DEPARTMENT OF THE ARMY
WALTER REED ARMY MEDICAL CENTER
6900 GEORGIA AVE NW
WASHINGTON DC 20307-5001

28 March 2005

REPLY TO
ATTENTION OF:
Health Physics

U.S. Nuclear Regulatory Commission
Region I
ATTN: Nuclear Materials Safety Branch (Mr. Jim Dwyer)
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Mr. Dwyer:

In response to our phone conversation earlier today, WRAMC hereby amends our 10 January 2005 license application as prescribed in the attachment to this letter.

WRAMC is currently operating under Amendment No. 78 to license No. 08-01738-02, which has been extended under timely renewal procedures.

Your point of contact for this Command is the undersigned, (202) 356-0060.

Sincerely,

John R. Mercier, Ph.D., PE, DABR
Lieutenant Colonel, Medical Service Corps
Chief, Health Physics

Enclosure

ATTACHMENT TO WRAMC's 28 March 2005 Letter to NRC

WRAMC hereby amends our 10 January 2005 license application as follows...

ITEM 5.D. Strontium-90 Sealed Sources.

a. Regarding the model number of the Tracerlab sources. Both model numbers, RA-1A and RA-2A, are correct. The sources are identical and both sources are stored in the same type box with the RA-1A designation. Vendor source data for the RA-1A and RA-2A are attached.

b. Delete the source by 3M, model 606C-CA. This was a typographical error in the application.

c. Add the source by Nuclear Enterprises, model 2503/3. Vendor source data for the 2503/3 is attached.

ITEM 5.N. Plutonium-239 and Americium-241 Sealed or Plated Sources. Add the following manufacturer and model number descriptions (vendor source data are attached):

Pu-239, North American Scientific (NAS), Model CAL2701
Pu-239, Isotope Products Laboratories (IPL), Model LB-239
Am-241, NAS, Model CAL2701
Am-241, IPL , Model LB-241
Am-241, New England Nuclear (NEN), Model NES-316
Am-241, International Chemical and Nuclear (ICN), Model R35B

ITEM 7.5 Human Use. Replace ITEM 7.5 with the following text:

For HUMAN USE (e.g., diagnosis, therapy and human studies), licensed material shall be used by or under the supervision of individuals designated by the Walter Reed Army Medical Center (WRAMC) Radiation Safety Committee (RSC). The training and experience of authorized users, authorized nuclear pharmacists, and authorized medical physicists will be evaluated using the criteria in 10 CFR 35. Upon approval recommendations of the Human Use Subcommittee of the RSC, the RSO may grant interim approvals for research protocols, authorizations and authorized users, with final approval by the RSC at the next routine RSC meeting. The Human Use Subcommittee is established by the RSC with the primary functions of reviewing and making approval recommendations for human research protocols, human use authorizations, and human use authorized users. The Human Use Subcommittee currently includes the following members: a nuclear medicine physician, a nuclear pharmacy representative, a radiation oncologist, a staff health physicist and a hematology physician. Changes to the structure or functions of the Subcommittee require RSC approval. However, the use of subject matter experts to advise or assist the Subcommittee does not require RSC approval.

ITEM 7.6 Human Use Emerging Technologies. Replace ITEM 7.6 with the following text:

For HUMAN USE EMERGING TECHNOLOGIES (e.g., diagnosis, therapy and human studies), licensed material shall be used by or under the supervision of individuals designated by the WRAMC RSC. The training and experience of authorized users will be evaluated using the criteria in 10 CFR 35 that most closely matches the new technology, as well as, complete vendor training specific to the new equipment and/or procedure. Also acceptable is equivalent training provided by a vendor-trained authorized user previously approved for the new technology. The RSO will not provide interim approvals for new technology users. Approval for authorized users by the RSC, with RSO concurrence, is required prior to implementation of the new technology. The RSC, with RSO concurrence, may provide interim approval of authorized users undergoing new technology training that takes place at WRAMC.

