

030-38188

| | | | |
|--|---|---|---------------------------|
| 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 |
| <h2 style="margin: 0;">APPLICATION FOR MATERIALS LICENSE</h2> | | 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, 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 | 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 |
| 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 | 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) <input checked="" type="checkbox"/> A. NEW LICENSE <input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER <input checked="" type="checkbox"/> C. RENEWAL OF LICENSE NUMBER <u>04-23311-02E</u> | 2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code) Robert A Gabardy 8020 Wing Span DR San Diego, CA 92119 |
| 3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED Reflex Industries, INC unit 105, 9530 Pathway ST Santee, CA 92071 | 4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION Robert A Gabardy TELEPHONE NUMBER <p style="text-align: center; font-weight: bold;">(619) 995-1922</p> |

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 31 AMOUNT ENCLOSED \$ 10,000.00 |

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

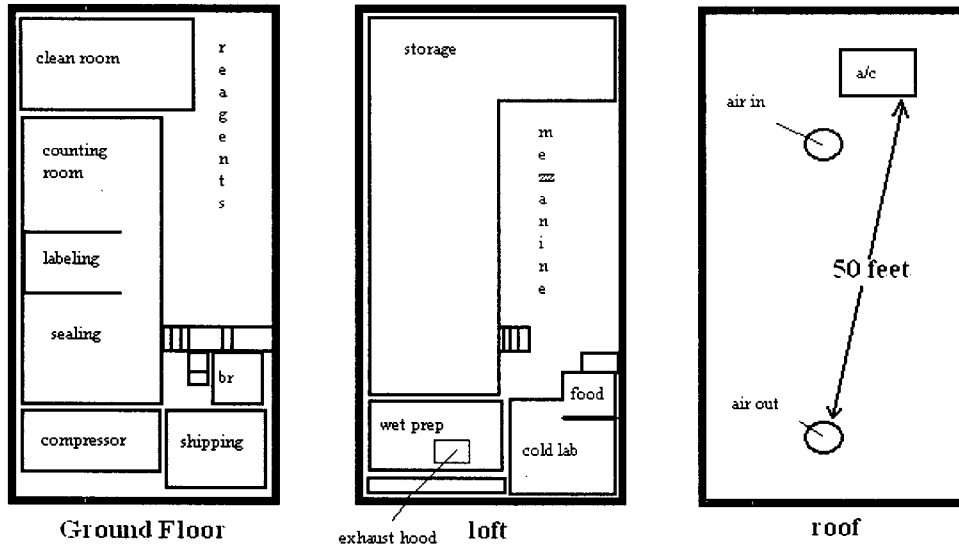
THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND 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 Robert A Gabardy, Radiation Safety Officer | SIGNATURE | DATE 11/06/2009 |
|--|---------------|---------------------------|

| FOR NRC USE ONLY | | | | | |
|------------------|---------|--------------|-----------------|--------------|----------|
| TYPE OF FEE | FEE LOG | FEE CATEGORY | AMOUNT RECEIVED | CHECK NUMBER | COMMENTS |
| S | | | | | |
| APPROVED BY | | | DATE | | |

West ^ Unit 105, 9530 Pathway ST, Santee, CA 92071



Reflex Industries, INC, license 3953-37 and 4410-37E

Surveys, wipe tests done in compliance with California radioactive materials possession license number **3953** issued to Reflex Industries, INC.

