Walker	Radiation Safety Officer, CDRH	(301) 796-2558	mary.walker@fda.hhs.gov

Mail all future correspondence regarding this license to:
Center for Devices and Radiological Health; WO62, Room 4126;10903 New Hampshire Avenue; Silver Spring, MD 20993

C. CERTIFYING OFFICIAL

I CERTIFY UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT

PRINTED NAME AND TITLE	SIGNATURE	DATE
Steven K. Pollack, Ph.D.		08/02/2012

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.

Sealed Source Leak Test Data

Source Am241 Serial No. AAM - 1 Activity 14 mCi Date _____

User Mary Walker Bldg WO62 Room 4143 Test method DRY WIPE

Detection Method and Instrument Ludlum Model 3030E w/ Ludlum 43-10-1 Counter

Reference Source Pu-239 P342 CPM: _____ DPM 420 2Pi Efficiency _____

Date	Total counts	Count time	Gross CPM	BKG CPM	Net CPM	Net DPM	uCi removable Contamination	Test done by
8/3/10	0.0	10 MIN	0.0	0.2	0.0	0.0	< 0.005	PS
P342	3718	"	371.8	0.2	371.6	0.88 uCi		

Maximum allowable removable contamination is 0.005 uCi

Sealed Source Leak Test Data

Source Am241 Serial No. AAM - 1 Activity 14 mCi Date _____

User Mary Walker Bldg WO62 Room 4143 Test method DRY WIPE

Detection Method and Instrument: Ludlum Model 3030E w/ Ludlum 43-10-1 Counter

Reference Source Pu-239 P342 CPM: _____ DPM 420 2Pi Efficiency _____

Date	Total counts	Count time	Gross CPM	BKG CPM	Net CPM	Net DPM	uCi removable Contamination	Test done by
8/22/08	0.0	10 MIN	0.0	0.0	0.0	0.0	< 0.005	PS
P342	3704	10 "	370.4	0.0	370.4	0.88 uCi		
11/21/08	1.0	10 "	0.1	0.0	0.1	0.24	< 0.005	PS
P342	3716	10 "	371.6	0.0	371.6	0.88 uCi		
1/13/09	1.0	10 "	0.1	0.0	0.1	0.24	< 0.005	PS
P342	3687	10 "	368.7	0.0	368.7	0.88 uCi		
5/5/09	0.0	10 "	0.0	0.0	0.0	0.0	< 0.005	PS
P342	3702	10 "	370.2	0.0	370.2	0.88 uCi		
7/28/09	0.0	10 "	0.0	0.0	0.0	0.0	< 0.005	PS
P342	3631	10 "	363.1	0.0	363.1	0.86 uCi		
12/29/09	1.0	10 "	0.1	0.1	0.0	0.0	< 0.005	PS
P342	3605	10 "	360.5	0.1	360.4	0.86 uCi		

Maximum allowable removable contamination is 0.005 uCi

Sealed Source Leak Test Data

Source Am 241 Serial No AAM-1 Activity 14 mCi Date N/A

User Mary Walker Bldg 1202 FW-2 Room DCLK Test method DRY WIPE

Detection Method and Instrument LUDLUM MODEL 3030E W LUDLUM 43-10-1 COUNTER

Reference Source P342 CPM: _____ DPM 420 2π Efficiency _____

Date	Total counts	Count time (min)	Gross CPM	BKG CPM	Net CPM	Net DPM	uCi removable Contamination	Test done by
6/26/07	1.0	10	0.1	0.0	0.1	0.1	< 0.005	PS
P342	3735	10	373.5	0.0	373.5	0.89 eff		
				PS 0.0				
				0.0				
8/27/07	3.0	10	0.3	0.2	0.1	0.1	< 0.005	PS
P342	3687	10	368.7	0.2	368	0.88 eff		
2/18/08	0.0	10	0.0	0.0	0.0	0.0	< 0.005	PS
P342	3703	10	370.3	0.3	370	0.88 eff		
8/29/08	1.0	10	0.1	0.2	0	0	< 0.005	PS
P342	3661	10	366.1	0.2	366	0.87 eff		
5/13/09	9.0	10	0.9	0.2	0.7	0.7	< 0.005	PS
P342	3638	10	363.8	0.2	364	0.87 eff		

Maximum allowable removable contamination is 0.005 uCi

Sealed Source Leak Test Data

Source Am-241 Serial No. AMM-1 Activity 14 mCi Date n/a

User: Frank Cerra Bldg 12720-2 TW Room entry204 Test method Dry Wipe

Detection Method and Instrument RD-14 System

Reference Source P342 (Pu-239) CPM: DPM 420 281 Efficiency

Date	Total counts	Count time (min)	Gross CPM	BKG CPM	Net CPM	Net DPM	uCi removable Contamination	Test done by
12/29/05	8	10	0.8	0.4	0.4	0.4	<0.005	JS
P342	3743	10	3793	0.4	379	0.9 x eff		
5/23/06	6	10	0.6	0.6	0.0	0.0	4	JS
P342	3993	10	3993	0.6	399	0.95 x eff	<0.005	

Maximum allowable removable contamination is 0.005 uCi

Sealed Source Leak Test Data

Source Am-241 Serial No AMM-1 Activity 14 mCi Date n/a

User Frank Cerre Bldg 12720-2 TW Room entry204 Test method Dry Wipe

Detection Method and Instrument RD-14 System

Reference Source P342 (Pu-239) CPM: _____ DPM 420 2Pi Efficiency _____

Date	Total counts	Count time (Min)	Gross CPM	BKG CPM	Net CPM	Net DPM	uCi removable Contamination	Test done by
6/15/04	0	10	0	0.4	0	0	< 0.005	RS
P342	4048	10	4048	0.4	404	0.95 eff		
9/3/04	7	10	730.7	0.5	0.2	0.0	< 0.005	RS
P342	3801	10	380.1	0.5	380	0.90 eff		
12/1/04	7	10	0.7	0.7	0	0	< 0.005	RS
P342	3996	10	399.6	0.7	399	0.95 eff		
3/4/05	6	10	0.6	0.6	0.0	0.0	< 0.005	RS
P342	4017	10	401.7	0.6	401	0.95 eff		
6/30/05	8	10	0.8	0.0	0.8	0.8	< 0.005	RS
P342	3963	10	396.3	0.0	396	0.94 eff		
9/2/05	2	10	0.2	0.30	0	0.0	< 0.005	RS
P342	3930	10	393.0	0.3	393	0.94 eff		

Maximum allowable removable contamination is 0.005 uCi

Sealed Source Leak Test Data

Source Am241 Serial No. AAM - 2 Activity 14 miCi Date _____

User Mary Walker Bldg WO62 Room 4143 Test method DRY WIPE

Detection Method and Instrument Ludlum Model 3030E w/ Ludlum 43-10-3 Counter

Reference Source Pu-239 P342 CPM _____ DPM 420 2Pi Efficiency _____

Date	Total counts	Count time	Gross CPM	BKG CPM	Net CPM	Net DPM	uCi removable Contamination	Test done by
3/31/10	1.0	10 MIN	0.1	0.2	0.0	0.0	< 0.005	PS
P342	3718	"	371.8	0.2	371.6	0.88 UPF		