ITEM 7.7 Non-Human Use. Replace ITEM 7.7 with the following text:

For NON-HUMAN USE (e.g., research and development),, licensed material shall be used by or under the supervision of individuals designated by the WRAMC RSC. The training and experience of authorized users, authorized nuclear pharmacists, and authorized medical physicists will be evaluated using the criteria expressed in NUREG 1556, Volume 7, Section 8.7.2 (December 1999). Although not a rule, investigators who meet the following criteria will normally receive final approval: 1) bachelors degree, 2) at least two months of hands-on laboratory experience using equivalent types and amounts of radioactive material, and 3) completion of a one-day didactic radiation safety course or equivalent training. Upon approval recommendations of the Non-Human Use Subcommittee of the RSC, the RSO may grant interim approvals for research protocols, authorizations and authorized users, with final approval by the RSC at the next routine RSC meeting. The Non-Human Use Subcommittee is established by the RSC with the primary functions of reviewing and making approval recommendations for non-human research protocols, non-human use authorizations, and non-human use authorized users. The Non-Human Use Subcommittee currently includes one senior health physicist and two staff health physicists. Changes to the structure or functions of the Subcommittee require RSC approval. However, the use of subject matter experts to advise or assist the Subcommittee does not require RSC approval.

ITEM 7.9c The RSC Review Process. Replace ITEM 7.9c with the following text:

Once satisfied that the byproduct material will be properly controlled and that patient and worker safety are adequately addressed, the Human Use Subcommittee or Non-Human Use Subcommittee, as appropriate, will recommended whether or not the RSO should grant an interim approval.

Enclosures, as

90-Sr-002

Tracerlab KELEKET
PIONEERS IN X-RAY ISOTOPES, NUCLEONICS
Tracerlab inc.
TELETYPE: WALTHAM 195 TWinbrook 4-6600
1601 TRAPELO ROAD • WALTHAM 54, MASSACHUSETTS

CERTIFICATE

FOR

RA-1A MEDICAL APPLICATOR

Serial No. 83

Sold to: Walter Reed Hospital
Army Medical Center
Washington 12, D. C.

AEC License No. 9622

Content: Strontium-90

Leakage Test

This Medical Applicator exhibited no detectable leak of activity previous to shipment.

The method used to demonstrate the absence of leakage is described in Section VI-A of the Instruction Manual Pertaining to the Usage of the RA-1A Medical Applicator.

Dosage Rate

The surface dosage rate of RA-1A MEDICAL APPLICATOR, SERIAL NO. 83 ON 2/28/62 WAS 22.1 ROENTGEN-EQUIVALENT-BETAS PER SECOND, as measured by the method described in Section III-B of the Instruction Manual. With respect to absolute calibration, this dosage rate is to be constructed as tentative; it may be adjusted at a future date as a result of more absolute measurements which will develop upon forthcoming basic improvements in the calibration technique.

Signed John L Kimpt
Tracerlab, Inc.

90-52-03

Tracerlab
PIONEERS IN X-RAY ISOTOPES, NUCLEONICS

TELETYPE: WALTHAM 195 TWinbrook 4-6400
1601 TRAPELO ROAD • WALTHAM 54, MASSACHUSETTS

9-4

CERTIFICATE

FOR

RA-2A MEDICAL APPLICATOR

Serial No. 119

Sold to: Finance & Acctg. Officer
Walter Read Army Medical Center
Washington 12, D. C.

AEC license No. 20771

Content: Recalibrated RA-2A Medical Applicator owned by customer

Leakage Test

This Medical Applicator exhibited no detectable leak of activity previous to shipment.

The method used to demonstrate the absence of leakage is described in Section VI-A of the Instruction Manual Pertaining to the Usage of the RA -2A Medical Applicator.

Dosage Rate

The surface dosage rate of RA -2A MEDICAL APPLICATOR, SERIAL NO. 119

ON 11/21/61 WAS 61.5 ROENTGEN-EQUIVALENT-RETAS

PER SECOND, as measured by the method described in Section III-B of the Instruction Manual. With respect to absolute calibration, this dosage rate is to be construed as tentative; it may be adjusted at a future date as a result of more absolute measurements which will develop upon forthcoming basic improvements in the calibration technique.

