



Food and Drug Administration
10903 New Hampshire Avenue
White Oak Building 66/Rm 4621
Silver Spring, Maryland 20993

September 23, 2010

Br. 2

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

RECEIVED
REGION I
2010 SEP 27 AM 10:40

Subject: Amendment of License 19-07538-01 RD

Dear Sir or Madam:

03004544
PMS

Enclosed are two copies of NRC Form 313 and attachments amending license number 19-07538¹. The intent of this amendment is to further limit the scope of our license by:

- deleting authorized users
- deleting both open source and sealed source materials

Also, we will be adding a new Radiation Safety Officer.

I appreciate the expeditious review of this request and will be open to any questions regarding it.

Sincerely Yours,

Petro Shandruk, RSO
Chief, Radiation Programs Branch
(301) 796-5889
petro.shandruk@fda.hhs.gov
FAX: (301) 847-8502
Center for Devices and Radiological Health,
Food and Drug Administration
WO #66, Room 4676
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Enc: License amendment and attachments (2 copies)

cc: Lillian J. Gill
Senior Associate Director, CDRH

573589

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 infocollects.resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOF-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)

Petro Shandruk, Radiation Safety Officer
FDA/CDRH/OCER/DMQRP, WO#66, Room 4676
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

Petro Shandruk, Radiation Safety Officer

TELEPHONE NUMBER

(301) 796-5889

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
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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
Petro Shandruk, Radiation Safety Officer

SIGNATURE
Petro Shandruk

DATE
9/23/10

FOR NRC USE ONLY

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

U. S. FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

REQUEST FOR AMENDMENT OF LICENSE 19-07538-01

DELETION OF: -PRINCIPAL USERS
-BYPRODUCT SOURCES
-CONDITONS

CHANGE OF: -LICENSEE ADDRESS
-RADIATION SAFETY
OFFICER

This request employs the number format used on the NRC MATERIALS LICENSE, Form 374. The changes in facility and Radiation Safety Officer will be preceded in the request by the italicized word *Add* and deletions of principal users, byproduct materials and Radiation Safety Officer by the italicized word *Delete*.

Licensee:

1. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
2. OCER/DMQRP
WO#66, Room 4676
10903 New Hampshire Avenue
Silver Spring, MD 20993

Items to be amended:

Page

Licensee Item No. 2.....	1
6. Byproduct, 7. Chemical and/or physical form, 8. maximum amount of possession...	1
Authorized use: 9. A through H.....	1
Conditions 10., 11. A - D., 14 A. - H., 15, 16, 17, 18, 19, 20.....	1

Licensee Item No. 2

OCER/DMQRP
WO#66, Room 4676
10903 New Hampshire Avenue
Silver Spring, MD 20993

Delete above and add: DIAM/OSEL
WO62, Room 4126
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

LICENSED MATERIALS

Delete 6. A, B, C, D, E, F, G, H

Note: We have not used 6. A - D materials for at least 5 years and have no plans to do so in the future. We have no current plans to use sealed sources as listed in 6E.

We have appropriately disposed of the sealed sources listed as 6. F –H
(see attachment)

Delete 7. and 8. to reflect the changes in item 6.

AUTHORIZED USE

9. A. through H

Delete 9. A. through .H (At this time we have no plans to use regulated materials.)

CONDITIONS

10. Licensed material may be used at the licensee's facilities located at 10903 New Hampshire Avenue, Silver Spring, MD *add/change* 10903 New Hampshire Avenue, WO62, Silver Spring, MD 20993-0002.

Note: Radioactive materials have never been used in the Center for Devices and Radiological Health laboratories housed in the third and fourth stories of the Life Sciences Laboratory Building (WO64).

- 11. A. Licensed material in item 6.A. through 6.D. shall be used by, or under the supervision of Peter Goering, Abiy B. Desta, or Michael D. O'Hara, Ph.D.
Delete Peter Goering, Abiy B. Desta and Michael D. O'Hara, Ph.D.
- 11. B. Licensed material in items 6.A., 6.B., and 6.D. shall be used by, or under the supervision of Thomas H. Umbreit, Ph.D.
Delete Thomas H. Umbreit, Ph.D.
- 11. C. Licensed material in items 6. E. through 6.H. shall be used by, or under the supervision of, Mary D. Walker or Peter Goering
Delete Peter Goering and Mary D. Walker
- 11. D. The radiation Safety Officer for this license is Petro Shandruk.
Delete Petro Shandruk
Add Mary Walker (new mailing address appears in item 2)
- 14. A, B, C, D, E, F, G, H *Delete* 14 A. – H. in the entirety
- 15. *Delete* 15 in its entirety
- 17. *Delete* 17 in its entirety
- 18. A., B. *Delete* 18. A., B. in their entirety
- 19. A., B. and C. *Delete* 19. A., B., and C in the their entirety