Maximum allowable removable contamination is 0.005 uCi

Sealed Source Leak Test Data

Source Am241 Serial No. AAM - 2 Activity 14 miCi Date _____

User Mary Walker Bldg WO62 Room 4143 Test method DRY WIPE

Detection Method and Instrumen: Ludlum Model 3030E w/ Ludlum 43-10-1 Counter

Reference Source Pu-239 P342 CPM: _____ DPM 420 2PI Efficiency _____

Date	Total counts	Count time	Gross CPM	BKG CPM	Net CPM	Net DPM	uCi removable Contamination	Test done by
8/22/08	0.0	10min	0.0	0.0	0.0	0.0	<0.005	RS
P342	3704	10"	370.4	0.0	370.4	0.88 eff		
11/24/08	0.0	10"	0.0	0.0	0.0	0.0	<0.005	RS
P342	3710	10"	371.0	0.0	371.0	0.88 eff		
1/13/09	1.0	10"	0.1	0.0	0.1	0.1	<0.005	RS
P342	3687	10"	368.7	0.0	368.7	0.88 eff		
5/28/09	0.0	10"	0.0	0.0	0.0	0.0	<0.005	RS
P342	3702	10"	370.2	0.0	370.2	0.88 eff		
9/2/09	0.0	10"	0.0	0.0	0.0	0.0	<0.005	RS
P342	3631	10"	363.1	0.0	363.1	0.86 eff		
12/29/09	0.0	10"	0.0	0.1	0.0	0.0	<0.005	RS
P342	3605	10"	360.5	0.1	360.4	0.86 eff		

Maximum allowable removable contamination is 0.005 uCi

Sealed Source Leak Test Data

Source Am 241 Serial No. AAM-2 Activity 14 mCi Date N/A

User MARY WALKER Bldg 1272 TW-2 Room DOCK Test method DRY WIPE

Detection Method and Instrument LUDLUM MODEL 3030E W LUDLUM 43-10-1 COUNTER

Reference Source P342 CPM: _____ DPM 420 2 π Efficiency _____

Date	Total counts	Count time (MIN)	Gross CPM	BKG CPM	Net CPM	Net DPM	uCi removable Contamination	Test done by
6/26/07	4.0	10	0.4	0.0	0.4	0.4	< 0.005	RS
P342	3735	10	373.5	0.0	3735	0.89 eff		
8/27/07	0	10	0	0.2	0.0	0.0	< 0.005	RS
P342	3687	10	368.7	0.2	368	0.88 eff		
12/3/07	1.0	10	0.1	0.3	0.2	0.2	< 0.005	
P342	3703	10	370.3	0.3	370	0.88 eff		
12/4/08	1.0	10	0.1	0.0	0.1	0.1	< 0.005	RS
P342	3697	10	369.7	0.0	370	0.88 eff		
3/13/08	0.0	10	0.0	0.2	0.0	0.0	< 0.005	RS
P342	3638	10	363.8	0.0	364	0.87 eff		

Maximum allowable removable contamination is 0.005 uCi

Sealed Source Leak Test Data

Source Am-241 Serial No. AMM-2 Activity 14 mCi Date n/a

User: Frank Cerra Bldg 12720-2 TW Room entry204 Test method Dry Wipe

Detection Method and Instrument RD-14 System

Reference Source P342 (Pu-239) CPM: _____ DPM 420 2Pi Efficiency _____

Date	Total counts	Count time	Gross CPM	BKG CPM	Net CPM	Net DPM	uCi removable Contamination	Test done by
2/4/05	6	10	0.6	0.4	0.2	0.2	<0.005	RS
P342	3793	10	379.3	0.4	379	450 2Pi		
32305	5 6/11	10	0.6	0.6	0.5	0.5	<0.005	RS
P342	3993	10	399.3	0.6	399	474 2Pi		

Maximum allowable removable contamination is 0.005 uCi

Sealed Source Leak Test Data

Source Am-241 Serial No AMM-2 Activity 14 mCi Date n/a

User: Frank Cerra Bldg 12720-2 TW Room entry204 Test method Dry Wipe

Detection Method and Instrument PD-14 System

Reference Source P342 (Pu-239) CPM: _____ DPM 420 2Pi Efficiency _____

Date	Total counts	Count time (min)	Gross CPM	BKG CPM	Net CPM	Net DPM	uCi removable Contamination	Test done by
6/15/04	4	10	0.4	0.4	0.0	0.0	< 0.005	PS
P342	4048	10	404.8	0.4	404	0.96 Eff		
9/3/04	3	10	0.3	0.5	0.0	0.0	< 0.005	PS
P342	3801	10	380.1	0.5	380	0.90 Eff		
12/1/04	3	10	0.3	0.7	0.0	0.0	< 0.005	PS
P342	3996	10	399.6	0.7	399	0.95 Eff		
3/1/05	8	10	0.8	0.6	0.2	0.2	< 0.005	PS
P342	4017	10	401.7	0.6	401	0.95 Eff		
6/30/05	5	10	0.5	0.0	0.5	0.5	< 0.005	PS
P342	3963	10	396.3	0.0	396	0.94 Eff		
9/2/05	7	10	0.7	0.3	0.4	0.4	< 0.005	PS
P342	3930	10	393.0	0.3	393	0.94 Eff		

Maximum allowable removable contamination is 0.005 uCi

Sealed Source Leak Test Data

Source Am 241 Serial No. _____ Activity 7.3uC Date 12/2/10

User: Spradley Bldg 12720 DN Room _____ Test method Dry wipe

Detection Method and Instrument LUCUM 3030E / w 43-10-1 counter

Reference Source Pu 239 P32 CPM: _____ DPM 4202 Efficiency _____
10 MIN

Date	Total counts	Count time	Gross CPM	BKG CPM	Net CPM	Net DPM	uCi removable Contamination	Test done by
12/2/10	0	10m	0	0	0	0	> 0.005uCi	R
P32	3735	1C	3735	0	3735	0.93uCi		
11/16/10	11.0	10	1.1	0.1	1.0	1.0	> 0.005uCi	R
P32	372	10	372.1	0.1	372	0.09uCi		
6/9/10	0	10	0	0.1	0	0	> 0.005uCi	R
P32	3681	10	3681	0.1	368	0.09uCi		
11/24/09								

Maximum allowable removable contamination is 0.005 uCi

Certificate of Calibration

Meter Owner: FDA

Calibration Date: 5/18/10

Calibration Due Date: 5/18/11

A.M. Calibration Services.
9620 Medical Center Drive
Rockville, MD 20850
Office: 301-610-6001
Fax: 301-610-6001
amcalibration@aol.com

AM Calibration Radioactive Material License: MD-31-206-01

Inspection Item: Ludlum 3030E #241562

Batteries Changed: No

Internal Adjustment: No

Scale	Meter Response (cpm)	True Response (cpm)	CF
X0.1	400	400	1.00
	4036	4,000	
X0.5	200	200	1.00
	20,196	20,000	
X1.0	401	400	1.00
	40,009	40,000	
X 2.0	800	800	1.00
	80,073	80,000	

The relative response for P-32/C-14 was determined to be 39.4%18.20% using the 43-10-1#255955

The relative response for was determined to be using the

The relative response for the Check Source was determined to be N/Ausing the

This certifies that the instrument described above was calibrated electronically (pulsing method), and compared with instrumentation whose calibration is traceable to the National Institute of Standards and Technology. Calibrated in accordance with ANSI-N323-1997 and as manufacturer recommended.

Calibrated by: Andrew J McAleer

AM Calibration verifies all the above before shipping, not responsible for any damages incurred in shipping.

This Memorandum

Shipper No. _____

Carrier No. _____

Page _____ of _____ Date _____

TO:

FROM:

PLACARDS TENDERED: YES ☐ NO ☐

COD

SHIPPER

CARRIER

PER

PER

DATE

3

This Memorandum is an acknowledgment that a Bill of Lading has been issued and is not Original Bill of Lading, nor a copy or duplicate, covering the property named herein, and is intended solely for filing or record.

Shipper No. _____

Carrier No. _____

Page 1 of 1

RSO, Inc. (Name of carrier) (SCAC)

Date 8/1/12

On Collect on Delivery shipments, the letters "COD" must appear before consignee's name or as otherwise provided in Item 430, Sec.1.

TO: Consignee RSO, Inc.

