



Doc#: 030-09023
Lic: # 20-00320-14E

PerkinElmer, Inc.
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August 9, 2012

Richard K. Struckmeyer
Office of Federal and State Materials and
Environmental Management Programs
Division of Materials Safety and State Agreements
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Docket # 030-09023
License # 20-00320-14E

Dear Mr. Struckmeyer,

This is an application for amendment to NRC Exempt Distribution License Number 20-0032-14E issued to PerkinElmer, Inc. (PKI). The purpose of this amendment request is to add additional products to be distributed under this exempt distribution license. In addition to the "radiolabeled and research compounds" already distributed under this license, we wish to add certain "check sources and calibration standards." Please find attached as Appendix 1 NRC Form 313, "Application for Materials License", with Items 1 through 6, 12 and 13 completed with detailed source and product information. Items 5 and 6 of Form 313 are attached as Appendix 2 and 3.

All of the requested additional products are currently handled by the PKI facility located in Downers Grove, Illinois operating under Illinois Agreement State Radioactive Materials License IL-01741-01 issued by the Illinois Emergency Management Agency, Division of Nuclear Safety and distributed under NRC Exempt Distribution License number 12-04933-06E. PKI requests to add these products to the portfolio of products distributed by our Boston, Massachusetts facility operating under Massachusetts Agreement State Radioactive Materials License Number 00-3200 issued by the Massachusetts Department of Public Health Radiation Control Program and distributed under NRC Exempt Distribution License number 20-00320-14E.

A copy of our current (Amendment 34) Massachusetts Radioactive Materials License (00-3200) is attached as Appendix 4.

The products to be distributed are encapsulated or check sources and calibration or counting standards in quantities not exceeding 10 CFR 30.71 Schedule B.

None of the sources require sealed source or device safety evaluations.

578081

Formal written procedures are maintained on file, for regulatory inspection, to ensure the quality of exempt products and their safe packaging, labeling and distribution.

The sources are used by our customers for quality control procedures on various radiation detection instrumentation products manufactured and sold by PerkinElmer, Inc. The radioactive material is to be used for its radioactive properties, and is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution. The isotopes are not contained in any food, beverage, cosmetic, drug, or other commodity (product) designed for ingestion or inhalation by, or application to, a human being nor incorporated into any device.

Each source provided to our customers has the required radioactive material label with all of the required information, including the isotope, activity, the radioactive caution symbol, and the words, "Radioactive Material." A printed certificate is provided to the customer with the radioactive material source and applicable safety information. Labels and product brochures with instructions are substantially similar to those in current use for exempt products distributed under our existing license. Example labels and brochures are provided as Appendix 5 of this application.

We plan to amend our Massachusetts possession license to allow us to establish a return policy for each of the sources.

Item 12 of NRC Form 313, "License Fees", has been left blank as it is our understanding pursuant to 10 CFR 170.12(b) that the amendment fee for review of this application for amendment to our existing license will be due upon notification by the Commission.

For business reasons we request that you review and approve this request at your earliest convenience.

Please call me at 617-950-9215 if you have questions concerning this application.

Thank you for your attention to this matter.

Sincerely,



Mark A. Kralian, CHP
Radiation Safety Officer

enclosures: NRC Form 313
Duplicate copy

c: Linda Lacy, Boston/Billerica Site Manager
Linda Meehan, Radiation Safety Committee Chairperson

Appendix 1
NRC Form 313

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 Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), 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
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

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
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

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 20-0032-14E
- ☐ C. RENEWAL OF LICENSE NUMBER _____

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

PerkinElmer, Inc.
549 Albany Street
Boston, MA 02118

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

120 and 130 East Dedham Street, Boston MA and
Buildings 250, 325 and 331 Treble Cove Road,
Billerica, MA

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Mark A. Kralian

BUSINESS TELEPHONE NUMBER
(617) 350-9215

BUSINESS CELLULAR TELEPHONE NUMBER
(774) 312-3686

BUSINESS EMAIL ADDRESS

mark.kralian@perkinelmer.com

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 I

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

Mark A. Kralian, CHP
Radiation Safety Officer

SIGNATURE



DATE

8/9/12

FOR NRC USE ONLY

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

Appendix 2

NRC Form 313, Item 5

Radioactive Material

NRC Form 313 Item 5. RADIOACTIVE MATERIAL

The types of products to be distributed fall into the following general categories:

- Liquid Scintillation Standards,
- Pico Calibrators,
- Spec-Chec Sources,
- TopCount Calibration/Normalization Plates,
- Instant Imager Calibration Sources, and
- MicroBeta and BetaPlate Calibration/Normalization Plates , and Victor/MultiLabel Plates.

The specific products, including catalogue numbers, radionuclides, physical forms, brief descriptions and the maximum activities of radioactive material that will be used in each source are listed in the tables that follow for each of the general categories named above.

Liquid Scintillation Counting (LSC) Standards are supplied in flame-sealed low potassium glass vials in conventional 20 mL vials and small 7 mL (Pico) vials (or 7 mL in the case of some Internal LSC Standards). The 1210 Series (H-3 and C-14) LSC Internal Standard Kits include 40 internal standard capsules containing either a tritium or C-14 -labeled organic compound in solid form. The LSC Standards are further divided into the following product categories:

- Internal LSC Standards
- Unquenched LSC Standards
- Quenched LSC Standards
- Extended Range Quenched LSC Standards
- Ultima Gold Quenched LSC Standards

Pico-Calibrators are matched sets of gamma point sources that are sealed with epoxy in 12 x 75 mm polypropylene tubes. The Pico-Calibrator sources are purchased from Canberra, Inc. in accordance with our product requirements.

Spec-Chec Reagent sources are used for testing PerkinElmer Sample Oxidizer performance (recovery, spillover and memory). The sample oxidizer is an instrument used for an automatic method of sample preparation for samples that are otherwise difficult to prepare for liquid scintillation counting.

TopCount, Instant Imager, MicroBeta, BetaPlate and Victor sources are products in plate reader formats that are used for calibration/normalization of their respective PerkinElmer radiometric detection plate readers. The radioactivity in these sources consists of C-14 labeled stearic acid and tritium labeled cholesterol in scintillation plastic discs based on polyvinyl toluene. The standard discs are glued with paraffin onto the bottom of the sample wells of the sample plate and sealed with a sealing tape.