Signed _____
Tracerlab, Inc.

90-51-11

NUCLEAR enterprises inc.

ASSOCIATE COMPANY: NUCLEAR ENTERPRISES (G.B.) EDINBURGH, SCOTLAND
935 TERMINAL WAY
SAN CARLOS, CALIFORNIA 94070
PHONE (415) 593-1455 CABLE: NUCENT

02300800

CUSTOMER'S ORDER NO. DADA1576-M-C948

SOLD TO
Walter Reed Army Med. Ctr.
Commercial Accounts Unit
P.O. Box M-338
Washington, D.C. 20012

SHIP TO
Walter Reed Army Med. Ctr.
Health Physics Officer
M/F 254-064-05(07)
Bldg. 133, Forest Glen Section
Silver Springs, MD 20810

DATE OF SHIPMENT 2/24/76 DATE ORDER RECEIVED 10/30/75 NO. PKGS. 1 SHIP VIA Navajo Freight ACCT 3511

Quan.	Cat. No.	Description	Size
1 ea	2503/3	Radiological Reference Source Serial No. 1587/10343/1 Licence No. [illegible]	
		Shipping Char	
		Complete Orde	
19866		F.O.B. San Carlos, California	

NOTICE OF SHIPMENT

TERMS NET 30 DAYS

NOTICE OF SHIPMENT

Auth 284 RMR 424 SS-239-Pu-002

CERTIFICATE OF CALIBRATION

MODEL CAL2701 ALPHA STANDARD

Radionuclide:	Pu-239	**Activity[1]:**	605.2 Bq (16.36 nCi)
Serial Number:	48262	**Reference Date:**	1200 PST January 1, 2004
Half Life[2]	$(2.411 \pm 0.003) \times 10^4$ years		

PRINCIPAL EMISSIONS[2]

Type	Energy (keV)	Intensity (%)
alpha	5104.7	10.6
alpha	5142.8	15.1
alpha	5155.5	73.2

SOURCE DESCRIPTION

Active Diameter:	33 mm	**Backing:**	stainless steel
Overall Diameter:	47 mm	**Cover:**	none
Thickness:	3.18 mm		

METHOD OF CALIBRATION

The source was calibrated by alpha spectroscopy against a standard traceable to the National Institute of Standards and Technology. This standard is indirectly (implicitly) traceable to the National Institute of Standards and Technology.

North American Scientific, Inc. actively participates in the Radioactivity Measurements Assurance Program conducted by the National Institute of Standards and Technology in cooperation with the Nuclear Energy Institute.

TOTAL UNCERTAINTY (99% Confidence Level)

Systematic uncertainty	3.00%
Random uncertainty	1.02%
Total uncertainty (quadratic sum)	± 3.17%

Seyed Miri
Calibration Laboratory

January 9, 2004
Date

REFERENCES

(1) Source 48262 contains the following radionuclidic impurities as of January 1, 2004 : 1.48% Am-241, 97.07% Pu-241 (beta emitter).
(2) Table of Radioactive Isotopes, 7th edition, 1986.

• LEAK TEST CERTIFICATION ON REVERSE •

North American Scientific, Inc. 7435 Greenbush Ave., North Hollywood, CA 91605 (818) 734-8600 Fax (818) 734-5200

~~239-Pu-001~~
~~Added to inventory~~
~~1/85~~

CERTIFICATE OF RADIOACTIVITY CALIBRATION

239-Pu-001 added 1/85

Isotope: Pu-239 Half-Life: 24110±100 y

Source No.: E-564

Was assayed as containing: 1.42 μCi

As of: 12-1-82 Dec.

METHOD OF CALIBRATION:

( ) The source was assayed on a 3" x 3" NaI (Tl) crystal in conjunction with a single-channel analyzer, using the MeV peak (a value of gamma rays per decay was used in the calculations), against standard No. , in the same geometrical arrangement.

