



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
White Oak Building 62 Rm 4126
Silver Spring, Maryland 20993

May 23, 2012

Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Subject: Amendment of License 19-07538-01

To Whom It May Concern:

NRC 10 CFR 30.36 (d) states that a license must be terminated within 60 days after no principal activities under the license have been conducted for a period of 24 months. All known sealed sources that were owned by CDRH and listed on License 19-07538-01 were transferred and ownership was relinquished by CDRH on June 1, 2010. Documentation of transfer (ATRO #2010:87) and leak testing is attached.

CDRH management is requesting to terminate license 19-07538-01. Enclosed are two copies of NRC Form 313, attachments amending license number 19-07538-01, and completed paperwork for authorization of transfer/Relinquishment of ownership of remaining CDRH radioactive sources. The intent of this amendment is the following:

- deleting authorized users
- deleting sealed source materials

Thank you for reviewing and considering this request.

Sincerely Yours,

Mary Walker

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

Center for Devices and Radiological Health
Food and Drug Administration
WO62-4126
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Phone: 301 796-2558
FAX: 301 796-9795
mary.walker@fda.hhs.gov

Enc: License amendment and attachments (2 copies)

cc: Steven K. Pollack, Ph.D., CDRH Management Contact for NRC License No. 19-07538-01

Br 2

03604544

2012 MAY 24 AM 10:09

RECEIVED
REGION 1

577649

NMSS/RGN1 MATERIALS-002

NRC FORM 313

(3-2009)

10 CFR 30, 32, 33,
34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 3/31/2012

APPLICATION FOR MATERIALS LICENSE

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollections.resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), 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.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION.
SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

OFFICE OF FEDERAL & STATE MATERIALS AND
ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA,
KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY,
NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH
CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,
SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND
APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS,
LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH
DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS,
UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
612 E. LAMAR BOULEVARD, SUITE 400
ARLINGTON, TX 76011-4125

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED
MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

☐ A. NEW LICENSE☒ B. AMENDMENT TO LICENSE NUMBER 19-07538-01☐ C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

Mary Walker, Radiation Safety Officer
FDA/CDRH/OSEL/DIAM, WO#62, Room 4126
10903 New Hampshire Avenue
Silver Spring, MD 20993

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

WO#62
10903 New Hampshire Avenue
Silver Spring, MD 20993

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Mary Walker, Radiation Safety Officer

TELEPHONE NUMBER

(301) 796-2558

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number; b. chemical and/or physical form; and c. maximum amount
which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR
TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY

AMOUNT
ENCLOSED

\$ 0.00

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING
UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN
CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND
CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 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.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Mary Walker, Radiation Safety Officer

SIGNATURE

Mary Walker

DATE

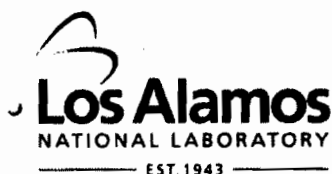
May 23, 2012

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		

APPROVED BY

DATE



*N2 Advanced Nuclear Technology
Off-Site Source Recovery (OSR) Project*
P.O. Box 1663, Mail Stop: J552
Los Alamos, New Mexico 87545
505-667-7440/Fax: 505-665-7913

Date: August 26, 2010
Refer to: N3: 2010-209

Raymond Manley, Chief
Radioactive Material Licensing &
Compliance Division
MD Department of the Environment
1800 Washington Blvd., Suite 750
Baltimore, MD 21230-1724

Re: ATRO #2010:87, License Number 19-07538-01

Dear Mr. Raymond Manley:

Enclosed please find a signed *Authorization to Transfer/Relinquishment of Ownership* form concerning:

FDA-CDRH
10903 New Hampshire Avenue
WO66-Rm 4676
Silver Spring, MD 20993-0002

The radioactive sources described on the form have been removed from FDA-CDRH of Silver Spring, MD and are in storage at NSSI in Houston, TX. The sources have been transferred to Department of Energy (DOE) ownership and are being stored under DOE license exemption.

This action was completed as part of the Off-Site Source Recovery (OSR) Project managed by this office. If you need any further information on this action, please contact the OSR Project Office at 505/667-7440.

Sincerely,

Richard Rasmussen, CHP, RRPT
Team Leader OSR Project

RR/amj

Cy: Mary Walker, FDA-CDRH
Abby Cuthbertson, DOE, NA-211
N3/OSRP File, MS: J552

Los Alamos
NATIONAL LABORATORY

JUN - 8 2010



ATRO # 2010:87

Off-Site Source Recovery Project
Authorization to Transfer/Relinquishment of Ownership/Custody

SOURCE OWNER: FDA-CDRH
LICENSE: MD
No.: 19-07538-01
CONTACT NAME: Mary Walker
ADDRESS: 10903 New Hampshire Avenue
WO66- Rm 4676
Silver Spring, MD 20993-0002

TELEPHONE: 301 796-2558
FAX: 301 796-9795

Pursuant to its authority under the Atomic Energy Act, the U.S. Department of Energy (DOE) National Nuclear Security Administration (NNSA) has directed Los Alamos National Security, LLC (LANS), to recover and store excess, unwanted, abandoned, orphan radioactive sealed sources and other radioactive material sources on behalf of DOE/NNSA.