For additional information, please contact:

Petro Shandruk
Radiation Safety Officer
U.S. Food and Drug Administration
Center for Devices and Radiological Health
OCER/DMQRP
WO#66, Room 4676
10903 New Hampshire Avenue
Silver Spring, MD 20993

Telephone: 301-796-5889
FAX: 301-847-8502
E Mail: petro.shandruk@fda.hhs.gov

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with the letter dated December 30, 2009,
1. Department of Health & Human Services Food and Drug Administration Center for Devices and Radiological Health	3. License number 19-07538-01 is amended in its entirety to read as follows:
2. OCER/DMQRP WO #66, Room 4676 10903 New Hampshire Avenue Silver Spring, Maryland 20993	4. Expiration date June 30, 2015
	5. Docket No. 030-04544 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Hydrogen 3	A. Any	A. 100 millicuries
B. Carbon 14	B. Any	B. 85 millicuries
C. Phosphorus 32	C. Any	C. 100 millicuries
D. Sulfur 35	D. Any	D. 300 millicuries
E. Any byproduct material with atomic numbers 3 through 83	E. Sealed Sources	E. 1 millicurie per source and 5 millicuries total
F. Plutonium 239	F. Plated Sources	F. 4 microcuries
G. Americium 241	G. Sealed Sources (Texas Nuclear Corporation, Custom Source)	G. 14 millicuries per source and 28 millicuries total
H. Americium 241	H. Sealed Sources (New England Nuclear Model NES-128S)	H. 8 microcuries

9. Authorized use:

- A. through D. Research and development as defined in 10 CFR 30.4.
E. through G. Calibration, standardizing, and testing of the licensee's instruments.
H. For storage incident to disposal.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 10903 New Hampshire Avenue, Silver Spring, Maryland.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
19-07538-01Docket or Reference Number
030-04544

Amendment No. 39

11. A. Licensed material in items 6.A. through 6.D. shall be used by, or under the supervision of, Peter Goering, Ably B. Desta, or Michael D. O'Hara, Ph.D.
- B. License material in items 6.A., 6.B., and 6.D. shall be used by, or under the supervision of Thomas H. Umbreit, Ph.D.
- C. Licensed material in items 6.E. through 6.H. shall be used by, or under the supervision of, Mary D. Walker or Peter Goering.
- D. The Radiation Safety Officer for this license is Petro Shandrak.
12. The licensee shall not use licensed material in or on human beings.
13. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.
14. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- D. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
- E. 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.
- F. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
19-07538-01Docket or Reference Number
030-04544

Amendment No. 39

- G. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.
- H. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- I. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.
15. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
16. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.
17. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
18. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.
- B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.
19. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
- A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
- B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
19-07538-01Docket or Reference Number
030-04544

Amendment No. 39

- C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.
20. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
21. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated January 27, 1998 (ML070160180)
 - B. Letter dated April 2, 1998 (ML070120466)
 - C. Letter dated January 6, 2000 (ML003678663)
 - D. Letter dated April 16, 2003 (ML031260073)
 - E. Letter dated August 5, 2004 (ML042190374)
 - F. Letter dated January 25, 2005 (ML050380492)
 - G. Application dated April 16, 2007 (ML071130143)

For the U.S. Nuclear Regulatory Commission

Date June 21, 2010

By

Elizabeth Ullrich
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

Monday, June 21, 2010 08:10:28

**Curriculum Vitae of:
Mary D. Walker**

Phone: [REDACTED]

Experience

- 8/92- Present Physical Scientist
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993
- 3/89 –8/92 Physical Scientist
National Institute for Standards and Technology
Gaithersburg, Maryland 20899
- 9/84 – 3/89 Radiological Physicist
The Institute for Radiological Imaging Sciences
20251 Century Blvd
Germantown, Maryland 20874
- 10/83 – 9/84 X-ray Technologist
Washington Radiology Associates
916 19th Street, N.W.; Suite 200
Washington, D.C. 20006
- 4/82 – 9/83 Radiation Technologist
George Washington University Hospital
2300 I Street