Street 5204 Minnick Road

City Laurel State MD Zip Code 20707

FROM: Shipper Food & Drug Administration
Ionizing Radiation Measurments Laboratory

Street 10903 New Hampshire Avenue

City Silver Spring State MD Zip Code 20993

24 hr. Emergency Contact Tel. No. 1-800-424-9300 Chemtrec CCN-19279

Route

Vehicle Number

No. of Units & Container Type	HM	BASIC DESCRIPTION Proper Shipping Name, Hazard Class UN or NA Number, Packing Group or UN or NA Number, Proper Shipping Name, Hazard Class, Packing Group	TOTAL QUANTITY (Weight, Volume, Gallons, etc.)	WEIGHT (Subject to Correction)	RATE	CHARGES (For Carrier Use Only)
1-Pail	X	UN2910, Radioactive material, excepted package, limited quantity of material, 7, solid, Cd-109, 0.03256 MBq, Co-57, 0.09916 MBq	0.476 cuft	5 lbs.		

PLACARDS TENDERED: YES ☐ NO ☒

Note — (1) Where the rate is dependent on value, shippers are required to state specifically in writing the agreed or declared value of the property, as follows: "The agreed or declared value of the property is hereby specifically stated by the shipper to be not exceeding _____ per _____."
(2) Where the applicable tariff provisions specify a limitation of the carrier's liability absent a release or a value declaration by the shipper and the shipper does not release the carrier's liability or declare a value, the carrier's liability shall be limited to the extent provided by such provisions. See NMFC Item 172.
(3) Commodities requiring special or additional care or attention in handling or stowing must be so marked and packaged as to ensure safe transportation. See Section 2(e) of Item 360, Bills of Lading, Freight Bills and Statements of Charges and Section 1(a) of the Contract Terms and Conditions for a list of such articles.

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 labeled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations.

Signature

REMIT C.O.D. TO:
ADDRESS

COD Amt: $

C.O.D. FEE: PREPAID ☐ COLLECT ☐ $

TOTAL CHARGES $

FREIGHT CHARGES
FREIGHT PREPAID except when box at right is checked ☐ Check box if charges are to be collect.

Subject to Section 7 of the conditions, if this shipment is to be delivered to the consignee without recourse on the consignor, the consignor shall sign the following statement:
The carrier shall not make delivery of this shipment without payment of freight and all other lawful charges.

(Signature of Consignor)

RECEIVED, subject to the classifications and tariffs in effect on the date of the issue of this Bill of Lading, the property described above in apparent good order, except as noted (contents and condition of contents of packages unknown), marked, consigned, and destined as indicated above which said carrier (the word carrier being understood throughout this contract as meaning any person or corporation in possession of the property under the contract) agrees to carry to its usual place of delivery at said destination, if on its route, otherwise to deliver to another carrier on the route to said destination. It is mutually agreed as to each carrier of all or any of, said property over all or any portion of said route to destination and as to each party at any time interested in all or any said property, that every service to be performed hereunder shall be subject to all the bill of lading terms and conditions in the governing classification on the date of shipment.

Shipper hereby certifies that he is familiar with all the lading terms and conditions in the governing classification and the said terms and conditions are hereby agreed to by the shipper and accepted for himself and his assigns.

SHIPPER Food & Drug Administration

PER _____

CARRIER RSO, Inc.

PER _____

DATE 8-1-12

3

Permanent post-office address of shipper.

Walker, Mary D.

From: Tara Neitzel [tara.neitzel@ezag.com]
Sent: Friday, July 27, 2012 2:46 PM
To: Walker, Mary D.
Cc: O'Bryan, Eugene R.; Doreen McBride; David Wellner
Subject: RE: Quote 8012 EZIP
Attachments: Return Packing List Burbank.pdf

Mary,
The return authorization number for your order is R5287. Please send the sources for disposal to EZIP's Burbank facility. Attached is a Return Packing List, please fill this out and include it with your shipment. Please let me know if you have any questions.

Thank you & Regards,
Tara Neitzel
Ref & Cal Customer Service
Tel: 661.309.1049
Fax: 661.257.8305
Email: tara.neitzel@ezag.com

From: Walker, Mary D. [mailto:Mary.Walker@fda.hhs.gov]
Sent: Friday, July 20, 2012 11:43 AM
To: analytics cust_serv
Cc: O'Bryan, Eugene R.; Tara Neitzel; Doreen McBride; David Wellner
Subject: Quote 8012 EZIP

Please process the attached quote # 8012 EZIP - 19 July 2012.

Shipping and Billing address:

FDA
Attn: Eugene O'Bryan
WO62 Rm 3120
10903 New Hampshire Ave
Silver Spring, MD 20993
301 796-2532
eugene.obryan@fda.hhs.gov

Thank you.

Mary Walker, Laboratory Leader
Ionizing Radiation Measurements Laboratory
Radiation Safety Officer, The Center for Devices and Radiological Health

Food and Drug Administration
10903 New Hampshire Avenue
W062-4126
Silver Spring, Maryland 20993-0002
301 796-2558
Office of Science and Engineering Laboratories
Division of Imaging and Applied Mathematics
mary.walker@fda.hhs.gov

From: Tara Neitzel [mailto:tara.neitzel@ezag.com]
Sent: Friday, July 20, 2012 12:07 PM
To: Walker, Mary D.
Cc: Doreen McBride
Subject: Quote 8012 EZIP

Dear Mary,
Please see attached requested quotation. Please let me know if I can be of any further assistance. Please send orders by email addressed to Eckert & Ziegler Isotope Products Laboratories in Valencia CA at analytics@ezag.com or by fax to 404-352-2837. Please include your "Ship To" and "Bill To" address in your email or fax.

Thank you & Regards,
Tara Neitzel
Ref & Cal Customer Service
tara.neitzel@ezag.com

Eckert & Ziegler Isotope Products
24937 Avenue Tibbitts
Valencia, CA 91355
Tel: 661.309.1049
Fax: 661.257.8305

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

Please consider the environment before printing this e-mail.

FDA/CDRH LEAK-TEST RESULTS

SAM NO	POS	TIME MIN	MM	AUTO CPM	AUTO %ERROR	AUTO DPM	AUTO EFF-1	KINEX %	ELAPSED TIME	
				3.30		6.17	53.	.96	4.57	Pu-239
				1.	33.	3.03	57.35	.31	9.22	Am-241 #1
				0.	.0	0.00	47.09	.50	13.87	Co-57
				2.00	7.	3.75		.33	18.52	Co-57
				2.	201.49	4.74	5.	.27	23. 5	Am-241 #2
				0.	1.6	0.00	5. 2	.32	27.80	Cd-109
				.00	1.E+00	0.00	56.74	0.33	32.45	Am-241
				0.	1.8	0.00	53.	0.35	37.08	C-14
				0.	1.2	0.00	30.1	.2	41.72	Cs-137
				.00	1.E+00	0.00	58.21	.36	.37	UNKNOWN
						10.86	5. .83	.27	51.02	RO mR/hR
						70.51	57. 8	0.30	55.67	LARGE Pb PIE
					3.	9615.26	52.	.40	60.34	RAD #1
					1	10950.34	5.	0.40	69.00	RAD #2
				148. 0	8.	291.95	52.	0.05	69.69	RAD #3
				0. 11.	1	182.89	35	.	32	INSIDE Box
			5	5.75	101.	11.39	50.	.25	78.05	OUTSIDE Box

Dade Moeller & Associates®

July 19, 2010

Mary Walker
Food and Drug Administration
Ionizing Radiation Measurements Laboratory
10903 New Hampshire Avenue
W062-4126
Silver Spring, Maryland 20993-0002

Re: Sample Analysis Report of Seven (7) Unknowns

Dear Ms. Walker:

As described in the proposal dated June 4, 2010, Dade Moeller & Associates, Inc (Dade Moeller) was retained to perform a survey of seven (7) "unknown" radioactive items for the Food and Drug Administration (FDA) at their Silver Spring, Maryland location. On June 14, 2010, Dade Moeller health physicist (HP), Mr. Mike Jedlicka carefully scanned each "unknown" item with the hand-held radiation detection equipment located in **Table 1**. Furthermore, swab type samples were collected on each "unknown" item (multiple locations per item) to assess for removable radioactive contamination. The results of the scans and sample analysis of the "unknowns" are located in **Table 2**. Following the completion of the scans and swab sample collection, additional samples were collected of the areas that these "unknowns" were stored as well as the area used by Dade Moeller to scan and sample the "unknowns." **Table 3** contains the results of the additional samples collected by Dade Moeller to ensure no contamination was spread during the work performed, as well as the results for the samples collected on the floor type lead storage safe at the FDA's request. As of June 22, 2010, only five (5) of the seven (7) "unknowns" were identified as listed in **Table 2**.