LIQUID SCINTILLATION STANDARDS

PART #	ISOTOPE	FORM	DESCRIPTION	ACTIVITY (μ Ci)
1210-120	H-3	Solid	H-3 LSC Internal Standard Kit	3.67
1210-121	H-3	Solid	H-3 LSC Internal Standard Kit	3.75
1210-122	C-14	Solid	C-14 LSC Internal Standard Kit	1.85
1210-123	C-14	Solid	C-14 LSC Internal Standard Kit	1.84
1210-124	C-14	Solid	C-14 LSC Internal Standard Kit	0.46
6004051	H-3	Liquid	H-3 Toluene LSC Internal Standard	10
6004052	H-3	Liquid	H-3 Water LSC Internal Standard	10
6004062	C-14	Liquid	C-14 Toluene LSC Internal Standard	10
6008401	H-3	Liquid	H-3 Quenched Series, 5 mL	1.40
6008402	C-14	Liquid	C-14 Quenched Series, 5 mL	0.70
6008400	H-3/C-14	Liquid	Set of Unquenched Stds., 5 mL 6008411, 6008412 & 6008413	0.14(H-3), 0.07 (C-14)
6008412	H-3	Liquid	H-3 Unquenched Std., 5 mL	0.14
6008413	C-14	Liquid	C-14 Unquenched Std., 5 mL	0.07
6008501	H-3	Liquid	H-3 Quenched Series, 15 mL	1.40
6008502	C-14	Liquid	C-14 Quenched Series, 15 mL	0.70
6008500	H-3/C-14	Liquid	Set of Unquenched Stds., 15 mL 6008511, 6008512 & 6008513	0.014 (H-3), 0.07 (C-14)
6008512	H-3	Liquid	Unquenched H-3 Std., 15 mL	0.14
6008513	C-14	Liquid	Unquenched C-14 Std., 15 mL	0.07
6018551	H-3	Liquid	H-3 Ext. Range Quenched Std., 5 mL	1.40
6018552	C-14	Liquid	C-14 Ext. Range Quenched Std., 5 mL	0.70
6018594	H-3	Liquid	H-3 Ext. Range Quenched Std., 15 mL	1.40
6018595	C-14	Liquid	C-14 Ext. Range Quenched Std., 15 mL	0.70
6018911	H-3	Liquid	H-3 Unquenched Low Level Std., 10 mL	0.04
6018912	C-14	Liquid	C-14 Unquenched Low Level Std., 10 mL	0.02
6018914	H-3/C-14	Liquid	Set of Unquenched Low Level Stds., 10 mL 6018911, 6018912 & 6018913	0.04 (H-3), 0.02 (C-14)
6018917	H-3	Liquid	H-3 Low Level Quenched Series, 15 mL	0.14
6018918	C-14	Liquid	C-14 Low Level Quenched Series, 15 mL	0.10
6007600	H-3	Liquid	H-3 Ultima Gold Quenched Series, 15 mL	1.40
6007601	C-14	Liquid	C-14 Ultima Gold Quenched Series, 15 mL	0.70
6007603	H-3	Liquid	H-3 Ultima Gold Quenched Series, 5 mL	1.40
6007604	C-14	Liquid	C-14 Ultima Gold Quenched Series, 5 mL	0.70
6010704	H-3	Liquid	H-3 Ultima Gold Low Level Quenched Std., 15 mL	0.40
6010705	C-14	Liquid	C-14 Ultima Gold Low Level Quenched Std., 15 mL	0.20

PICO-CALIBRATORS

PART #	ISOTOPE	FORM	DESCRIPTION	ACTIVITY (μ Ci)
5080125	I-125	Solid	I-125 PICO Calibrator (Set/1)	0.091
5080225	I-125	Solid	I-125 PICO Calibrator (Set/2)	0.182
5080325	I-125	Solid	I-125 PICO Calibrator (Set/3)	0.272
5080425	I-125	Solid	I-125 PICO Calibrator (Set/4)	0.364
5080525	I-125	Solid	I-125 PICO Calibrator (Set/5)	0.455
5080625	I-125	Solid	I-125 PICO Calibrator (Set/6)	0.546
5081025	I-125	Solid	I-125 PICO Calibrator (Set/10)	0.910
5081225	I-125	Solid	I-125 PICO Calibrator (Set/12)	1.092
5081525	I-125	Solid	I-125 PICO Calibrator (Set/15)	1.365
5081625	I-125	Solid	I-125 PICO Calibrator (Set/16)	1.456
5082025	I-125	Solid	I-125 PICO Calibrator (Set/20)	1.820
5082425	I-125	Solid	I-125 PICO Calibrator (Set/24)	2.184
5082525	I-125	Solid	I-125 PICO Calibrator (Set/25)	2.275
5080129	I-129	Solid	I-129 PICO Calibrator (Set/1)	0.050
5080229	I-129	Solid	I-129 PICO Calibrator (Set/2)	0.100
5080329	I-129	Solid	I-129 PICO Calibrator (Set/3)	0.150
5080429	I-129	Solid	I-129 PICO Calibrator (Set/4)	0.200
5080529	I-129	Solid	I-129 PICO Calibrator (Set/5)	0.250
5080629	I-129	Solid	I-129 PICO Calibrator (Set/6)	0.300
5081029	I-129	Solid	I-129 PICO Calibrator (Set/10)	0.500
5081229	I-129	Solid	I-129 PICO Calibrator (Set/12)	0.600
5081529	I-129	Solid	I-129 PICO Calibrator (Set/15)	0.750
5081629	I-129	Solid	I-129 PICO Calibrator (Set/16)	0.800
5082029	I-129	Solid	I-129 PICO Calibrator (Set/20)	1.000
5082429	I-129	Solid	I-129 PICO Calibrator (Set/24)	1.200
5082529	I-129	Solid	I-129 PICO Calibrator (Set/25)	1.250
5080157	Co-57	Solid	Co-57 PICO Calibrator (Set/1)	0.091
5080257	Co-57	Solid	Co-57 PICO Calibrator (Set/2)	0.182
5080357	Co-57	Solid	Co-57 PICO Calibrator (Set/3)	0.273
5080457	Co-57	Solid	Co-57 PICO Calibrator (Set/4)	0.364
5080557	Co-57	Solid	Co-57 PICO Calibrator (Set/5)	0.455
5080657	Co-57	Solid	Co-57 PICO Calibrator (Set/6)	0.546
5081057	Co-57	Solid	Co-57 PICO Calibrator (Set/10)	0.910
5081257	Co-57	Solid	Co-57 PICO Calibrator (Set/12)	1.092
5081557	Co-57	Solid	Co-57 PICO Calibrator (Set/15)	1.365
5081657	Co-57	Solid	Co-57 PICO Calibrator (Set/16)	1.456
5082057	Co-57	Solid	Co-57 PICO Calibrator (Set/20)	1.820
5082457	Co-57	Solid	Co-57 PICO Calibrator (Set/24)	2.180
5082557	Co-57	Solid	Co-57 PICO Calibrator (Set/25)	2.280
5080151	Cr-51	Solid	Cr-51 PICO Calibrator (Set/1)	0.910
5080251	Cr-51	Solid	Cr-51 PICO Calibrator (Set/2)	1.820
5080351	Cr-51	Solid	Cr-51 PICO Calibrator (Set/3)	2.730