Education

- 1/91 – 5/95 Georgetown University
Washington, D.C. 20057
Degree: M.S., Radiation Science
- 9/86 – 5/88 Montgomery College
Rockville, Maryland 20850
Degree: A.A., Electronics Technology
- 8/79 – 05/81 University of Maryland
Baltimore, Maryland 21201
Degree: B.S., Radiation Science

Experience

8/92- Present

Physical Scientist
Food and Drug Administration

- Design and conduct experimental and theoretical studies for the evaluation of the performance of radiation devices
- Provide necessary support to maintain an adequate and verifiable measurement program for FDA field inspections and surveys. This includes: researching, evaluating, and developing procurement specifications for needed instrumentation; providing scientific consultation to FDA district and other Center Offices on specific problems; and implementing new measurement techniques
- Perform measurements needed to characterize new state of the art mammography x-ray generators
- Investigate the response of radiation devices in newly established x-ray reference beams. The CDRH Calibration Laboratory is responsible for maintaining and calibrating instruments that are used to enforce both the Radiation Control for Health and Safety Act (RCHSA) of 1968 and the Mammography Quality Standards Act (MQSA) of 1992. The Radiation Metrology Branch is presently updating the CDRH Calibration Laboratory. I am responsible for overseeing the programming to design the database applications and maintaining the system to support the calibration laboratory, as well as merging existing data into the new application. Data includes information related to customer and CDRH inventory equipment, shipping and receiving of equipment that is used by both federal and state field inspectors, test and reference instrument calibration data, and quality control. I was one of the major investigators in characterizing the new mammography laboratory.
- Experimentally evaluate radiation instruments that are used to enforce regulatory standards. For example, I conducted a study that evaluated thin window ionization chambers that are used for diagnostic x-ray instruments and mammography chambers to enforce MQSA. The chambers were evaluated based upon their response to target material, filter material and thickness, x-ray tube potential, and HVL.
- Consult with other government agencies, standards-setting organizations, manufacturers, University researchers and professional societies on matters related to my areas of responsibility in radiation metrology. For example, I worked with personnel from the University of Wisconsin (UWI) and the National Institute of Standards and Technology (NIST) in making measurements using a Free Air Chamber (FAC) that was developed by UWI.
- Served on Standard committees of National Organizations such as the Conference of Radiation Control Program Directors (CRCPD), The Health Physics Society (HPS) and the National Voluntary Laboratory Accreditation Program (NVLAP)

Experience (continued)

- Was available as technical assessor for the CRCPD, NVLAP, and HPS accreditation programs for calibration laboratories. As assigned, I reviewed draft
- Documents of standards organizations and professional societies, and provided input on radiation metrology.

Awards:

- Individual CDRH Special Recognition Award – 2008
- Group Recognition Award for White Oak Relocation - 2008
- X-ray Calibration Laboratory Staff CDRH Special Recognition Award – 2004
- Individual OSEL Reward and Recognition Award - 2003
- Individual FDA Outstanding Service Award – 2001

3/89-8/92

Physical Scientist
National Institute of Standards and Technology

- Provided proficiency testing of radiation instruments to secondary laboratories for x-ray, Co-60, and Cs-137 calibrations
- Assisted in the setup and maintenance of secondary laboratories. Assistance includes an on-site laboratory assessment, reviewing laboratory protocol, and providing assistance to the lab in deficiency areas.
- Served on the state CRCPD & Health Physics Society steering committee
- Provided liaison with NVLAP personnel & NIST technical groups on gamma & x-ray calibrations
- Performed measurements such as half-value layer, scatter, beam alignment, and ion chamber recombination for characterization of the reference field and instrument
- Performed quality control on electrical calibrations on equipment used in the radiation calibration process
- Used computer for quality control, writing or developing of reports, radiation & instrument calibration, & laboratory characterization
- Participated in chalks talks
- Worked with guest scientists or colleagues on special projects in area of expertise
- Served as group property office
- Provided primary standard calibration services for radiation instruments using NIST x-ray sets, and Co-50 & Cs-137 calibration ranges
- Assisted in the calibration of electrical instrumentation and equipment used for the calibration of radiation instruments
- Performed quality control measures to insure that the radiation instrument calibrations were accurate.