( ) The source was assayed in a windowless internal proportional counter against standard No.

(✓) The source was assayed by alpha spectrometry on a surface barrier detector in conjunction with a single-channel analyzer, against Pu-239 standard No. 100107-1 in the same geometrical arrangement.

( ) The source was prepared from a weighed aliquot of a solution whose activity in uCi/gm was determined by the method indicated above.

ERROR CALACULATION:

a) Systematic errors (SE)
1. Accuracy of the standard: ± 5.1%
2.

b) Randon errors (RE)
1. Precision of source count, e_1:
2. Precision of standard count, e_2:
3. Error due to background, e_3:

c) Total Error
TE=SE + RE = ± 6.8%

$RE = \sqrt{+ e_1^2 + e_2^2 + e_3^2} = \pm 1.7\%$

IPL participates in a NBS measurement assurance program to establish and maintain implicit traceability for a number of nuclides, based on the blind assay (and later NBS certification) of Standard Reference Materials.

NOTES

(✓) The error given is calculated at the 99 % confidence level.

( ) This calibration is directly/indirectly based on NBS Standard Reference Material No.

D Henkel

Carlos A. Henkel
Quality Assurance

ISOTOPE PRODUCTS LABORATORIES
1800 No. Keystone St., Burbank, California 91504

ISOTOPE PRODUCTS LABORATORIES 1800 NO KEYSTONE ST., BURBANK, CALIFORNIA 91504
(213) 843-7000

DATA SHEET

CUSTOMER: Walter Reed Army Medical Center P.O.# DADA15-82-M-E747 DATE: 2-23-83

CATALOG # LB-239 (Special) QUANTITY: 1

CAPSULE TYPE: LB (Configured as gamma source)

NATURE OF ACTIVE DEPOSIT: Electrodeposited and diffusion bonded plutoniumoxide

ACTIVE DIAMETER: 1 3/4" (44mm)

BACKING: 0.005" Ni foil

COVER: 0.001" Al window and 100-200 µg/cm² Gold

ISOTOPE	SOURCE #	ACTIVITY	CALIB. DATE	UNCERTAINTY
Pu-239	E-564	1.42 µCi	12-1-82	± 6.8 %

REMARKS: Pu content: Pu-239 : 99.12 %
Pu-240 : 0.875 %
Pu-241 : 0.014 %
Am content: Am-241: 0.0127 % (by 60 KEV assay)
Leak test and calibration certificate enclosed

Auth 221 RMR 926
SS-241-Am-19

CERTIFICATE OF CALIBRATION

MODEL CAL2701 ALPHA STANDARD

Radionuclide:	Am-241	**Activity:**	648.7 Bq (17.53 nCi)
Serial Number:	48261	**Reference Date:**	1200 PST January 1, 2004
Half Life[1]:	432.7 ± 0.5 years		

PRINCIPAL EMISSIONS[1]

Type	Energy (keV)	Intensity (%)
alpha	5443.01	12.8
alpha	5485.70	85.2

SOURCE DESCRIPTION

Active Diameter:	33 mm	**Backing:**	stainless steel
Overall Diameter:	47 mm	**Cover:**	none
Thickness:	3.18 mm		

METHOD OF CALIBRATION

The source was calibrated by an alpha spectrometer against a standard traceable to the National Institute of Standards and Technology. This standard is indirectly (implicitly) traceable to the National Institute of Standards and Technology.

North American Scientific, Inc. actively participates in the Radioactivity Measurements Assurance Program conducted by the National Institute of Standards and Technology in cooperation with the Nuclear Energy Institute.

TOTAL UNCERTAINTY (99% Confidence Level)

Systematic uncertainty	3.00%
Random uncertainty	1.12%
Total uncertainty (quadratic sum)	± 3.20%

Seyed Miri
Calibration Laboratory

January 9, 2004
Date

REFERENCES

(1) Table of Radioactive Isotopes, 7th edition, 1986.