LANS has determined that the sealed source(s) identified below meet the requirements of the Los Alamos National Laboratory Off-Site Source Recovery Project and, on behalf of DOE/NNSA, authorizes FDA-CDRH to transfer the sealed source(s) to the following designated LANS support subcontractor:

NSSI / Sources & Services, Inc.
Texas Department of State Health Services
Radioactive Material License No. L02991

FDA-CDRH affirms it is the owner/custodian of the sealed source(s) identified below, and hereby irrevocably relinquishes all rights, title and ownership/custody in the sealed source(s) to DOE/NNSA in furtherance of the OSRP. LANS accepts the sealed sources on behalf of DOE/NNSA, pursuant to DOE/NNSA contract no. DE-AC52-06NA25396, upon the execution of the Acknowledgment of Receipt of the source(s) by the designated LANS support subcontractor below.

SOURCE INFORMATION

Isotope:	Mfr/Model:	Serial No:	Activity (Ci):
239Pu	EBER	P34	0.000004
241Am	TXNUC/Custom	1	0.014
241Am	TXNUC/Custom	2	0.014
241Am	NEN/NES-128S	Blue Disk	0.0000073

SOURCE OWNER:

OFFICIAL NAME/TITLE: PETRO SHANDRUK
NAME (Please Print or Type)
SIGNATURE: Petro Shandruk
TITLE (Please Print or Type) R.S.O.
DATE: 6/1/10

LANS AUTHORIZATION:

OFFICIAL NAME/TITLE: Rick Rasmussen, Team Leader, Off-Site Source Recovery Project
SIGNATURE: Rick Rasmussen
DATE: 6/7/2010

ACKNOWLEDGEMENT OF RECEIPT BY DESIGNATED LANS SUPPORT SUBCONTRACTOR:

NSSI / Sources & Services, Inc.
OFFICIAL NAME/TITLE: CARLOS RINCON
NAME (Please Print or Type)
SIGNATURE: Carlos Rincon
TITLE (Please Print or Type) Hmm
DATE: 8-4-10

**Invoice Number**

7-170-42054

Invoice Date

Jul 27, 2010

Account Number

1164-2152-6

Page

4 of 5

FedEx Express Shipment Detail By Payor Type (Original)

Picked up: Jul 18, 2010

Cons. Ref.: ATDH 2010-07

Ref. #:

Payor: Shipper

Ref. #:

- The Additional Handling Surcharge was assessed for packaging.
- Fuel Surcharge - FedEx has applied a fuel surcharge of 8.00% to this shipment.
- Distance Based Pricing, Zone 6

Automation
Tracking ID
Service Type
Package Type
Zone
Packages
Rated Weight
Delivered
Svc Area
Signed by
FedEx Use

USAB
866862465405
FedEx Standard Overnight
Customer Packaging
06
1
11.0 lbs, 5.0 kgs
Jul 20, 2010 13:49
A2
V.ALLEN
020016645/0001371/_

Sender
DAVID WELLNER
RSO INC
5204 MINNICK RD
LAUREL MD 20707-3138 US

Recipient
CARLCE RINON
MSSI SHURCE AND SERVICES INC
5711 ETHERIDGE ST
HOUSTON TX 77087 US

Transportation Charge
Additional Handling Surcharge
Inaccessible Dangerous Goods
Courier Pickup Charge
Fuel Surcharge
Total Charge

78.05
7.50
35.00
4.00
6.56
USD \$131.11

Picked up: Jul 18, 2010

Cons. Ref.: ATDH 2010-07

Ref. #:

Payor: Shipper

Ref. #:

- Fuel Surcharge - FedEx has applied a fuel surcharge of 8.00% to this shipment.
- The Additional Handling Surcharge was assessed for packaging.
- Distance Based Pricing, Zone 6
- FedEx has audited this shipment for correct packages, weight, and service. Any changes made are reflected in the invoice amount.
- We calculated your charges based on a dimensional weight of 10.00lbs, 12" x 12" x 13", divided by 194.