5080451	Cr-51	Solid	Cr-51 PICO Calibrator (Set/4)	3.640
5080551	Cr-51	Solid	Cr-51 PICO Calibrator (Set/5)	4.550
5080651	Cr-51	Solid	Cr-51 PICO Calibrator (Set/6)	5.460
5081051	Cr-51	Solid	Cr-51 PICO Calibrator (Set/10)	9.100
5081251	Cr-51	Solid	Cr-51 PICO Calibrator (Set/12)	10.920
5081551	Cr-51	Solid	Cr-51 PICO Calibrator (Set/15)	13.650
5081651	Cr-51	Solid	Cr-51 PICO Calibrator (Set/16)	14.560
5082051	Cr-51	Solid	Cr-51 PICO Calibrator (Set/20)	18.200
5082451	Cr-51	Solid	Cr-51 PICO Calibrator (Set/24)	21.840
5082551	Cr-51	Solid	Cr-51 PICO Calibrator (Set/25)	22.750
6018503	Cs-137	Solid	Cs-137 PICO Calibration Source (1280-141 equivalent)	0.250
6018504	I-129	Solid	I-129 Calibration Source (1270-102 equivalent)	0.050
6018505	I-129	Solid	I-129 Calibration Source	0.035
6018508	I-129	Solid	I-129 Calibration Tray	0.840
6018512	I-129	Solid	I-129 Matched Pair	0.100

SPEC-CHEC SOURCES

PART #	ISOTOPE	FORM	DESCRIPTION	VOLUME (mL)	ACTIVITY (μ Ci)
6002134	H-3	Liquid	H-3 High DPM Spec Chec	25	19.00
6002135	C-14	Liquid	C-14 High DPM Spec Chec	25	11.00
6002136	H-3	Liquid	H-3 Low DPM Spec Chec	25	0.70
6002137	C-14	Liquid	C-14 Low DPM Spec Chec	25	0.70
6002138	H-3/C-14	Liquid	High Activity Spec Chec Kit		
			6002134 - H-3 High DPM	25	19.00
			6002135 - C-14 High DPM	25	11.00
6002139	H-3/C-14	Liquid	Low Activity Spec Chec Kit		
			6002136 - H-3 Low DPM	25	0.70
			6002137 - C-14 Low DPM	25	0.70

TOPCOUNT CALIBRATION/NORMALIZATION PLATES or INSTANT IMAGER CALIBRATION SOURCES

PART #	ISOTOPE	FORM	DESCRIPTION	ACTIVITY (μ Ci)
7001044	H-3/C-14	Liquid	Cal/Norm Plate, 96-Well Plate	5.0 (H-3) 2.0 (C-14)
7001045	H-3	Liquid	Cal/Norm Plate, 24-Well Plate	5.0 (H-3)
7001068	C-14	Liquid	Calibration Plate Kit 9600	100.0 (C-14)
7001129	H-3	Liquid	SPC Norm Plate Kit	25.0 (H-3)
7001173	C-14	Liquid	Calibrator For Instant Imager	96.0 (C-14)

MICROBETA & BETAPLATE CALIBRATION/NORMALIZATION PLATES or VICTOR/MULTILABEL PLATES

PART #	ISOTOPE	FORM	DESCRIPTION	ACTIVITY (μCi)
1450-471	H-3/C-14	Liquid	Normalization Standard, MicroBeta2-BOM	0.27 (H-3) 0.16 (C-14)
1450-478	H-3/C-14	Liquid	SSO-Calibration Standard SVC 1450, MicroBeta2-Option	2.40 (H-3) 0.49 (C-14)
1450-477	H-3	Liquid	Normalization Standard, MicroBeta2-Option	4.80 (H-3)
1450-2020	H-3	Liquid	MicroBeta adjustment tool for 384 upgrade, MicroBeta2-Option	2.40 (H-3)
1205-432	H-3	Liquid	Normalization Standard H-3, BetaPlate-Option	0.80 (H-3)
1205-433	C-14	Liquid	Normalization Standard C-14, BetaPlate-Option	0.46 (C-14)
1205-438	H-3	Liquid	SSO-Calibration Cass H-3 SN 559; for engineers; BetaPlate Option	1.60 (H-3)
60000774	C-14	Liquid	2100 Luminescence Adjustment Plate	6.0 (C-14)
60000128	C-14	Liquid	Coordinate Adjustment Plate	7.50 (C-14)
1420-442	C-14	Liquid	Victor Test Plate	6.80 (C-14)
61003195	C-14	Liquid	Photometer Test Plate	4.50 (C-14)
1420-4430	C-14	Liquid	Victor Light Test Plate	6.80 (C-14)
2009-0030	C-14	Liquid	Multilabel Test Plate with Photometry & Luminescence	4.50 (C-14)
2009-0070	C-14	Liquid	Multilabel Test Plate with Photometry & Luminescence	4.50 (C-14)

Appendix 3

NRC Form 313, Item 6

Purpose(s) For Which Licensed Material Will Be Used

NRC Form 313 Item 6: Purpose(s) For Which Licensed Material Will Be Used

The products to be distributed under this license are used by our clients for quality control procedures on various radiation detection instrumentation products manufactured and sold by PerkinElmer, Inc.