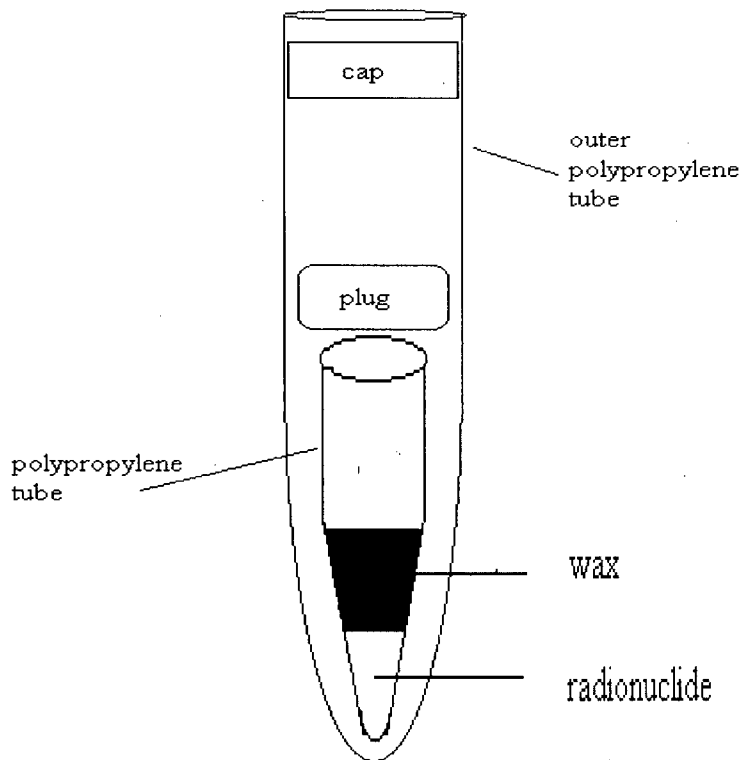
California distribution for exempt amounts of Co-57, number 4410-37E has been rendered moot by USNRC regulations dated 30NOV2008.

An inner tube, approximately 8mm in diameters is enclosed in an outer tube 12x75mm in diameter and length. The labels for I-125 or Co-57 tubes are presented in supplement 5.

The I-125 or Co-57 radionuclides are embedded in a solid, dry resin.

Reflex had marketed the Calibrators under the name "Quanti-Calibrators". MP Biomedicals, our principle distributor now, USNRC license number 34-23925-01E, markets the Calibrators under the name "Iso-Calibrators".

Quanti-Calibrator Assembly

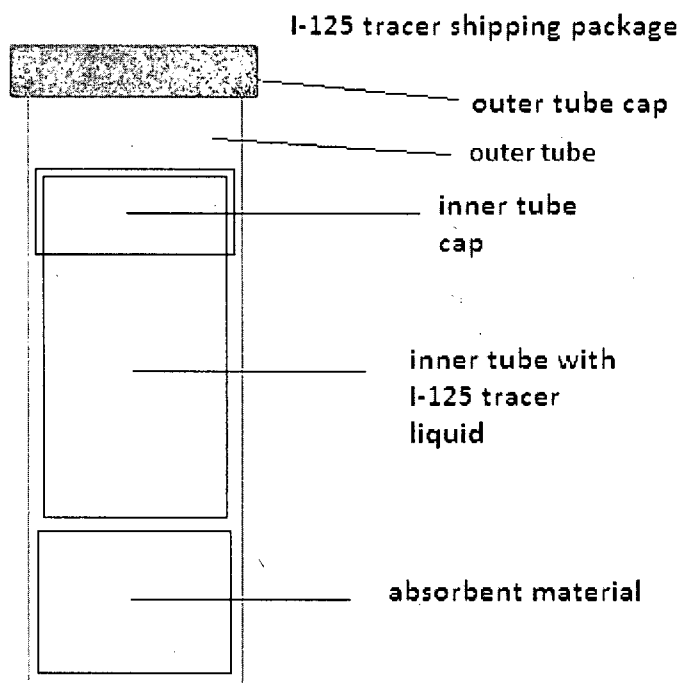


Supplement 4b to USNRC form 313 submitted by Reflex Industries, INC

I-125 tracer is contained within inner tube with a maximum volume of 40mL.

Absorbent in the outer vial is sufficient to adsorb and solidify at least 80mL of liquid.

Maximum amount of I-125 at time of shipment will be 10uCi.