Talks

"NIST Involvement With QA/QC Procedures for Secondary Level Calibration Laboratories," M. Walker, National Institute of Standards and Technology, Gaithersburg; H. T. Heaton, II and F. Cerra, Food and Drug Administration, Center for Devices and Radiological Health, Rockville, MD. Health Physics Society Annual Meeting. July 1991.

Amplified Curriculum Vitae

Mary D. Walker

Experience (continued)

9/84-3/89

Radiological Physicist
The Institute for Radiological Image Sciences

- Performed Computerized Tomography (CT) dosimetry
- Evaluated CT scanners for acceptance testing
- Performed data collection and analysis for research projects and computer data input

Papers

- "Field Trial of an Automated Quality Assurance Program for CT Scanners." D. Goodenough, Ph.D., K. Weaver, M.S., F. Atkins, Ph.D., M. Walker, B.S., R.T. 1987 RSNA, Chicago, IL, Dec. 1987. Presented by D. Goodenough. "Caveats on Modulation Transfer Function for CT Scanners." D. Goodenough, Ph.D., K. Weaver, M.S., F. Atkins, Ph.D., M. Walker, B.S., R.T. 1987 RSNA, Chicago, IL, Dec. 1987. Presented by D. Goodenough.
- "Practical and Theoretical Aspects of CTDI." K. Weaver, M.S., D. Goodenough, Ph.D., F. Atkins, Ph.D., C. Stockham, Ph.D., M. Walker, B.S., R.T. 1987 RSNA, Chicago, IL, Nov. 1987. Presented by K. Weaver. "CT Quality Assurance: An Automated Approach With a Personal Computer." D. Goodenough, Ph.D., K. Weaver, M.S., F. Atkins, Ph.D., M. Walker, B.S., R.T. 1986 RSNA, Chicago, IL Nov. 1986. Principal Exhibitor, D. Goodenough. "An automated Approach to CT Quality Assurance." K. Weaver, M.S., D. Goodenough, Ph.D., F. Atkins, Ph.D., C. Stockham, Ph.D., M. Siddell, B.S., R.T., 1985 RSNA, Chicago, IL Nov. 1985. Presented by K. Weaver. "Practical Experience With CT Dose Index: Caveats for Dose Measurements in CT." D. Goodenough, Ph.D., K. Weaver, M.S., F. Atkins, Ph.D., M. Walker, B.S., R.T. 1986 RSNA, Chicago, IL, Dec. 1986. Presented by D. Goodenough.
- "An automated Approach to CT Quality Assurance." K. Weaver, M.S., D. Goodenough, Ph.D., F. Atkins, Ph.D., C. Stockham, Ph.D., M. Siddell, B.S., R.T., 1985 RSNA, Chicago, IL Nov. 1985. Presented by K. Weaver.

10/83-9/84

Radiologic Technologist
Washington Radiology

Performed x rays in area of fluoroscopy, IVPs, & routine exams

6/81-9/83

Radiation Technologist
George Washington University

- Assisted in research projects
- Evaluated personnel badge exposures for diagnostic x ray
- Performed compliance testing of x-ray equipment
- Performed x rays in area of fluoroscopy, IVPs, portables, and routine exams

Recent Classes and Training

Training, Classes, and Seminars

FY 2010

- Attended the Annual National Council for Radiation Protection Measurements Meeting
- Computed Tomography Imaging (28 hour/7 week course @Montgomery College)
- Radiation Safety Officer Training (40 hour/1 week course @ Dade Moeller Radiation Safety Academy)
- Contracting Basics for COTRs (24 hour/3day course @ USDA Graduate School)
- Microsoft Access (16 hour/2 day course @Fred Pryor-Career Track)
- Negotiating with Confidence to Meet Agency Needs(2 hour Webinar-Mike Bevis)
- The ACR Dose Index Registry & Pediatric CT and Radiation: Lessons Learned.....Now It's time for the Exam (3 Hour Radiological Health Seminar @ CDRH Staff College Radiological Health Seminar)

**Los Alamos
NATIONAL LABORATORY**



ATRO # 2010:87

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

SOURCE OWNER:	FDA-CDRH	TELEPHONE:	301 796-2558
LICENSE:	MD	FAX:	301 796-9795
	No.: 19-07538-01		
CONTACT NAME:	Mary Walker		
ADDRESS:	10903 New Hampshire Avenue		
	WO66- Rm 4676		
	Silver Spring, MD 20993-0002		

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

LANS AUTHORIZATION:

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

ACKNOWLEDGEMENT OF RECEIPT BY DESIGNATED LANS SUPPORT SUBCONTRACTOR:

NSSI / Sources & Services, Inc.