Appendix 4

Massachusetts Radioactive Materials License Number 00-3200



THE COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH
RADIATION CONTROL PROGRAM
MATERIALS LICENSE

Pursuant to Massachusetts General Laws Chapter 111, Sections 3, 5M, 5N, 5O and 5P and Massachusetts Regulations for the Control of Radiation, Section 120.100, Licensing of Radioactive Material, and in reliance on statements and representation heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer radioactive materials 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 105 CMR 120.000. This license shall be deemed to contain the conditions specified in 105 CMR 120.000 and is subjected to all applicable rules, regulations of the Department of Public Health, Commonwealth of Massachusetts, now or hereafter in effect and to any conditions specified below.

Licensee		3. License Number: 00-3200 is amended in its entirety, in accordance with the application dated September 1, 2009 (received November 24, 2010), to read as follows:
1. PerkinElmer, Inc.		Amendment No: 34
2. 549 Albany Street Boston, Massachusetts 02118		4. Expiration Date: July 31, 2014
		5. Docket No: 03-0355
6. Radioactive Material	7. Chemical / Physical Form	8. Maximum Possession Limit
A. Any radioactive material with atomic numbers 1 through 83	A. Any	A. Not to exceed 10 curies per radionuclide and 100 curies total
B. Any radioactive material with atomic numbers 84 through 95	B. Any	B. Not to exceed 50 millicuries per radionuclide and 2 curies total
C. Hydrogen-3	C. Any	C. 100,000 curies
D. Carbon-14	D. Any	D. 500 curies
E. Phosphorus-32	E. Any	E. 100 curies
F. Phosphorus-33	F. Any	F. 20 curies
G. Sulfur-35	G. Any	G. 400 curies
H. Strontium-90/Yttrium-90	H. Any	H. 4 curies

COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM MATERIALS LICENSE SUPPLEMENTARY STREET	LICENSE NUMBER: 00-3200
	DOCKET NUMBER: 03-0355
	AMENDMENT NUMBER: <u>34</u>

6. Radioactive Material	7. Chemical / Physical Form	8. Maximum Possession Limit
I. Any radioactive material with atomic numbers 1 through 83	I. Any	I. Not to exceed 200 curies per radionuclide and 5000 curies total
J. Any radioactive material with atomic numbers 84 through 95	J. Any	J. Not to exceed 60 millicuries per radionuclide and 5 curies total
K. Hydrogen-3	K. Any	K. 50,000 curies
L. Carbon-14	L. Any	L. 1,000 curies
M. Phosphorus-32	M. Any	M. 400 curies
N. Sulfur-35	N. Any	N. 1,000 curies
O. Nickel 63	O. Any	O. 1,000 curies
P. Strontium-90/Yttrium-90	P. Any, Except Sealed Sources	P. 385 curies
Q. Samarium-153	Q. Any	Q. 2,000 curies
R. Uranium (depleted in the isotope Uranium-235)	R. Metal	R. 400 kilograms
S. Cobalt-60	S. Any	S. 4 curies
T. Cesium-137	T. Any	T. 4 curies
U. Gadolinium-153	U. Any	U. 4 curies
V. Iridium-192	V. Any	V. 4 curies
W. Selenium-75	W. Any	W. 4 curies
X. Ytterbium-169	X. Any	X. 4 curies

COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM MATERIALS LICENSE SUPPLEMENTARY STREET	LICENSE NUMBER: 00-3200
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6. Radioactive Material	7. Chemical / Physical Form	8. Maximum Possession Limit
Y. Cesium-137	Y. Sealed Source (As listed in the SS&D Registry Sheet CA-0598-D-106-S)	Y. 50 millicuries per source; 50 millicuries total

9. Authorized use:

A. through Y.

- (1) Research and development as defined in 105 CMR 120.005.
- (2) For possession, use, and processing incident to manufacture of radiochemicals, radiopharmaceuticals, and sealed sources.
- (3) For storage prior to distribution of manufactured radiochemicals, radiopharmaceuticals and sealed sources.
- (4) For packaging and distribution of manufactured radiochemicals and sealed sources to persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses issued by the Agency, the U.S. Nuclear Regulatory Commission or any Agreement State.
- (5) For packaging and distribution of manufactured radiopharmaceuticals,
 - i. to persons authorized to receive and distribute to medical-use licensees (i.e. possess 105 CMR 120.500 or equivalent type license) the licensed material pursuant to the terms and conditions of specific licenses issued by the Agency, the U.S. Nuclear Regulatory Commission or any Agreement State, or,
 - ii. to persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses issued by the Agency, the U.S. Nuclear Regulatory Commission or any Agreement State who will use it in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM MATERIALS LICENSE SUPPLEMENTARY STREET	LICENSE NUMBER: 00-3200
	DOCKET NUMBER: 03-0355
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(6) For use in calibration of PerkinElmer, Inc.'s instruments.

(7) For storage as radioactive wastes.

CONDITIONS

10. A. Licensed material in Items 6.A. through 6.H. may only be used or stored at licensee's facilities located at 120 and 130 East Dedham Street; Item 6.Y. may only be used or stored at 130 E. Dedham Street, all in Boston, Massachusetts.
- B. Licensed material in Items 6.I. through 6.R. may only be used or stored at licensee's facilities located at Building 250, Building 325, 331 Treble Cove Road, North Billerica, Massachusetts.
- C. Licensed material in Items 6.S through 6.X. may only be used or stored at licensee's facilities located at 120 and 130 East Dedham Street, Boston, Massachusetts; and at Building 250, Building 325, 331 Treble Cove Road, Billerica, Massachusetts.
11. This license is subject to an annual fee as determined by the Executive Office for Administration and Finance.
12. A. Licensed material shall be used by, or under the supervision of, individuals designated in writing by the Radiation Safety Committee, Linda Meehan, Chairperson.
- B. The Radiation Safety Officer for this license is Mark A. Kralian.
13. This license does not authorize commercial distribution of licensed material to pursuant to 105 CMR 120.128(J) or 105 CMR 120.128(L) ; to persons generally licensed pursuant to 105 CMR 120.122 or equivalent regulations of the U.S. Nuclear Regulatory Commission or any Agreement State; or to persons exempt from licensing pursuant to 105 CMR 120.104(A) through (C) inclusive, or equivalent regulations of the U.S. Nuclear Regulatory Commission or any Agreement State.
14. This license does not authorize distribution to persons licensed pursuant to 105 CMR 120.544, 120.547, 120.552, 120.568, 120.559, or 120.570.

COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM MATERIALS LICENSE SUPPLEMENTARY STREET	LICENSE NUMBER: 00-3200
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	AMENDMENT NUMBER: <u>34</u>

15. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at alternative intervals approved by the Agency, after evaluation of information specified by 105 CMR 120.128(N), an Agreement State or the U.S. Nuclear Regulatory Commission.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use of transfer as a sealed source.
- E. Tests for leakage and/or contamination shall be capable of detecting the presence of 185 Bq (0.005 μ Ci) of radioactive material on the test sample. If the test reveals the presence of 185 Bq (0.005 μ Ci) or more of removable contamination, the source shall be removed from service and decontaminated, repaired or disposed of. A report of this shall be filed with the Director of the Radiation Control Program within 5 days of the date the leak test result is known. The report shall specify the source involved, the test results and the corrective action(s) taken. Records of leak test results shall be kept in units of becquerel or microcurie and shall be maintained for inspection by the Agency.
- F. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically authorized by the Agency, an Agreement State, or the U.S. Nuclear Regulatory Commission to perform such services.
16. The licensee shall conduct a physical inventory every six (6) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained until inspection by the agency and shall include the quantities and kinds of radioactive material, location of sealed sources, and the date of the inventory.

COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM MATERIALS LICENSE SUPPLEMENTARY STREET	LICENSE NUMBER: 00-3200
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17. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided:
 - A. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - B. A record of each disposal permitted under this license condition shall be retained for three years. The record shall include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual(s) who performed the disposal.
18. The licensee shall not receive title to, own, acquire, deliver, receive, possess, use, or transfer hydrogen-3 under this license for research in, or development, manufacture, storage, testing, or transportation of atomic weapons or components thereof.
19. The licensee shall only transport radioactive material or deliver radioactive material to a carrier for transport in accordance with the provisions of 49 CFR Parts 170 through 189, 10 CFR Part 71, and 105 CMR 120.770 "Transportation of Radioactive Material."
20. Except as specifically provided otherwise by this license, the licensee shall conduct its program in accordance with statements, representations and procedures contained in the documents, including any enclosures, listed below. The Massachusetts Regulations for the Control of Radiation (105 CMR 120.000) shall govern, unless statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Letter dated December 11, 2007
 - B. Letter dated February 14, 2008
 - C. Letter dated February 19, 2008
 - D. Letter dated March 21, 2008
 - E. Letter dated May, 20, 2008
 - F. Letter dated September 12, 2008
 - G. Letter dated December 2, 2008
 - H. Letter dated March 20, 2009

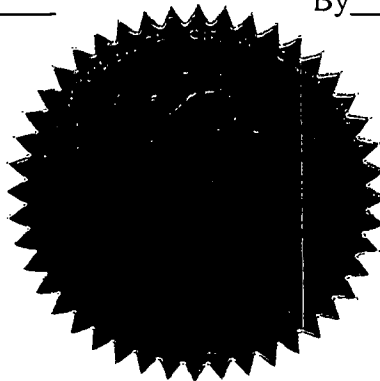
COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM MATERIALS LICENSE SUPPLEMENTARY STREET	LICENSE NUMBER: 00-3200
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- I. Letter dated March 31, 2009
- J. Letter dated May 14, 2009
- K. Letter dated February 25, 2009 with Waste Minimization Plan of same date
- L. Letter dated February 26, 2009 with Renewal Application of same date
- M. Letter dated June 22, 2009
- N. Letter dated February 5, 2010
- O. Letter dated July 30, 2010
- P. Letter dated October 15, 2010
- Q. Application dated September 1, 2009 (Received November 24, 2010)

FOR THE COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH
RADIATION CONTROL PROGRAM

Date 12/22/2010

By Robert L. Gallagher
Robert L. Gallagher, Acting Director



Appendix 5

Example Labels



CERTIFICATE OF RADIOACTIVITY

Unquenched Reference Standards for Liquid Scintillation Counting Part Number 6008400

Radionuclide	Activity	Lot No. = Assay Date	Serial No.
Tritium (^3H)	280,100 dpm/std \pm 1.6%	Oct. 22, 2010	50
Carbon-14	132,900 dpm/std \pm 1.3%	Oct. 22, 2010	50

REFERENCE STANDARD:

National Institute of Standards and Technology SRM 4947C (^3H) and SRM 4222C (^{14}C)

METHOD OF STANDARDIZATION:

The ^3H bulk solution is standardized by liquid scintillation counting using SRM 4947C as the reference material.

The ^{14}C bulk solution is standardized by liquid scintillation counting using SRM 4222C as the reference material.

I hereby certify that the above information is accurate.

Chemist



CERTIFICATE OF RADIOACTIVITY

PRODUCT: ^3H PICO Quenched Standard Set

PART NUMBER: 6008401

RADIONUCLIDE: ^3H (Tritium)

LOT NO. = ASSAY DATE: Sep. 17, 2010

ASSAYED VALUE: 282,000 dpm/std $\pm 1.6 \%$

SERIAL NUMBER: 6

REFERENCE STANDARD: National Institute of Standards and Technology SRM 4947C

METHOD OF STANDARDIZATION:

The bulk solution is standardized by liquid scintillation counting using SRM 4947C as the reference material.

COMMENTS:

The dpm value of each set of standards is confirmed by liquid scintillation counting against a reference standard set. The assigned value is automatically calculated by the liquid scintillation spectrometer using an appropriate algorithm.