Supplement 5a to USNRC form 313 submitted by Reflex Industries, INC

Representative I-125 tracer inner tube label (minimum content):

"

I-125 anti-human-IgE (or some other I-125 labeled tracer)

Cat: **I125HIGE** Lot: **IHIGE1001a** expiry: **01MAR2010**

Activity: **10uC** on **01JAN2010** in **40mL** aqueous buffer

"

Representative I-125 tracer outer tube label (minimum content):

"

less than **10uCI-125** anytime

reflexindustriesinc.com

"

I-125 and Co-57 solid reference source representative labels:

580091

Reflex Industries, INC
reflexindustriesinc.com

Radioactive Material
I-125 Quanti-Calibrator

less than 0.4uCi-125 anytime

577840

MP Biomedicals
mpbio.com

Radioactive Material
I-125 ISO-Calibrator

less than 0.4uCi-125
anytime

703177

QuantiCalibrator

mfg by Reflex Industries, INC
Santee, CA 92071 800.525-8712

less than 0.4uCi
Co-57

www.iemdiagnostika.com

738792

Iso-Calibrator

MP BIOMEDICALS
formerly ICN Biomedicals
800.888-7008 949.260-1032
diagtech@mpbio.com

less than 0.4uCi
Co-57

Sup 5b 1/12

ISO-CALIBRATORS™

GAMMALOG™

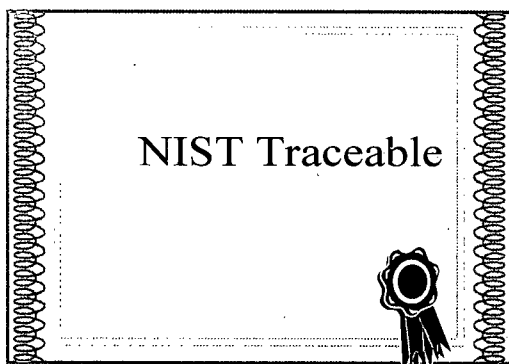
Certificate of Calibration

MP Biomedicals, LLC

Diagnostics Division

29525 Fountain Parkway

Solon, OH 44139



toll free 800.854-0530

fax 800.334-6999

custserv@mpbio.com

reference order number **423673**



| | |
|----------------|------------------|
| catalog | 07-400125 |
| isotope | <i>I-125</i> |
| halflife(days) | 59.46 |
| lot | DEC09BRO |
| set of | 25 |
| set number | 577812 |
| start DPM | 300,314 |
| begin on | 09Nov2009 |
| expiry | 23May2010 |
| rad correction | 100.4% |

Seq 5b

2

Iso-Calibrator™ Reference Sources

| | |
|--------------|--|
| NAME | Iso-Calibrators™, I-125 or Co-57 |
| INTENDED USE | Iso-Calibrators™ are solid reference sources for gamma counter calibration and daily validation of performance. Available as matched sets to simultaneously determine detector balancing in multi-well gamma counters or as single sources, to track single detector performance with traceability to NIST standards. |
| SUMMARY | Iso-Calibrators™ have been designed to approximate the most commonly used radioassay counting configuration, the 12X75mm convex tube. The tube is polypropylene to avoid breakage and the dried point source is sealed in the tube. I-125 is trapped in a cationic resin for long-term stability. Co-57 is first complexed with EDTA and then trapped in the same resin. |
| PRINCIPLE | <p>Only the same isotope used in a radioassay can be used in reference sources if a true estimate of gamma counter performance is to be determined. For example, if I-129 is used to monitor gamma counter performance spectrum drift of over 40% would have to occur for I-129 to be affected. I-125 would lose almost half of its counts. The result, a false sense of security while assay results degrade.</p> <p>To check for long term gamma counter stability, I-125 and Co-57 efficiency can be tracked using the GammaLog. Both I-125 and Co-57 Iso-Calibrators™ will decrease in activity each day. The GammaLog follows this decay and allows the counting efficiency to be determined independent of isotope decay.</p> <p>Mock sources of I-129 and Am-241 present an altogether different problem. Am-241 used in such sources has an energy peak that extends as low as 6keV. Most gamma counters have poor resolution at this level and the effect on counting is unpredictable. For multi-well gamma counters, the low energy peak of Am-241 may falsely indicate the need for an expensive service call.</p> |

Sup 5b

3

RADIOACTIVE MATERIAL - NOT FOR HUMAN USE

Introduction into Foods, Beverages, Cosmetics, Drugs or Medicinals or into products manufactured for commercial distribution is prohibited.