Further analysis was completed on July 14, 2010 of the two (2) remaining "unknowns." Unknown #2 and Unknown #5 were picked up by Dade Moeller and hand delivered to Dade Moeller's Radio-Analytical & Calibration Laboratory on July 12, 2010. Unknown #2 (lead pig) was soaked with deionized water for 30 minutes and scraped with a razor blade to remove the surface contamination. The water was pipetted into two (2) twenty milliliter (20 mL) glass vials for analysis. Unknown #5 was subject to direct gamma analysis. The results of the analyses are listed in **Table 4**. All "unknowns" are summarized using the data located in **Table 2** and **Table 4** of this report.

Table 1 – Radiation Detection Equipment

Radiation Detection Equipment			
Meter Number	**Description**	**Serial Number**	**Calibration Date**
1	Ludlum Model 3 equipped with a Ludlum Model 44-9 PancakeGM (PanGM), Ludlum Model 43-2 Alpha Scintillator (ZnS), and Ludlum Model 44-3 Low Energy Gamma Scintillator (NaI).	Model 3 – 164026 Model 44-9 – PR168846 Model 43-2 – PR171007 Model 44-3 – PR168781	April 20, 2010
2	Bicron Fieldspec Handheld MCA	00F3-287	Self Calibrating

Table 2 – Results of Scans and Sample Analysis of Unknowns (as of June 22, 2010)

Results Table – Unknowns										
		Maximum Count Rate or Dose Rate								
Unknown Number	Description	PanGM Results (kcpm)	ZnS Results (kcpm)	NaI Results (kcpm)	Dose Rate (μR/hr)	Sample Number	Location	Gamma Analysis Results	Alpha / Beta Analysis Results (dpm)	Nuclide Identified
1	Lead "pig" bottom portion, approx 1" in diameter x 1" high. See Picture 1	60	n/a	n/a	4-6	1A	Plastic Bag	n/a	n/a	Pb-210
						1B	Inside – Side	323.7 cpm	19,117.0 dpm	
						1C	Inside – Bottom	238.9 cpm	14,181.5 dpm	
2	Lead storage container with lid, approx 5" diameter x 2" tall (excluding handle). See Picture 2	10	3	n/a	22.5	2A	Plastic Bag	n/a	n/a	Unknown, too low of activity to positively ID – further analysis required.
						2B	Inside – Bottom	n/a	130 cpm	
						2C	Inside – Bottom	n/a	199 cpm	
						2D	Outside – Top	n/a	n/a	
3	Lead "pig" top, approx 1.5" in diameter. See Picture 3	n/a	n/a	n/a	30	3A	Plastic Bag	n/a	n/a	Cs-137
						3B	Inside – Top	489.9 dpm	404 dpm	
						3C	Outside – Top	n/a	n/a	
4	Disc labeled (MOD 40108-3 S/N 101 C-14; 1mC; 1-77; approx 1" in diameter x 0.25" tall.	0.4	n/a	n/a	n/a	4A	Plastic Bag	n/a	n/a	C-14 (by label only)
						4B	Top	n/a	n/a	
						4C	Bottom	n/a	n/a	
5	Small plastic disc with orange foil at center; approx 0.75" in diameter and 0.25" tall. See Picture 5	1	n/a	1.6	n/a	5A	Plastic Bag	n/a	n/a	Unknown, too low of activity to positively ID – further analysis required.
						5B	Top	n/a	n/a	
						5C	Bottom	n/a	n/a	
6	Bottom of lead "pig" Bottom of unknown #3. Approx 1.5" in diameter and 1" high. See Picture 6	8	n/a	2.5	n/a	6A	Plastic Bag	n/a	n/a	Cs-137
						6B	Inside – Bottom	1,920.9 dpm	1,986 dpm	
7	Thoriated Optical Lens; approx 5.5" in diameter and 3" tall. See Picture 7	n/a	n/a	n/a	3550 (3.55 mR/hr)	7A	Plastic Bag	n/a	n/a	Th-232
						7B	All Surfaces	n/a	n/a	

Table 3 – Results of Additional Samples Collected and Samples of Floor Type Lead Storage Safe

Results Table – Work/Storage Areas and Lead Storage Safe			
Sample Number	**Description or Location**	**Gamma Analysis Results**	**Alpha / Beta Analysis Results**
1	Work Area	~ Background	~ Background
2	Work Area	~ Background	~ Background
3	Drawer – Storage Location	~ Background	~ Background
4	Cabinet – Top Shelf (Storage Location)	~ Background	~ Background
5	Cabinet – Bottom Shelf (Storage Location)	~ Background	~ Background
6	Outside Drawer	~ Background	~ Background
7	Outside Cabinet	~ Background	~ Background
8	Bench Area Above Storage Drawer	~ Background	~ Background
9	Floor (Storage Location)	~ Background	~ Background
10	Floor (Work Area)	~ Background	~ Background
11	Lead Storage Safe – Outside Top	~ Background	~ Background
12	Lead Storage Safe – Outside Bottom	~ Background	~ Background
13	Lead Storage Safe – Inside Top	~ Background	~ Background
14	Lead Storage Safe – Inside Bottom Sides	~ Background	~ Background
15	Lead Storage Safe – Inside Bottom	~ Background	~ Background

Table 4 – Results of Sample Analysis of Unknown #2 and #5 (July 14, 2010)

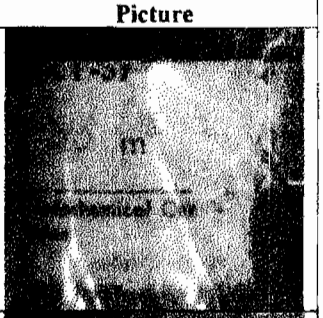
Results of Unknown # 2 and #5					
Unknown Number	**Description**	**Sample Number**	**Location**	**Gamma Analysis Results**	**Nuclide Identified**
2	Lead storage container with lid, approx 5" diameter x 2" tall (excluding handle). See Picture 2	1A	dH_2O and scrapings from inside bottom of lead pig	2669.20 cpm	Ra-226
		1B	dH_2O and scrapings from inside bottom of lead pig	3861.68 cpm	Ra-226
5	Small plastic disc with orange foil at center; approx 0.75" in diameter and 0.25" tall. See Picture 5	1	Direct gamma analysis	7804.82 cpm	Co-57

Based on the results located in **Tables 2** and **4** above, we have summarized the items as follows:

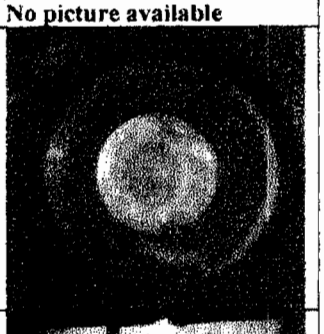
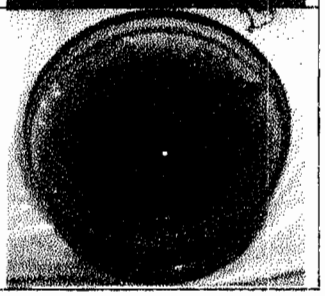
- **Item 1** – Bottom portion to a lead storage "pig." The samples taken inside the lead "pig" exhibited an average of approximately 16,650 dpm (7.5 nCi) of Lead-210 (Pb-210). Samples 1B and 1C showed positive results for Pb-210 in both the liquid scintillation counter (LSC) as well as gamma counter.