I hereby certify that the above information is accurate.

Chemist



CERTIFICATE OF RADIOACTIVITY

PRODUCT: ^{14}C PICO Quenched Standard Set

PART NUMBER: 6008402

RADIONUCLIDE: ^{14}C (Carbon-14)

LOT NO. = ASSAY DATE: Sep. 02, 2010

ASSAYED VALUE: 122,400 dpm/std. $\pm 1.3\%$

SERIAL NUMBER: 11

REFERENCE STANDARD: National Institute of Standards and Technology SRM 4222C

METHOD OF STANDARDIZATION:

The bulk solution is standardized by liquid scintillation counting using SRM 4222C as the reference material.

COMMENTS:

The dpm value of each set of standards is confirmed by liquid scintillation counting against a reference standard set. The assigned value is automatically calculated by the liquid scintillation spectrometer using an appropriate algorithm.

I hereby certify that the above information is accurate.

Chemist



CERTIFICATE OF RADIOACTIVITY

PRODUCT: Unquenched Low Level ^3H Toluene Standard

PART NUMBER: 6018911

RADIONUCLIDE: ^3H (Tritium)

LOT NO. = ASSAY DATE: Oct. 22, 2010

ASSAYED VALUE: 88,300 dpm/std \pm 1.6 %

SERIAL NUMBER: 25

REFERENCE STANDARD: National Institute of Standards and Technology SRM 4947C

METHOD OF STANDARDIZATION:

The bulk solution is standardized by liquid scintillation counting using SRM 4947C as the reference material.

I hereby certify that the above information is accurate.

Chemist



CERTIFICATE OF RADIOACTIVITY

PRODUCT: Unquenched Low Level ^{14}C Toluene Standard

PART NUMBER: 6018912

RADIONUCLIDE: ^{14}C (Carbon-14)

LOT NO. = ASSAY DATE: Oct. 22, 2010

ASSAYED VALUE: 41,420 dpm/std \pm 1.3 %

SERIAL NUMBER: 25

REFERENCE STANDARD: National Institute of Standards and Technology SRM 4222C

METHOD OF STANDARDIZATION:

The bulk solution is standardized by liquid scintillation counting using SRM 4222C as the reference material.

I hereby certify that the above information is accurate.

Chemist



CERTIFICATE OF RADIOACTIVITY

PRODUCT: ^3H Ultima Gold Low Level Quenched Standard Set

PART NUMBER: 6010704

RADIONUCLIDE: ^3H (Tritium)

LOT NO. = ASSAY DATE: Nov. 24, 2010

ASSAYED VALUE: 94,570 dpm/std \pm 1.6 %

SERIAL NUMBER: 10

REFERENCE STANDARD: National Institute of Standards and Technology SRM 4947C

METHOD OF STANDARDIZATION:

The bulk solution is standardized by liquid scintillation counting using SRM 4947C as the reference material.

COMMENTS:

The dpm value of each set of standards is confirmed by liquid scintillation counting against a reference standard set. The assigned value is automatically calculated by the liquid scintillation spectrometer using an appropriate algorithm.

I hereby certify that the above information is accurate.

Chemist



CERTIFICATE OF RADIOACTIVITY

PRODUCT: ^{14}C Ultima Gold Low Level Quenched Standard Set

PART NUMBER: 6010705

RADIONUCLIDE: ^{14}C (Carbon-14)

LOT NO. = ASSAY DATE: Aug. 20, 2010

ASSAYED VALUE: 38,590 dpm/std \pm 1.3 %

SERIAL NUMBER: 6

REFERENCE STANDARD: National Institute of Standards and Technology SRM 4222C

METHOD OF STANDARDIZATION:

The bulk solution is standardized by liquid scintillation counting using SRM 4222C as the reference material.

COMMENTS:

The dpm value of each set of standards is confirmed by liquid scintillation counting against a reference standard set. The assigned value is automatically calculated by the liquid scintillation spectrometer using an appropriate algorithm.

I hereby certify that the above information is accurate.

Chemist



CERTIFICATE OF RADIOACTIVITY

PRODUCT: ^3H Toluene Internal Standard

CATALOG/PART NUMBER: 6004051

RADIONUCLIDE: ^3H (Tritium)

LOT NO. = ASSAY DATE: April 28, 2010

ASSAYED VALUE: 2.47×10^6 dpm/g ± 2.21 % (Uncertainty at 99% Level)

REFERENCE STANDARD: National Institute of Standards and Technology SRM 4947C

METHOD OF STANDARDIZATION:

The assayed value was determined by direct gravimetric comparison to the reference standard.

I hereby certify that the above information is accurate.

Chemist



CERTIFICATE OF RADIOACTIVITY

PRODUCT: Tritiated Water Internal Standard

CATALOG/PART NUMBER: 6004052

RADIONUCLIDE: ^3H (Tritium)

LOT NO. = ASSAY DATE: April 19, 2010

ASSAYED VALUE: 2.64×10^6 dpm/g ± 1.62 % (Uncertainty at 99% Level)

REFERENCE STANDARD: National Institute of Standards and Technology SRM 4927C

METHOD OF STANDARDIZATION:

The assayed value was determined by direct gravimetric comparison to the reference standard.

I hereby certify that the above information is accurate.

Chemist



CERTIFICATE OF RADIOACTIVITY

PRODUCT: ^{14}C Toluene Internal Standard

CATALOG/PART NUMBER: 6004062

RADIONUCLIDE: ^{14}C (Carbon-14)

LOT NO. = ASSAY DATE: April 19, 2010

ASSAYED VALUE: 5.16×10^5 dpm/g \pm 1.15 % (Uncertainty at 99% Level)

REFERENCE STANDARD: National Institute of Standards and Technology SRM 4222C

METHOD OF STANDARDIZATION:

The assayed value was determined by direct gravimetric comparison to the reference standard.

I hereby certify that the above information is accurate.