Exempt quantities should not be combined.

PRECAUTIONS RELATING TO THE HANDLING, USE, STORAGE AND DISPOSAL OF THIS RADIOACTIVE MATERIAL

Iso-Calibrators™ are radioactive materials. As such, you should exercise certain precautions in order to minimize your exposure to radioactivity.

We suggest that you

- (1) always wear gloves when handling radioactive materials and wash your hands afterwards
- (2) limit the time you handle radioactive material in order to minimize exposure
- (3) secure any radioactive materials from unauthorized use or removal from the area in which they are intended to be used
- (4) be certain radioactive materials are clearly marked and used only in areas designated for radioactive material use and storage
- (5) when expired and prior to disposal in ordinary waste, you must remove any Iso-Calibrator™ label indicating the presence of radioactive materials

Sup 5b 4

Reflex Industries, INC
 9530 Pathway ST, unit 105
 Santee, CA 92071
 vox: 619.562-1821
 fax: 619.562-9768

California radioactive materials possession license number **3950-37**
 Robert A Gabardy, RSO
 emergency contact number: **619.995-1922**

shipped to:

MP Biomedicals, LLC
 29525 Fountain PRKWY
 Solon, OH 44139

Ohio radioactive materials possession license number

| purchase order | shipped via | item description | on cal μ C/tube | caldate | shipdate | now | | total activity (μ C) |
|----------------|--------------|------------------|---------------------|-----------|-----------|--------------|---------------------|---------------------------|
| | | | | | | μ C/tube | tubes | |
| | FEDEX | | | | | | | |
| | PI | | | | | | | |
| item | 1 | I-125 DEC09BRO | 0.100 | 05Dec2009 | 06Nov2009 | 0.140 | 40 | 5.61 |
| | | | | | | | total I-125 shipped | 5.61 |
| item | 1 | Co-57 BLU090906 | 0.100 | 06Sep2009 | 06Oct2009 | 0.093 | 1 | 0.09 |
| | | | | | | | total Co-57 shipped | 0.09 |
| | | | | | ship date | | | 06Nov2009 |

per DOT This is a specific licensee-to- licensee transfer of radioactive material

Robert A Gabardy, RSO

Sup 5b
5
PROPOSED

QUANTI-CALIBRATORS™

Daily LOG™

Certificate of Calibration

company name here

QC

street

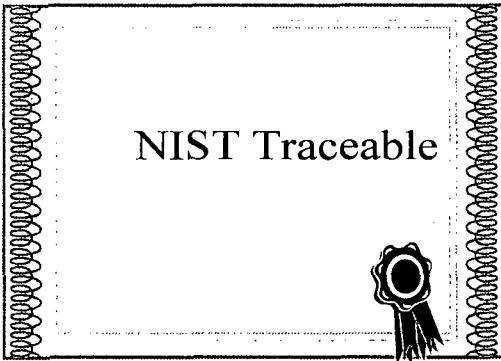
city, state, zip

attn:

whomever

purchase order

whatever



www.IEMdiagnostika.com

Reflex Industries, INC

9530 Pathway ST, unit 105

Santee, CA

92071

800.542-1123

619.562-1821

| | |
|----------------|------------------|
| catalog | QCI-501 |
| isotope | <i>I-125</i> |
| halflife(days) | 59.46 |
| lot | DEC09BRO |
| set of | 1 |
| set number | 505250 |
| start DPM | 353,287 |
| begin on | 26Oct2009 |
| expiry | 25Apr2010 |
| rad correction | 100.0% |
| actual DPM | 353,287 |

Sup 5b
PROPOSED

Quanti-Calibrator™ Reference Sources

NAME Quanti-Calibrators™, I-125 or Co-57

INTENDED USE Quanti-Calibrators™ are solid reference sources for gamma counter calibration and daily validation of performance. Available as matched sets to simultaneously determine detector balancing in multi-well gamma counters or as single sources, to track single detector performance with traceability to NIST standards.

SUMMARY Quanti-Calibrators™ have been designed to approximate the most commonly used radioassay counting configuration, the 12X75mm convex tube. The tube is polypropylene to avoid breakage and the dried point source is sealed in the tube. I-125 is trapped in a cationic resin for long-term stability. Co-57 is first complexed with EDTA and then trapped in the same resin.