- **Item 2** – Lead storage container. Sample analysis yielded an average of approximately 165 cpm on the LSC for the samples collected on the inside bottom (samples 2B and 2C) of the storage container; no elevated gamma counts were seen with either sample. Samples was subjected to soak with deionized water for 30 minutes and scraped with a razor blade to remove the surface contamination. The water was pipetted into two (2) twenty milliliter (20 mL) glass vials for analysis. Gamma analysis yielded a total of approximately 6,531 counts per minute (summation of Sample 1A and 1B, Table 4) of Radium-226 (Ra-226) that was removed from the lead pig. Utilizing a Ra-226 standard, approximately 6,941 dpm (3.13 nCi) of Ra-226 was removed from the lead pig.
- **Item 3** – Top to lead storage "pig." The Bicron Fieldspec identified the contamination to be Cesium-137 (Cs-137). Additionally, a positive ID was seen by the LSC and gamma counter for Cs-137. An average of approximately 447 dpm (0.2 nCi) of removable Cs-137 was made by the LSC and gamma counter.
- **Item 4** – This item was labeled as being Carbon-14 (C-14). Approximately 400 cpm was measured with the hand-held Model 44-9 PanGM. No removable activity was detected during sample analysis. The source ID of C-14 based on label and low count rate of beta emission only.
- **Item 5** – Item exhibited 1,000 and 1,600 cpm with the Model 44-9 PanGM and Model 44-3 NaI, respectively. No removable activity was detected during sample analysis. Direct gamma analysis was performed on this source. Results yielded an approximate activity of 27,122 dpm (12.22 nCi) of Cobalt-57 (Co-57).
- **Item 6** – Bottom to lead storage "pig." This is the bottom portion to Item #3. The Bicron Fieldspec identified the contamination to be Cesium-137 (Cs-137). Additionally, a positive ID was made by the LSC and gamma counter for Cs-137. An average of approximately 1,953 dpm (0.88 nCi) of removable Cs-137 was found by the LSC and gamma counter.
- **Item 7** – This item is a Thoriated lens (Thorium-232 or Th-232) used in optical systems and older camera lens. No removable activity was detected during sample analysis.

Item Pictures

Item Number	Picture
1	
2	

July 19, 2010

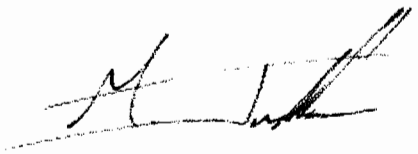
Item Number	Picture
3	
4	No picture available
5	
6	
7	

July 19, 2010

All samples were analyzed at Dade Moeller's Radio-Analytical & Calibration Laboratory (RACL) in Gaithersburg, Maryland. The RACL follows a rigorous Quality Assurance program that meets and follows the standards provided under ISO/IEC 17025:2005, NELAC Standard, ANSI NQA-1, ANSI N323A, MDE License MD-31-244-01 and other applicable standards. All RACL personnel are trained in key aspects of the quality system. The original analytical data are maintained by the RACL for regulatory purposes. Copies of raw data, analytical standard operating procedures, and QA/QC information are available upon request.

Please let me know if you have questions or concerns about the above materials. Dade Moeller is available to assist the FDA in the disposal of these materials at your request.

Sincerely,



Mike Jedlicka
Health Physicist and Laboratory Manager
Dade Moeller & Associates, Inc.
Radio-Analytical & Calibration Laboratory

FORM 540 — Radiation Service Organization

UNIFORM LOW-LEVEL RADIOACTIVE WASTE MANIFEST

SHIPPING PAPER

1. EMERGENCY TELEPHONE NUMBER (Include Area Code): 1-866-464-4680

ORGANIZATION: Chemtrec

2. IS THIS AN "EXCLUSIVE USE" SHIPMENT? ☑ YES ☐ NO

3. TOTAL NUMBER OF PACKAGES IDENTIFIED ON THIS MANIFEST: 2

4. DOES EPA REGULATED WASTE REQUIRING A MANIFEST ACCOMPANY THIS SHIPMENT? ☐ YES ☑ NO — If "Yes," provide Manifest Number

EPA MANIFEST NUMBER

5. SHIPPER – NAME AND FACILITY
Food & Drug Administration
Irradiating Radiation Lab
12555 River Mountains Avenue
Silver Spring, MD 20908

NA — SHIPMENT NUMBER: 10101

CONTACT: Mary Walker

6. CARRIER – Name and Address
R&O, Inc.
2304 Silvanus Road
Laurel, MD 20707
Truck #: 98223
Trailer #: NA

CONTACT: David Walker

SIGNATURE: [signature] authorizing waste receipt

DATE: 9-7-10

SHIPPER I.D. NUMBER: NA
☐ COLLECTOR
☐ PROCESSOR
☑ GENERATOR TYPE (Specify): B
TELEPHONE NUMBER (Include Area Code): (301)756-3656
EPA I.D. NUMBER: MDD-06-067-0000
SHIPPING DATE: 09/07/2010
TELEPHONE (Include Area Code): (301)363-3482

7. FORM 540 AND 540A — PAGE 1 OF 1
FORM 541 AND 541A — PAGE ( ) OF ( )
FORM 542 AND 542A — Block PAGE(S)
ADDITIONAL INFORMATION — Items PAGE(S)

8. DESIGNEE – Name and Facility
R&O, Inc.
5304 Ritchie Road
Landover, MD 20707

SIGNATURE: [signature] Authorized Designee acknowledging waste receipt

DATE: 9-7-10

9. MANIFEST NUMBER (Use this number on all continuation pages): 10101

CONTACT: David Walker
TELEPHONE (Include Area Code): (301)363-3482
DATE: 9-7-10

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 are in proper condition for transportation and disposal as described in accordance with the requirements of 10 CFR Parts 20 and 61, or equivalent state regulations.

AUTHORIZED SIGNATURE: Mary Walker — TITLE: Physicist — DATE: Sept 7 2010

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 (Ci)	(Bq)	17. LSA/SCO CLASS	18. TOTAL WEIGHT OR VOLUME (Use appropriate units)	19. IDENTIFICATION NUMBER OF PACKAGE
Radioactive material, excepted package-limited quantity of material, 7, UN 2910 ,Drum	NA	NA	Solid Lead	Co-137	Pb-210	Ra-226	4.53278E-04	1.17410E-08	NA	10 LBS; 0.68 FT3	87673
Radioactive material, low specific activity (LSA-II), 7, UN3321 ,Box	NA	NA	Solid Lab Trash	Th-232			2.46886E+01	6.60000E-01	LSA-II	10 LBS; 1.3 FT3	87674