Lilibeth Valero
Chemist



CERTIFICATE OF RADIOACTIVITY

HIGH ACTIVITY SPEC CHEC KIT Part Number 6002138

Radionuclide	Activity	Lot No. = Assay Date
Tritium (^3H)	1.54×10^6 dpm/ml $\pm 1.38 \%$	May 19, 2010
Carbon-14	8.94×10^5 dpm/ml $\pm 0.97 \%$	May 19, 2010

REFERENCE STANDARD:

National Institute of Standards and Technology SRM 4947C (^3H) and SRM 4222C (^{14}C)

METHOD OF STANDARDIZATION:

The ^3H bulk solution is standardized by liquid scintillation counting against a calibrated set of quenched standard. The calibration of the quenched standard was done by using NIST SRM 4947C.

The ^{14}C bulk solution is standardized by liquid scintillation counting against a calibrated set of quenched standard. The calibration of the quenched standard was done by using NIST SRM 4222C.

I hereby certify that the above information is accurate.

Chemist



CERTIFICATE OF RADIOACTIVITY

LOW ACTIVITY SPEC CHEC KIT Part Number 6002139

Radionuclide	Activity	Lot No. = Assay Date
Tritium (^3H)	50,090 dpm/ml \pm 1.65 %	May 19, 2010
Carbon-14	48,430 dpm/ml \pm 1.04 %	May 19, 2010

REFERENCE STANDARD:

National Institute of Standards and Technology SRM 4947C (^3H) and SRM 4222C (^{14}C)

METHOD OF STANDARDIZATION:

The ^3H bulk solution is standardized by liquid scintillation counting against a calibrated set of quenched standard. The calibration of the quenched standard was done by using NIST SRM 4947C.

The ^{14}C bulk solution is standardized by liquid scintillation counting against a calibrated set of quenched standard. The calibration of the quenched standard was done by using NIST SRM 4222C.

I hereby certify that the above information is accurate.

Chemist



LEAK TEST AND TRACEABILITY CERTIFICATE

Source Serial No.: 96-5054

<u>Source Drawing</u>	<u>Radionuclide</u>	<u>Nominal Activity</u>
<u>X</u> PN 6020000/7001044	3H/14C	<5 uCi/<2uCi
___ PN 6020001/7001045	3H	<5 uCi
___ PN 6020005/7001129	3H	<25 uCi

**THE LEAK TEST INDICATED BY CHECKED BOXES WERE APPLIED TO
DETERMINE THE INTEGRITY OF THE SOURCE(S) IN THIS SHIPMENT**

LEAK TEST NOT APPLICABLE:

The active area of this source is protected by a very thin coating. Although the deposit is adherent, it is not designed or certified to pass a standard leak test. The inactive portions of the source have been checked using the standard wipe test and found not to exceed 0.005 uCi removable activity at time of shipment.

Date: _____

Signature: _____

TRACEABILITY INFORMATION

Shipper Instructions:

Leak Test Certificate to customer

Copy on file

Attach shipping label here.



LEAK TEST AND TRACEABILITY CERTIFICATE

Source Serial No.: LUMI-4015

<u>Source Drawing</u>	<u>Radionuclide</u>	<u>Nominal Activity</u>
<u> </u> PN 6020000/7001044	3H/14C	<5 uCi/<2uCi
<u> </u> PN 6020001/7001045	3H	<5 uCi
<u> X </u> PN 6020005/7001129	3H	<25 uCi

**THE LEAK TEST INDICATED BY CHECKED BOXES WERE APPLIED TO
DETERMINE THE INTEGRITY OF THE SOURCE(S) IN THIS SHIPMENT**

LEAK TEST NOT APPLICABLE:

The active area of this source is protected by a very thin coating. Although the deposit is adherent, it is not designed or certified to pass a standard leak test. The inactive portions of the source have been checked using the standard wipe test and found not to exceed 0.005 uCi removable activity at time of shipment.

Date: _____

Signature: _____

TRACEABILITY INFORMATION

Shipper Instructions:

Leak Test Certificate to customer

Copy on file

Attach shipping label here.



NORMALIZATION STANDARD
for 1,2,3,6 and 12-det Microbeta
Liquid Scintillation Counter
Product No. 1450-471

CERTIFICATE

Radioactive isotopes: Tritium and Carbon-14

The activities of standards and the reference dates for all standards are as follows:

1, 2, 3 and 6-det

³H (position G11): 265800 dpm 01 May 2010 Ref. Date

¹⁴C (position H12): 101400 dpm 01 May 2010 Ref. Date

12-det

³H (position G10): 266900 dpm 01 May 2010 Ref. Date

¹⁴C (position G12): 101200 dpm 01 May 2010 Ref. Date

The 1450-471 is from the production Lot No. 52110

Product Description

The 1450-471 Liquid Scintillation Standard set consists of four activity standards. The activity standards are precisely calibrated samples of carbon-14 labeled [1-¹⁴C] stearic acid and tritium labeled [1,2-³H(N)]-cholesterol in scintillation plastic discs based on polyvinyl toluene. The labeled compounds are produced by PerkinElmer and Amersham respectively. The standard discs are glued with paraffin onto the bottom of the sample wells of the sample plate and sealed with a sealing tape.

Activity Calibration

The tritium standards are calibrated against reference standards of tritium labeled toluene by the National Institute of Standards and Technology (NIST). The Standard Reference Material (SRM) No. 4947C is certified to have an estimated accuracy of ± 1.2 %. The carbon-14 standards are calibrated against reference standards of ¹⁴C-n-hexadecane supplied by the National Institute of Standards and Technology (NIST). The Standard Reference Material (SRM) No. 4222C is certified to have an estimated accuracy of ± 0.81 %. The tolerance of the activity of the discs is ± 1 %.

Definition of Use

The 1450-471 standard set is intended to use with LS counter Microbeta to normalize the instrument and measure day to day ³H and ¹⁴C counting efficiencies for comparison with original factory specifications and for verifying stable system performances. For specific instructions on use of these standards with Microbeta, the instrument manual should be consulted.

Precautions on Storage and Use

Fluors are susceptible to photo-chemical degradation. The standard set should be stored in a dark place at room temperature. The long-term stability for ³H has shown 1 % decrease in activity per year and recommended shelf-life is not more than 3 years.