PRINCIPLE Only the same isotope used in a radioassay can be used in reference sources if a true estimate of gamma counter performance is to be determined. For example, if I-129 is used to monitor gamma counter performance spectrum drift of over 40% would have to occur for I-129 to be affected. I-125 would lose almost half of its counts. The result, a false sense of security while assay results degrade.

To check for long term gamma counter stability, I-125 and Co-57 efficiency can be tracked using the Daily Log. Both I-125 and Co-57 Quanti-Calibrators™ will decrease in activity each day. The Log follows this decay and allows the counting efficiency to be determined independent of isotope decay.

Mock sources of I-129 and Am-241 present an altogether different problem. Am-241 used in such sources has an energy peak that extends as low as 6keV. Most gamma counters have poor resolution at this level and the effect on counting is unpredictable. For multi-well gamma counters, the low energy peak of Am-241 may falsely indicate the need for an expensive service call.

Sy 5 b 7
PROPOSED

RADIOACTIVE MATERIAL - NOT FOR HUMAN USE

Introduction into Foods, Beverages, Cosmetics, Drugs or Medicinals or into products manufactured for commercial distribution is prohibited.

Exempt quantities should not be combined.

PRECAUTIONS RELATING TO THE HANDLING, USE, STORAGE AND DISPOSAL OF THIS RADIOACTIVE MATERIAL

Multi-Calibrators™ are radioactive materials. As such, you should exercise certain precautions in order to minimize your exposure to radioactivity.

We suggest that you

- (1) always wear gloves when handling radioactive materials and wash your hands afterwards
- (2) limit the time you handle radioactive material in order to minimize exposure
- (3) secure any radioactive materials from unauthorized use or removal from the area in which they are intended to be used
- (4) be certain radioactive materials are clearly marked and used only in areas designated for radioactive material use and storage
- (5) when expired and prior to disposal in ordinary waste, you must remove any Quanti-Calibrator™ label indicating the presence of radioactive materials

Sup SB
PROPOSED 8

from:

Reflex Industries, INC
9530 Pathway ST, unit 105
Santee, CA 92071

Outer Shipping List

ship to:

company name here
QC
street
city, state, zip

attn: whomever

PO: **whatever**

| | | | | |
|-----------|----------------------------------|----------|----------------|---------------|
| ship date | Tuesday, October 27, 2009 | ship via | ups | |
| item | 1 Multi-Calibrators, I-125 | set of | catalog number | set |
| | | 1 | QCI-501 | 505250 |

DEC09BRO

calibrated on:

26Oct2009

activity at
calibration

0.2 *u*C I-125

expiry

25Apr2010

This package conforms to the conditions and limitations specified in the 49 CFR 173.421 for excepted radioactive materials, limited quantity, UN2910. Less than 0.5 mR/hr activity at the surface of the package at any time

Sup 5b 9

Rad Shipping List

from:

PROPOSED

Reflex Industries, INC
9530 Pathway ST, unit 105
Santee, CA 92071

INNER

ship to:

company name here

QC

street

city, state, zip

attn:

whomever

PO:

whatever

| | | | |
|-----------|-------------------|----------|-----|
| ship date | WED, APR 22, 2009 | ship via | UPS |
|-----------|-------------------|----------|-----|

| item | set of | catalog number | set |
|----------------------------|--------|----------------|--------|
| 1 Multi-Calibrators, I-125 | 1 | QCI-501 | 505250 |

CAUTION



Radioactive Materials

Contains less than 10 μC I-125 as a solid reference source

DEC09BRO

calibrated on:

26Oct2009

activity at
calibration

0.2 μC I-125

expiry

25Apr2010

This package conforms to the conditions and limitations specified in the 49 CFR 173.421 for excepted radioactive materials, limited quantity, UN2910. Less than 0.5 mR/hr activity at the surface of the package at any time