FOR CONSIGNEE USE ONLY

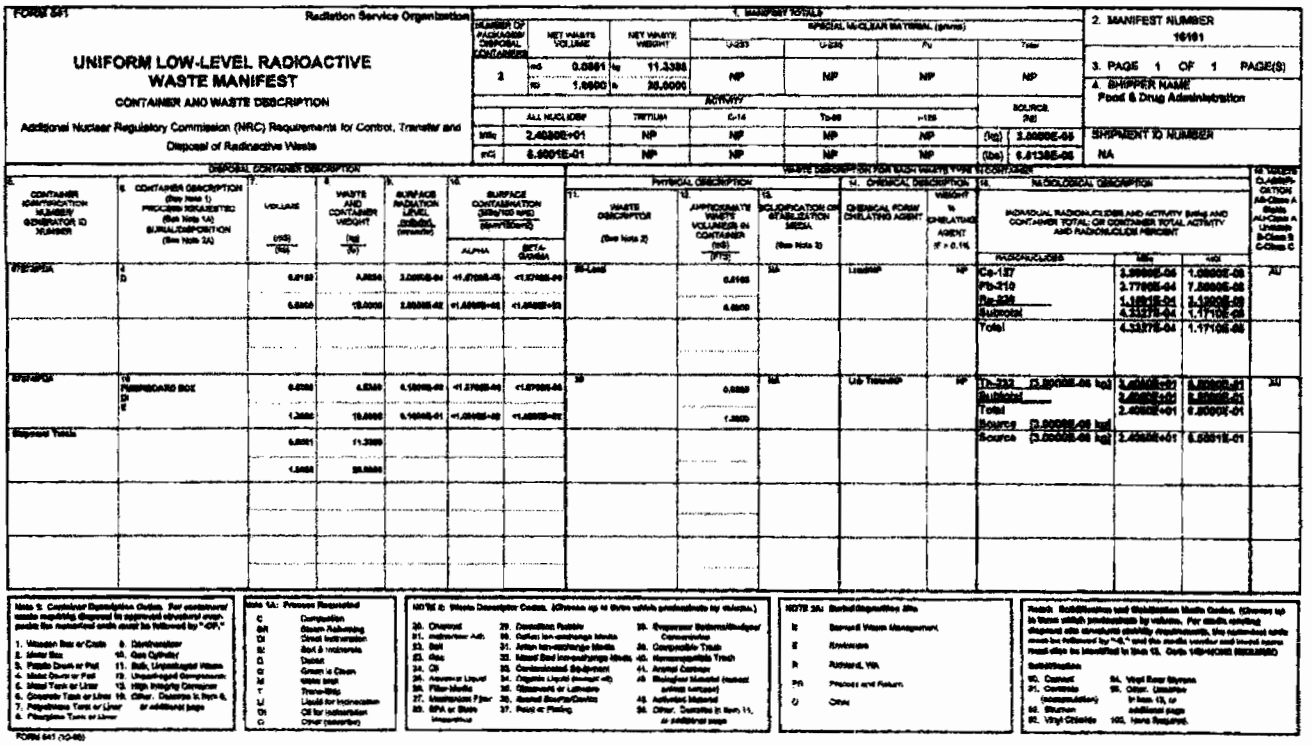
TENNESSEE "LICENSE FOR DELIVERY" NO: _____

SOUTH CAROLINA TRANSPORT PERMIT NO: _____

US ECOLOGY GENERATOR NO: _____

US ECOLOGY PERMIT NO: _____

FORM 540 (10-88)



FORM 541 Radiation Service Organization

UNIFORM LOW-LEVEL RADIOACTIVE WASTE MANIFEST

CONTAINER AND WASTE DESCRIPTION

Additional Nuclear Regulatory Commission (NRC) Requirements for Control, Transfer and Disposal of Radioactive Waste

1. MANIFEST TOTALS							2. MANIFEST NUMBER 16161
NUMBER OF PACKAGES/ DISPOSAL CONTAINERS	NET WASTE VOLUME	NET WASTE WEIGHT	SPECIAL NUCLEAR MATERIAL (grams) U-233	U-235	Pu	Total	3. PAGE 1 OF 1 PAGE(S)
2	m3 0.0001 / ft3 1.0000	kg 11.3398 / lb 30.0000	NP	NP	NP	NP	4. SHIPPER NAME Food & Drug Administration
ACTIVITY	ALL NUCLIDES*	TRITIUM	C-14	Tc-99	I-129	SOURCE Rel	
MBq	2.46380E+01	NP	NP	NP	NP	(kg) 3.00000E-05	SHIPMENT ID NUMBER
mCi	6.6601E-01	NP	NP	NP	NP	(lbs) 6.61386E-05	NA

DISPOSAL CONTAINER DESCRIPTION							WASTE DESCRIPTION FOR EACH WASTE TYPE IN CONTAINER							
5. CONTAINER IDENTIFICATION NUMBER/ GENERATOR ID NUMBER	6. CONTAINER DESCRIPTION (See Note 1) PROCESS REQUESTED (See Note 1A) BURIAL/IMPORTATION (See Note 2A)	7. VOLUME (m3) (ft3)	8. WASTE AND CONTAINER WEIGHT (kg) (lb)	9. SURFACE RADIATION LEVEL (mR/hr) (mrem/hr)	10. SURFACE CONTAMINATION (dpm/100 cm2) ALPHA	BETA-GAMMA	PHYSICAL DESCRIPTION 11. WASTE DESCRIPTION (See Note 3)	12. APPROXIMATE WASTE VOLUMES IN CONTAINER (m3) (ft3)	13. SOLIDIFICATION OR STABILIZATION MEDIA (See Note 3)	H. CHEMICAL DESCRIPTION CHEMICAL FORM/ CHELATING AGENT	WEIGHT % CHELATING AGENT IF > 0.1%	14. RADIOLOGICAL DESCRIPTION INDIVIDUAL RADIONUCLIDES AND ACTIVITY (MBq) AND CONTAINER TOTAL OR CONTAINER TOTAL ACTIVITY AND RADIONUCLIDE PERCENT RADIONUCLIDES	MBq	mCi	15. WASTE CLASSIFICATION All Class A Mixed A Unstable B Class B C Class C
[illegible]	A D	0.0100	0.0254	3.0000E-04	<1.0700E-05	<1.0700E-05	Ml-Lab	0.0100	NA	Lissamin	NP	Cs-137	2.9900E-04	1.0800E-05	AU
		0.3400	15.0000	2.0000E-02	<1.0000E-05	<1.0000E-05		0.3400				Pb-210	2.7700E-04	7.5000E-05	
												Ra-226	1.1901E-04	3.1900E-06	
												Subtotal	4.3337E-04	1.1710E-05	
												Total	4.3337E-04	1.1710E-05	
[illegible]	1A FIBREBOARD BOX B C	0.0350	0.3340	0.1000E-04	<1.3700E-04	<1.0700E-04	39	0.0350	NA	Lib Thorotrast	NP	Th-232 (1.9000E-06 kg)	1.4000E+01	3.8000E-01	AU
		1.3000	15.0000	5.1000E-01	<1.0000E-03	<1.0000E-03		1.3000				Subtotal	2.4000E+01	6.5000E-01	
												Total	2.4000E+01	6.5000E-01	
Disposal Totals		0.0001	11.3300									Source (3.0000E-05 kg)	2.4000E+01	6.5001E-01	
		1.3400	30.0000												

Note 1: Container Description Codes. For containers/ waste requiring disposal in approved disposal containers the numerical code must be followed by "-DF."

1. Wooden Box or Crate
2. Metal Box
3. Plastic Drum or Pail
4. Metal Drum or Pail
5. Metal Tank or Liner
6. Concrete Tank or Liner
7. Polyethylene Tank or Liner
8. Reinforced Tank or Liner
9. Combination
10. Gas Cylinder
11. Bulk, Unpackaged Waste
12. Unpackaged Components
13. High Integrity Container
19. Other. Describe in Item 9, or additional page

Note 1A: Process Requested

C Composition
CR Steam Reforming
DI Direct Incineration
E Soil & Materials
D Debris
G Grass or Clean waste prod
M Metals
T Trans-Mig
LI Liquids for Incineration
OI Oil for Incineration
O Other (describe)

NOTE 2: Waste Description Codes. (Choose up to three which predominate by volume.)