• LEAK TEST CERTIFICATION ON REVERSE •

North American Scientific, Inc. 7435 Greenbush Ave., North Hollywood, CA 91605 (818) 734-8600 Fax (818) 734-5200

241-Am-014X

Added to inventory 1/85

CERTIFICATE OF RADIOACTIVITY CALIBRATION

Isotope: Am-241 Half-Life: 432.2 ± 0.5y

Source No.: E-563

Was assayed as containing: 0.141 μCi (3.13×10^5 dpm)

As of: 8-1-82

METHOD OF CALIBRATION:

( ) The source was assayed on a 3" x 3" NaI (Tl) crystal in conjunction with a single-channel analyzer, using the MeV peak (a value of gamma rays per decay was used in the calculations), against standard No. , in the same geometrical arrangement.

(✓) The source was assayed in a windowless internal proportional counter against standard No. 4904 NF-50 (Am-241)

( ) The source was assayed by alpha spectrometry on a surface barrier detector in conjunction with a single-channel analyzer, against standard No. in the same geometrical arrangement.

( ) The source was prepared from a weighed aliquot of a solution whose activity in uCi/gm was determined by the method indicated above.

ERROR CALACULATION:

a) Systematic errors (SE)
1. Accuracy of the standard: ± 1.1%
2.

b) Randon errors (RE)
1. Precision of source count, e_1:
2. Precision of standard count, e_2:
3. Error due to background, e_3:

c) Total Error
TE=SE + RE = ± 3.03%

$RE = \sqrt{+ e_1^2 + e_2^2 + e_3^2} = \pm 1.93\%$

IPL participates in a NBS measurement assurance program to establish and maintain implicit traceability for a number of nuclides, based on the blind assay (and later NBS certification) of Standard Reference Materials.

NOTES

(✓) The error given is calculated at the 99 % confidence level.

( ) This calibration is directly/indirectly based on NBS Standard Reference Material No.

Carlos A. Henkel
Quality Assurance

ISOTOPE PRODUCTS LABORATORIES
1800 No. Keystone St., Burbank, California 91504

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(213) 843-7000

DATA SHEET

CUSTOMER: Walter Reed Army Med Center P.O.# DADA15-82-M-E810 DATE: 8-13-82

CATALOG # LB-241 QUANTITY: 1

CAPSULE TYPE: LB

NATURE OF ACTIVE DEPOSIT: Electroplated and diffusion bonded Am metal

ACTIVE DIAMETER: 1 3/4" (44 mm)

BACKING: 0.005" Ni disk

COVER: 100-200 $\mu g/cm^2$ Gold

ISOTOPE	SOURCE #	ACTIVITY	CALIB. DATE	UNCERTAINTY
Am-241	E-563	0.141 μCi (3.13×10^5 dpm)	8-1-82	±3.03 %

REMARKS: Leak test and calibration certificate enclosed.

241-Am-017

Added to inventory 1/85

CERTIFICATE OF RADIOACTIVITY CALIBRATION

Americium-241 Reference Source

NES-316

Half-Life: 432.2±0.5 years
Lot Number: 316011480A

The activity of Americium-241 was found to be 2.27×10^5 alpha particles per minute expressed as the 2π alpha emission or 204 nanocuries expressed as the total activity content on January 14, 1980. → 452,880 dpm

DESCRIPTION OF THE SOURCE

The activity has been electrodeposited on a silver matrix and overplated with a 1.7 micron gold window. This was put into an aluminum mount having a diameter of 25 mm and a height of 3.2 mm.

The source was calibrated by absolute alpha counting in a 2π proportional counter using the National Bureau of Standards Americium-241 alpha disc standard number SRM 4904-E-77 as a reference check.

ERRORS

Random Errors

a. Precision of the NENC measurement	± 1.5%

Systematic Errors

a. Accuracy of the NBS Standard	± 1.3%

Overall Error

1.5	+	1.3	=	± 2.8%

The total activity content was calibrated assuming a backscatter error of not greater than 2.0%, raising the total error for activity content to ± 4.8%.