OFFICIAL NAME/TITLE:	_____	_____
	NAME (Please Print or Type)	TITLE (Please Print or Type)
SIGNATURE:	_____	DATE: _____

FDA / CORH LEAK TEST RESULTS

PAGE: 1

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ID: SAMPLE SCREEN          24 MAY 2010 14:01
USER: 1                     COMMENT:
PRESET TIME : 4.00
DATA CALC : SL DPM H# : YES SAMPLE REPEATS: 1 PRINTER : STD
COUNT BLANK : NO IC# : NO REPLICATES : 1 RS232 : OFF
TWO PHASE : NO AGC : NO CYCLE REPEATS : 1 DISK : STD
SCINTILLATOR: LIQUID LUMEX: NO LOW SAMPLE REJ: 0
DATA BUFFER IS FULL. DATA WILL GO TO PRINTER ONLY.
RPM LIST : OFF
LOW LEVEL : NO HALF LIFE CORRECTION DATE: none
ISOTOPE 1: AUTO XERROR: 0.00 FACTOR: 1.000000 BKG. SUB: 28
  
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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	XERROR					
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 Pb
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 B0
17	**	4.00	51.9	5.75	101.03	11.39	50.47	0.25	78.97	OUTSIDE B0

**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 19, 2010

Cont. Ref.: ATRD 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	USAB	Sender	Recipient
Tracking ID	866862465405	DAVID WELLNER	CARLCE RINON
Service Type	FedEx Standard Overnight	RSO INC	MSSI SURCE AND SERVICES INC
Package Type	Customer Packaging	5204 MINNICK RD	5711 ETHERIDGE ST
Zone	06	LAUREL MD 20707-3138 US	HOUSTON TX 77087 US
Packages	1		
Rated Weight	11.0 lbs, 5.0 kgs	Transportation Charge	78.05
Delivered	Jul 20, 2010 13:49	Additional Handling Surcharge	7.50
Svc Area	A2	Inaccessible Dangerous Goods	35.00
Signed by	V.ALLEN	Courier Pickup Charge	4.00
FedEx Use	020016645/0001371/_	Fuel Surcharge	6.56
		Total Charge	USD 131.11

Picked up: Jul 19, 2010

Cont. Ref.: ATRD 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 10.0lbs, 12" x 12" x 13", divided by 194.

Automation	USAB	Sender	Recipient
Tracking ID	866862465416	DAVID WELLNER	CARLOS RINON
Service Type	FedEx Standard Overnight	RSO INC	MSSI SOURCE AND SERVICES INC
Package Type	Customer Packaging	5204 MINNICK RD	5711 ETHERIDGE ST
Zone	06	LAUREL MD 20707-3138 US	HOUSTON TX 77087 US
Packages	1		
Actual Weight	9.0 lbs, 4.1 kgs	Transportation Charge	73.90
Rated Weight	10.0 lbs, 4.5 kgs	Inaccessible Dangerous Goods	35.00
Delivered	Jul 20, 2010 13:49	Courier Pickup Charge	4.00
Svc Area	A2	Fuel Surcharge	6.23
Signed by	V.ALLEN	Additional Handling Surcharge	7.50
FedEx Use	020016645/0001371/_	Total Charge	USD 126.63

Picked up: Jul 19, 2010

Cont. Ref.: ATRD 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	USAB	Sender	Recipient
Tracking ID	866862465427	DAVID WELLNER	CARLOS RINNON
Service Type	FedEx Standard Overnight	RSO INC	NSSI SOURCE AND SERVICES INC
Package Type	Customer Packaging	5204 MINNICK RD	5711 ETHERIDGE ST
Zone	06	LAUREL MD 20707-3138 US	HOUSTON TX 77087 US
Packages	1		
Rated Weight	11.0 lbs, 5.0 kgs	Transportation Charge	78.05
Delivered	Jul 20, 2010 13:49	Inaccessible Dangerous Goods	35.00
Svc Area	A2	Fuel Surcharge	6.56
Signed by	V.ALLEN	Courier Pickup Charge	4.00
FedEx Use	020016645/0001371/_	Total Charge	USD 123.61

This is to acknowledge the receipt of your letter (application) dated

9/23/10, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (19-07539-01) 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** 573589.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.