20. Charcoal
21. Activated Carbon
22. Soil
23. Ores
24. Oil
25. Aqueous Liquid
26. Filter Media
27. Mechanical Filter
28. EPA or State Hazardous
29. Demolition Rubble
30. Cation Ion-exchange Media
31. Anion Ion-exchange Media
32. Mixed Bed Ion-exchange Media
33. Contaminated Equipment
34. Organic Liquid (Solvent, etc)
35. Glassware or Labware
36. Animal Body/Parts/Debris
37. Paint or Plating
38. Resin or Sludge
39. Evaporator Bottoms/Sludges/ Concentrates
40. Compactible Trash
41. Noncompactible Trash
42. Animal Carcass
43. Biological Material (natural animal carcass)
44. Activated Material
45. Other. Describe in Item 11, or additional page

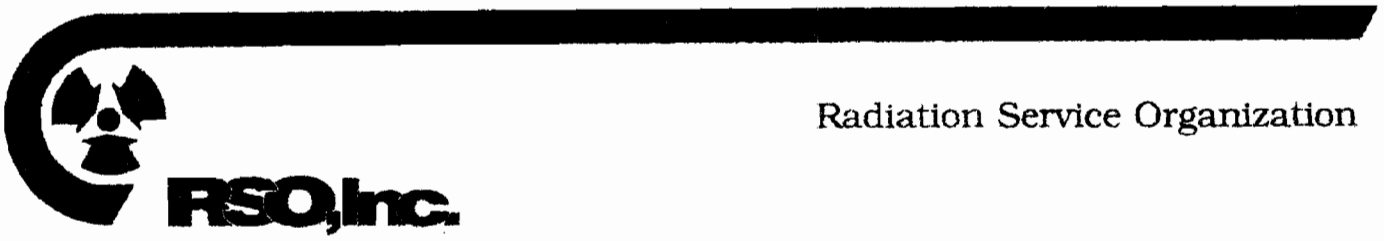
NOTE 2A: Burial/Disposition Site

W Barnwell Waste Management
E Envirocare
R Richland, WA
PR Process and Return
O Other

Note 3: Solidification and Stabilization Waste Codes. (Choose up to three which predominate by volume. For waste meeting disposal site structural stability requirements, the numerical code must be followed by "-S," and the media vendor and brand name must also be identified in Item 13. Code 149-NONE REQUIRED

Solidification
10. Cement
21. Cementite (Vermiculite)
84. Sturnon
85. Vinyl Chloride
94. Vinyl Resi Styrene
99. Other. Describe in Item 13, or additional page
100. None Required

FORM 541 (10-98)



June 22, 2011

Attn Mary Walker
Food & Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Re: Radioactive Waste Disposal Tracking

Dear Mary Walker:

RSO, Inc. (RSO) receives monthly reports for low-level radioactive waste shipped for processing and burial. These reports document the final shipment in the "cradle to grave" tracking of waste shipments. Waste containers collected at your facility are assigned an RSO identification number at the time of the waste pickup. The ID number is tracked through all processing and the disposal at the designated facility.

The Duratek Customer Monthly Report No. 4 lists the RSO ID number in the *Manifest Line Item* Column 6. Column 7, *Volume Returned/Buried*, lists the Cu. Ft. of waste after processing i.e. incineration or compaction. Column 5, *Date Shipped* is the burial shipment date, not the collection date. This is the final volume of your waste buried for each container. RSO may delete or block out other information from the report, which pertains to other generators.

If you need additional information or have questions about these reports please feel free to contact me at (301) 953-2482 ext. 309.

Sincerely,

Christina Hirschmann

Christina Hirschmann
Radioactive Material Broker

Attachment(s)

ENERGYSOLUTIONS

Customer Monthly Report

Broker/Generator Item Number Information

Report 4

Customer #: 54 For Shipments between 05/01/2011 and 05/31/2011
Radiation Service Organization, Inc./Laurel, MD
5204 Minnick Road
P.O. Box 1450
Laurel, MD 20725-1450
Contact: David Wellner

Manifest Number	Date Received	Generator Name	Shipment Number	Date Shipped	Manifest Line Item	Volume Returned/Buried (cu. ft.)	Reported Activity Returned/Buried (mCi.)	Adjusted Activity Returned/ Buried(mCi)
54-T103819	09/22/2010	Food and Drug Administration/Silver Spring, MD	T112189	05/19/2011	57873	0.05887	0.0000	0.0000
						0.05887	0.0000	0.0000

ENERGYSOLUTIONS

Customer Monthly Report

Burial and Return Summary

Customer #: 54 **For Shipments between 05/01/2011 and 05/31/2011**
Radiation Service Organization, Inc./Laurel, MD
5204 Minnick Road
P.O. Box 1450
Laurel, MD 20725-1450
Contact: David Wellner

Manifest Number	Received Date	Shipment Number	Date Shipped	Shipping Destination	Volume Returned/Buried (cu. ft.)	Weight Returned/Buried (lbs)	Reported Activity Returned/Buried (mCi.)
54-T103819	08/22/2010	T112189	05/19/2011	ES CLIVE	0.82414	56	0.0004
					0.82414	56	0.0004
54-T111067	03/11/2011	T112235	05/19/2011	ES CLIVE	6.60000	597	1.3700
					6.60000	597	1.3700
Totals:	**2**				**7.42414**	**653**	**1.3704**

FORM 540 — Radiation Service Organization

UNIFORM LOW-LEVEL RADIOACTIVE WASTE MANIFEST
SHIPPING PAPER

1. EMERGENCY TELEPHONE NUMBER (Include Area Code): 1-866-424-9300

ORGANIZATION: Chemtrec

2. IS THIS AN "EXCLUSIVE USE" SHIPMENT? [X] YES [ ] NO

3. TOTAL NUMBER OF PACKAGES IDENTIFIED ON THIS MANIFEST: 2

4. DOES EPA REGULATED WASTE REQUIRING A MANIFEST ACCOMPANY THIS SHIPMENT? [ ] YES [X] NO
If "Yes," provide Manifest Number below:

EPA MANIFEST NUMBER:

5. SHIPPER – NAME AND FACILITY
Food & Drug Administration
Ionizing Radiation Lab
10903 New Hampshire Avenue
Silver Spring, MD 20993

SHIPMENT NUMBER: NA 18181

CONTACT: Mary Walker

6. CARRIER – Name and Address
RSO, Inc.
6204 Minnick Road
Laurel,, MD 20707
Truck #: 98223
Trailer #: N/A

CONTACT: David Wellner

SIGNATURE – Authorized carrier acknowledging waste receipt

SHIPPER I.D. NUMBER: NA
[ ] COLLECTOR
[ ] PROCESSOR
[X] GENERATOR TYPE (Specify): G

TELEPHONE NUMBER (Include Area Code): (301)738-3668

EPA I.D. NUMBER: MDD-00-827-0000

SHIPPING DATE: 09/07/2010

TELEPHONE (Include Area Code): (301)983-2482

DATE: 9-7-10

7. FORM 540 AND 540A PAGE 1 OF 1 PAGE(S)
FORM 541 AND 541A 1 PAGE(S)
FORM 542 AND 542A None PAGE(S)
ADDITIONAL INFORMATION None PAGE(S)

8. MANIFEST NUMBER (Use this number on all continuation pages): 18181

9. CONSIGNEE - Name and Facility
RSO, Inc.
6204 Minnick Road
Laurel, MD 20707

CONTACT: David Wellner

TELEPHONE (Include Area Code): (301)983-2482

SIGNATURE – Authorized consignee acknowledging waste receipt

DATE: 9-7-10

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 are in proper condition for transportation and disposal as described in accordance with the requirements of 10 CFR Parts 20 and 61, or equivalent state regulations.

AUTHORIZED SIGNATURE: Mary Walker TITLE: Physicist / Supervisory Scientist DATE: Sept 7, 2010

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	16. TOTAL PACKAGE ACTIVITY mCi	17. LSA/SCO CLASS	18. TOTAL WEIGHT OR VOLUME (Use appropriate units)	19. IDENTIFICATION NUMBER OF PACKAGE
Radioactive material, excepted package-limited quantity of material, 7, UN 2910 ,Drum	NA	NA	Solid Lead	Co-137	Pb-210	Ra-226	4.5327E-04	1.1710E-05	NA	18 LBS; 0.88 FT3	57873
Radioactive material, low specific activity (LSA-II), 7, UN3321 ,Box	NA	NA	Solid Lab Trash	Th-232			2.4060E+01	6.5000E-01	LSA-II	10 LBS; 1.3 FT3	57874

FOR CONSIGNEE USE ONLY

TENNESSEE "LICENSE FOR DELIVERY" NO: _____

SOUTH CAROLINA TRANSPORT PERMIT NO: _____

US ECOLOGY GENERATOR NO: _____

US ECOLOGY PERMIT NO: _____

20.