Automation
Tracking ID
Service Type
Package Type
Zone
Packages
Actual Weight
Rated Weight
Delivered
Svc Area
Signed by
FedEx Use

USAB
866862465418
FedEx Standard Overnight
Customer Packaging
06
1
9.0 lbs, 4.1 kgs
10.0 lbs, 4.5 kgs
Jul 20, 2010 13:49
A2
V.ALLEN
020016645/0001371/_

Sender
DAVID WELLNER
RSO INC
5204 MINNICK RD
LAUREL MD 20707-3138 US

Recipient
CARLOS RINON
MSSI SOURCE AND SERVICES INC
5711 ETHERIDGE ST
HOUSTON TX 77087 US

Transportation Charge
Inaccessible Dangerous Goods
Courier Pickup Charge
Fuel Surcharge
Additional Handling Surcharge
Total Charge

73.90
35.00
4.00
6.23
7.50
USD \$126.63

Picked up: Jul 18, 2010

Cons. Ref.: ATDH 2010-07

Ref. #:

Payor: Shipper

Ref. #:

- Fuel Surcharge - FedEx has applied a fuel surcharge of 8.00% to this shipment.
- Distance Based Pricing, Zone 6

Automation
Tracking ID
Service Type
Package Type
Zone
Packages
Rated Weight
Delivered
Svc Area
Signed by
FedEx Use

USAB
866862465427
FedEx Standard Overnight
Customer Packaging
06
1
11.0 lbs, 5.0 kgs
Jul 20, 2010 13:49
A2
V.ALLEN
020016645/0001371/_

Sender
DAVID WELLNER
RSO INC
5204 MINNICK RD
LAUREL MD 20707-3138 US

Recipient
CARLOS RINNON
NSSI SOURCE AND SERVICES INC
5711 ETHERIDGE ST
HOUSTON TX 77087 US

Transportation Charge
Inaccessible Dangerous Goods
Fuel Surcharge
Courier Pickup Charge
Total Charge

78.05
35.00
6.56
4.00
USD \$123.61

FDA / CORN LEAK TEST RESULTS

PAGE: 1

24 MAY 2010 14:01

ID = SAMPLE SCREEN

USER: 1 COMMENT:

PRESET TIME : 4.00

DATA CALC : SL DPM H# : YES SAMPLE REPEATS: 1 PRINTER : STD

COUNT BLANK : NO ICW : NO REPLICATES : 1 RS232 : OFF

TWO PHASE : NO AGC : NO CYCLE REPEATS : 1 DISK : STD

SCINTILLATOR: LIQUID LUMEX: NO LOW SAMPLE REQ: 0

DATA BUFFER IS FULL. DATA WILL GO TO PRINTER ONLY.

RWM LIST : OFF

LOW LEVEL : NO HALF LIFE CORRECTION DATE: none

ISOTOPE 1: AUTO %ERROR: 0.00 FACTOR: 1.000000 BKG. SUB: 28

BACKGROUND QUENCH CURVE: Off COLOR QUENCH CORRECTION: Off

Quench Limits Low:-8.631 High:304.88

SAM NO	POS	TIME MIN	H#	AUTO		AUTO DPM	AUTO EFF-1	LUMEX %	ELAPSED TIME	
				CPM	%ERROR					
1	**	4.00	23.8	3.50	160.36	6.17	56.69	0.96	4.57	Pu-239
2	**	4.00	18.5	1.75	311.68	3.03	57.75	0.31	9.22	Am-241 #1
3	**	4.00	21.9	0.00	1.E+06	0.00	57.08	0.52	13.87	Co-57
4	**	4.00	39.6	2.00	273.86	3.75	53.32	0.33	18.52	Co-57
5	**	4.00	17.5	2.75	201.65	4.74	57.96	0.29	23.15	Am-241 #2
6	**	4.00	22.2	0.00	1.E+06	0.00	57.02	0.32	27.80	Cd-109
7	**	4.00	23.6	0.00	1.E+06	0.00	56.74	0.33	32.45	Am-241
8	**	4.00	22.6	0.00	1.E+06	0.00	56.95	0.35	37.08	C-14
9	**	4.00	16.3	0.00	1.E+06	0.00	58.19	0.34	41.73	Cs-137
10	**	4.00	16.2	0.00	1.E+06	0.00	58.21	0.34	46.37	UNKNOWN
11	**	4.00	20.2	6.25	93.64	10.88	57.43	0.27	51.02	20 mR/hr
12	**	4.00	20.1	40.50	20.44	70.51	57.44	0.30	55.67	LARGE Pb Pb6
13	**	4.00	20.7	5512.00	1.35	9615.26	57.33	0.00	60.34	RAD #1
14	**	4.00	20.0	6292.00	1.26	10950.34	57.46	0.00	65.00	RAD #2
15	**	4.00	51.0	148.00	8.96	291.95	50.69	0.05	69.66	RAD #3
16	**	4.00	25.3	103.00	11.11	182.68	56.38	0.07	74.32	INSIDE Bo>
17	**	4.00	51.9	5.75	101.03	11.39	50.47	0.25	78.97	OUTSIDE Bo>

This is to acknowledge the receipt of your letter/application dated

05/23/2012, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (Termination)

☒ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 577649.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.