NEN® New England Nuclear
549 Albany Street, Boston, Massachusetts 02118
CALL TOLL-FREE: 800-225-1572 Telex 94-0996
(In Massachusetts and International: 617-482-9595)

Kevin McCarthy

International Chemical & Nuclear Corporation

Chemical and Radionsotopes Division

2727 Campus Drive
Irvine, California 92664
Tel: (714) 833-2500

241-Am-015

2½ x ½ rocks

GAMMA SPECTROMETER SOURCES

These sources are being offered in two types, thin disc and well type, applicable to all methods of NaI (TI) crystal gamma spectrometry type measurements. Each gamma emitting isotope is prepared as a sealed source in a solid plastic mounting. The sources are individually labeled with their isotopic designation, serial number, and contain approximately 100,000 gammas/min. in the photopeak on the date of calibration. Each set of Gamma Spectrometer Standards consists of the following isotopes:

Isotope	Half-Life	Energy of Gamma in Mev For Calibration Purposes	Abundance Gamma/disc
[redacted]	433 years	0.0595	0.353
^{57}Co	270 days	0.122 & 0.136	0.962
^{133}Ba	7.2 years	0.357	0.69
^{137}Cs	30 years	0.662	0.846
^{22}Na	2.60 years	1.28	1.0
^{54}Mn	312.7 days	0.834	1.0
^{65}Zn	243.8 days	1.115	0.506
^{60}Co	5.26 years	1.33	1.0

General Description of Sources

Disc Type (R-34)

The overall dimensions are 15/16" dia. x 0.055" thick. The isotope is laminated between two layers of plastic, each layer being about 0.025" thick. These discs are furnished with the standard ICN one inch planchet 5/16 inches in height. The isotope is distributed in an area of 1 sq. cm. This area of source mount is considered to be otpimum for ease of customer sample preparation on ICN counting equipment.

Rec'd 14 Feb 73

Well Type (R-35 and R-60)

The well type standards are supplied in two different sizes to fit all standard well detectors. Model R-35 rods are 1/2" O.D. by 2-11/32" long. Model R-60 rods are 5/8" O.D. by 5" long. The isotope is permanently fixed along the center of the longitudinal axis. The active area is approximately 1/8" from the bottom of the standard.

Calibration of R-34, R-35 and R-60

The photon emission rate of a standard source is obtained by measuring the counting rate of the reference gamma photopeak with a multi-channel analyzer, for which the photopeak counting efficiency was determined as a function of incident gamma ray energy. The sets of sources are then prepared and compared with the respective standard sources by gross gamma counting to determine the gamma photopeak emission rate.

The photopeak counting efficiency curve of incident gamma ray energy was obtained by counting the reference gamma photopeak under identical geometry conditions of several NBS standards; these results were checked by using ICN 4π techniques.

The overall error in determining the photon emission rate is ±5%.

The gamma spectrum obtained in the standardization is also used as a radiochemical purity check.

Sample Preparation for Gamma Pulse Height Analysis

In general, the method used to mount a sample for pulse height analysis to determine its gamma scintillation spectrum depends to some extent on what use is to be made of the data and what degree of precision must be achieved. For the widely used arrangement of a source located centrally beneath one face of a cylindrical sodium iodide crystal, it is advisable to prepare the source with as little backing material as is possible. However, there are often uses of the instrument, such as mere identification of a moneoenergetic primary gamma ray in which the common mounting techniques used for routine beta and gamma counting are entirely satisfactory. The latter sources may consist of powders or precipitates spread on filter paper backed by metallic planchets, aliquots, or slurries evaporated in shallow dishes, liquids contained in vials, unprocessed irradiated targets, or electrolytic deposits on metal disks.

In cases where two or more gamma rays are emitted by a sample and each of them must be resolved and quantitatively measured, it is usually desirable to minimize the amount of scattered radiation entering the crystal and suppress the Compton distribution as far as possible. To this end, the sample should be mounted on a ring supported on the periphery to provide an air backing.

If the spectrometer is to be calibrated in terms of counting efficiency as a function of incident photon energy, it is important to mount all reference standards and samples in nearly identical fashion.