FORM 540 (10-08)

FORM 541 — Radiation Service Organization

UNIFORM LOW-LEVEL RADIOACTIVE WASTE MANIFEST

CONTAINER AND WASTE DESCRIPTION

Additional Nuclear Regulatory Commission (NRC) Requirements for Control, Transfer and Disposal of Radioactive Waste

1. MANIFEST TOTALS

NUMBER OF PACKAGES/ DISPOSAL CONTAINERS	NET WASTE VOLUME		NET WASTE WEIGHT		SPECIAL NUCLEAR MATERIAL (grams) U-233	U-235	Pu	Total
2	m3	0.0561	kg	11.3398	NP	NP	NP	NP
	ft3	1.9800	lb	25.0000				

ACTIVITY	ALL NUCLIDES	TRITIUM	C-14	Tc-99	I-129	SOURCE (kg)	
MBq	2.4060E+01	NP	NP	NP	NP	(kg)	3.0000E-06
mCi	6.5001E-01	NP	NP	NP	NP	(lbs)	6.6139E-06

2. MANIFEST NUMBER: 16181

3. PAGE 1 OF 1 PAGE(S)

4. SHIPPER NAME: Food & Drug Administration

SHIPMENT ID NUMBER: NA

DISPOSAL CONTAINER DESCRIPTION / **WASTE DESCRIPTION FOR EACH WASTE TYPE IN CONTAINER**

5. CONTAINER IDENTIFICATION NUMBER/ GENERATOR ID NUMBER	6. CONTAINER DESCRIPTION (See Note 1) PROCESS REQUESTED (See Note 1A) BURIAL/DISPOSITION (See Note 2A)	7. VOLUME (m3) (ft3)	8. WASTE AND CONTAINER WEIGHT (kg) (lb)	9. SURFACE RADIATION LEVEL (mR/hr) (mrem/hr)	10. SURFACE CONTAMINATION (MBq/100 cm2) (dpm/100cm2) ALPHA	BETA-GAMMA	11. WASTE DESCRIPTOR (See Note 2)	12. APPROXIMATE WASTE VOLUME(S) IN CONTAINER (m3) (FT3)	13. SOLIDIFICATION OR STABILIZATION MEDIA (See Note 3)	14. CHEMICAL DESCRIPTION: CHEMICAL FORM CHELATING AGENT	WEIGHT % CHELATING AGENT IF > 0.1%	15. RADIOLOGICAL DESCRIPTION: INDIVIDUAL RADIONUCLIDES AND ACTIVITY (MBq) AND CONTAINER TOTAL; OR CONTAINER TOTAL ACTIVITY AND RADIONUCLIDE PERCENT — RADIONUCLIDES	MBq	mCi	16. WASTE CLASSIFICATION A/I-Class A Stable A/U-Class A Unstable B-Class B C-Class C
97975/FDA	4 D	0.0183	0.0839	2.0000E-04	<1.5700E-06	<1.5700E-06	99-Lead	0.0183	NA	Lead/NP	NP	Ce-137	3.9900E-06	1.0800E-06	AU
		0.0600	15.0000	2.0000E-02	<1.0000E+02	<1.0000E+02		0.0600				Pb-210	2.7780E-04	7.5000E-06	
												Ra-226	1.1631E-04	3.1300E-06	
												Subtotal	4.3327E-04	1.1710E-05	
												Total	4.3327E-04	1.1710E-05	
97974/FDA	19 FIBERBOARD BOX DI E	0.0300	4.5360	5.1000E-03	<1.5700E-06	<1.5700E-06	99	0.0384	NA	Lab Trash/NP	NP	Th-232 [3.0000E-06 kg]	2.4060E+01	6.5000E-01	AU
		1.3600	19.0000	5.1000E-01	<1.0000E+02	<1.0000E+02		1.3600				Subtotal	2.4060E+01	6.5000E-01	
												Total	2.4060E+01	6.5000E-01	
												Source [3.0000E-06 kg]			
Shipment Totals		0.0561	11.3398									Source [3.0000E-06 kg]	2.4060E+01	6.5001E-01	
		1.9800	25.0000												

Note 1: Container Description Codes. For containered waste requiring disposal in approved structural overpacks the numerical code must be followed by "-OP."

1. Wooden Box or Crate
2. Metal Box
3. Plastic Drum or Pail
4. Metal Drum or Pail
5. Metal Tank or Liner
6. Concrete Tank or Liner
7. Polyestrene Tank or Liner
8. Fiberglass Tank or Liner
9. Decontaminator
10. Gas Cylinder
11. Bulk, Unpackaged Waste
12. Unpackaged Components
13. High Integrity Container
19. Other. Describe in Item 9, or additional page

Note 1A: Process Requested

C Compaction
SR Steam Reforming
DI Direct Incineration
SI Sort & Incinerate
D Decon
O Ocean to Clean
M Metal Melt
T Trans-Ship
LI Liquid for Incineration
OI Oil for Incineration
O Other (describe)

NOTE 2: Waste Descriptor Codes. (Choose up to three which predominate by volume.)

20. Charcoal
21. Incinerator Ash
22. Soil
23. Gas
24. Oil
25. Aqueous Liquid
26. Filter Media
27. Mechanical Filter
28. EPA or State Hazardous
29. Demolition Rubble
30. Cation ion-exchange Media
31. Anion ion-exchange Media
32. Mixed Bed ion-exchange Media
33. Contaminated Equipment
34. Organic Liquid (except oil)
35. Glassware or Labware
36. Sealed Source/Device
37. Paint or Plating
38. Evaporator Bottoms/Sludges/ Concentrates
39. Combustible Trash
40. Noncombustible Trash
41. Animal Carcass
42. Biological Material (except animal carcass)
43. Adhered Material
99. Other. Describe in Item 11, or additional page

NOTE 2A: Burial/Disposition Site

B Barnwell Waste Management
E Envirocare
R Richland, WA
PR Process and Return
O Other

Note 3: Solidification and Stabilization Media Codes. (Choose up to three which predominate by volume. For media meeting disposal site structural stability requirements, the numerical code must be followed by "-S." and the media vendor and brand name must also be identified in Item 13. Code 100=NONE REQUIRED

Solidification

90. Cement
91. Concrete (encapsulation)
92. Bitumen
93. Vinyl Chloride
94. Vinyl Ester Styrene
99. Other. Describe in Item 15, or additional page
100. None Required.

FORM 541 (10-96)

Radiation Service Organization

June 22, 2011

Attn Mary Walker
Food & Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Re: Radioactive Waste Disposal Tracking

Dear Mary Walker:

RSO, Inc. (RSO) receives monthly reports for low-level radioactive waste shipped for processing and burial. These reports document the final shipment in the "cradle to grave" tracking of waste shipments. Waste containers collected at your facility are assigned an RSO identification number at the time of the waste pickup. The ID number is tracked through all processing and the disposal at the designated facility.

The Duratek Customer Monthly Report No. 4 lists the RSO ID number in the *Manifest Line Item* Column 6. Column 7, *Volume Returned/Buried*, lists the Cu. Ft. of waste after processing i.e. incineration or compaction. Column 5, *Date Shipped* is the burial shipment date, not the collection date. This is the final volume of your waste buried for each container. RSO may delete or block out other information from the report, which pertains to other generators.

If you need additional information or have questions about these reports please feel free to contact me at (301) 953-2482 ext. 309.

Sincerely,

Christina Hirschmann

Christina Hirschmann
Radioactive Material Broker

Attachment(s)

P.O. Box 1450, Laurel, Maryland 20725-1450
Washington (301) 953-2482 Fax (301) 498-3017 Baltimore (410) 792-7444

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