Sup 5b 10
PROPOSED

QUANTI-CALIBRATORS™

Daily LOG™

Certificate of Calibration

company name here

QC

street

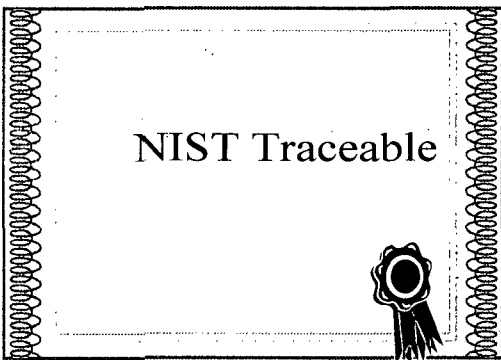
city, state, zip

attn:

whomever

purchase order

whatever



www.IEMdiagnostika.com

Reflex Industries, INC

9530 Pathway ST, unit 105

Santee, CA

800.542-1123

92071

619.562-1821

| | |
|----------------|------------------|
| catalog | QCC-C01 |
| isotope | <i>Co-57</i> |
| halflife(days) | 271.70 |
| lot | BLU091201 |
| set of | 1 |
| set number | 703170 |
| start DPM | 240,813 |
| begin on | 26Oct2009 |
| expiry | 28Nov2010 |
| rad correction | 100.0% |
| actual DPM | 240,813 |

from:

Sup 5b T1
PROPOSED
Reflex Industries, INC
9530 Pathway ST, unit 105
Santee, CA 92071

Outer Shipping List

ship to:

company name here
QC
street
city, state, zip

attn:
PO:

whomever
whatever

| | | | | |
|-----------|----------------------------------|----------|----------------|---------------|
| ship date | Tuesday, October 27, 2009 | ship via | UPS | |
| item | 1 Multi-Calibrators, Co-57 | set of | catalog number | set |
| | | 1 | QCC-C01 | 703170 |

BLU091201
calibrated on: 26Oct2009
activity at calibration 0.1 *u*C Co-57
expiry 28Nov2010

This package conforms to the conditions and limitations specified in the 49 CFR 173.421 for excepted radioactive materials, limited quantity, UN2910. Less than 0.5 mR/hr activity at the surface of the package at any time

Sup 5b 12/12
PROPOSED

Rad Shipping List

from:

Reflex Industries, INC
9530 Pathway ST, unit 105
Santee, CA 92071

inner

ship to:

company name here
QC
street
city, state, zip

attn: whomever

PO: **whatever**

| | | | | |
|-----------|----------------------------------|----------|-----|-----------------------------------|
| ship date | Tuesday, October 27, 2009 | ship via | UPS | |
| item | 1 Multi-Calibrators, Co-57 | set of | 1 | catalog number QCC-C01 set 703170 |

CAUTION



Radioactive Materials

Contains less than 10uCi I-125 as a solid reference source

BLU091201

calibrated on:

26Oct2009

activity at
calibration

0.1 uCi Co-57
expiry

28Nov2010

This package conforms to the conditions and limitations specified in the 49 CFR 173.421 for excepted radioactive materials, limited quantity, UN2910. Less than 0.5 mR/hr activity at the surface of the package at any time

FAXED

Reflex Industries
9530 Pathway ST, unit 105
Santec, CA 92071
fax: 619.562-9768 voice: 619.562-1821

fax

| | | |
|-------|---|--|
| to: | James L Thompson US Nuclear regulatory commission, Region IV | fax: 817.860-8263 vox: 817.276-6538 |
| from: | Bob Gabardy | Thursday, August 22, 2002 |
| re: | license 04-23311-02E | |

Following up on your recent inspection of 04AUG2002, please find the amount of I-125 shipped in previous years:

| Calendar year | <i>uC</i> I125 shipped |
|---------------|------------------------|
| 2001 | 1,741 |
| 2000 | 2,136 |
| 1999 | 1,712 |
| 1998 | 2,191 |
| 1997 | 1,994 |
| 1996 | 2,165 |
| 1995 | 1,870 |
| 1994 | 1,738 |
| 1993 | 2,269 |

uC Co-57 shipped

How far back do I need to go?

Bob

Sup 6 will be done each calendar year

Diagnostics for a Developing World™

022786