Approved by: _____



CALIBRATION STANDARD
for 12-detector MicroBeta™
Liquid Scintillation Counter
Product No. 1450-477

CERTIFICATE

The activities of standards and the reference dates for all standards are as follows:

³ H	Reference Date:	<u>1 April 2010</u>
	(position A1):	<u>235200</u> dpm
	(position A4):	<u>234700</u> dpm
	(position A7):	<u>233400</u> dpm
	(position A10):	<u>240300</u> dpm
	(position D1):	<u>239600</u> dpm
	(position D4):	<u>237900</u> dpm
	(position D7):	<u>239600</u> dpm
	(position D10):	<u>233200</u> dpm
	(position G1):	<u>238000</u> dpm
	(position G4):	<u>235400</u> dpm
	(position G7):	<u>236100</u> dpm
	(position G10):	<u>237700</u> dpm

Single photon standards: Reference Date: 1 April 2010
(positions A2, A5, A8, A11, D2, D5, D8, D11
G2, G5, G7, G10): 100 SQP(I)

1450-477 Serial No. 42710 A

Product Description

1450-477 Liquid Scintillation Standard is a calibration cassette which consists of:

- twelve precisely calibrated samples of tritium labelled [1,2-³H(N)]-Cholesterol scintillation plastic discs based on polyvinyl toluene.
- twelve single photon standards containing labelled thymidine (methyl-³H)thymidine in inorganic scintillation glass powder; these are glued with paraffin onto the bottom of the plastic cup.

The labelled compounds are produced by PerkinElmer and Amersham respectively. The standard is sealed with a sealing tape.

Activity Calibration

The tritium standards are calibrated against reference standards of tritium labelled toluene by the National Institute of Standards and Technology (NIST), Standard Reference Material (SRM) No. 4947C, the estimated accuracy of which was ± 1.2 %. The tolerance of the activity of the discs is ± 1 %.

Approved by: _____

Definition of Use

The 1450-477 standard set is restricted to MicroBeta service purposes only. The standard set of tritium and single photon standards is compatible with twelve detector MicroBeta.

Precautions on Storage and Use

Fluors are susceptible to photo-chemical degradation. The standard set should be stored in a dark place at room temperature. The long-term stability for ³H has shown a 1 % decrease in activity per year and recommended shelf-life is not more than 3 years.

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.



**TRITIUM
NORMALIZATION STANDARD
for BetaPlate™
Liquid Scintillation Counter
Product No. 1205-432**

CERTIFICATE

The activity of each standard disc and the reference date are as follows:

^3H : 239200 dpm 01Mar 2010 Ref. Date

The 1205-432 is from the production Lot No. 22210

Product Description

The 1205-432 Liquid Scintillation Standard set consists of six precisely calibrated samples of tritium labelled [7(n)- ^3H]-cholesterol in scintillation plastic discs based polyvinyl toluene. The labelled compound is produced by PerkinElmer.

Activity Calibration

The tritium standards are calibrated against reference standards of tritium labelled toluene by the National Institute of Standards and Technology (NIST), Standard Reference Material (SRM) No. 4947C, the estimated accuracy of which was $\pm 1.2\%$. The tolerance of the activity of the discs is $\pm 1\%$.

Definition of Use

The 1205-432 standard set is intended for use with LS counter BetaPlate to normalize the instrument and measure day to day ^3H counting efficiency for comparison with original factory specifications and for verifying stable system performances. For specific instructions on use of these standards with BetaPlate, the instrument manual should be consulted.

Precautions on Storage and Use

Fluors are susceptible to photo-chemical degradation. The standard set should be stored in a dark place at room temperature. The long-term stability for ^3H has shown 1 % decrease in activity per year and recommended shelf-life is not more than 3 years.

Approved by: _____

CALIBRATION STANDARD
for BETAPLATE BS
Liquid Scintillation Counter

Product No.: 1204-438

**The use of this standard is restricted to
Betaplate service purposes only.
The activities of tritium disks are
stated on the label of the calibration
standard strip.**

CERTIFICATE

This standard set consists of tritium (positions A1,B1,C1,D1) and single photon (positions A2,B2,C2,D2) standards. The tritium standards are prepared from polyvinyl toluene-based scintillation plastic disks. The single photon standards are prepared from inorganic scintillation glass powder, which are glued with paraffin onto the bottom of the strip well.

The tritium standard contains labelled cholesterol ((7(n)-3H)-cholesterol) produced by Amersham International plc, UK, and calibrated against reference standards of tritiated toluene, supplied by the National Institute of Standards and Technology, USA. The Standard Reference Material No. 4947 is certified to have an estimated accuracy of $\pm 1.0\%$.

The single photon standard contains labelled thymidine (methyl- ^3H)thymidine produced by Amersham International plc, UK. The activity of the isotope is less than 10^4 Bq / standard.

NOTE: The standard set of tritium and single photon is compatible with Betaplate BS from serial number 20 400 012.

Precautions on Storage and Use: Fluors are susceptible to photo-chemical degradation. The standard set should be stored in a dark place at room temperature. The long-term stability for ^3H has shown a 1% decrease in activity per year and the recommended shelf-life is not more than 3 years.

Approved by: _____

1204-438 TRITIUM / SINGLE PHOTON CALIBRATION STANDARD

DET 1/POS D1	DET 2/POS C1	DET 3/POS B1	DET 4/POS A1
DPM SAMPLE 1	DPM SAMPLE 2	DPM SAMPLE 3	DPM SAMPLE 4
234200	234900	229200	228600

LOT: 7xxxxx A DATE: 1-SEP-1999 SINGLE PHOTON: D2,C2,B2,A2 SQP(I)=100

1204-438 TRITIUM / SINGLE PHOTON CALIBRATION STANDARD

DET 1/POS D1	DET 2/POS C1	DET 3/POS B1	DET 4/POS A1
DPM SAMPLE 1	DPM SAMPLE 2	DPM SAMPLE 3	DPM SAMPLE 4
233600	233100	227000	239300

LOT: 7xxxxx B DATE: 1-SEP-1999 SINGLE PHOTON: D2,C2,B2,A2 SQP(I)=100

1204-438 TRITIUM / SINGLE PHOTON CALIBRATION STANDARD

DET 1/POS D1	DET 2/POS C1	DET 3/POS B1	DET 4/POS A1
DPM SAMPLE 1	DPM SAMPLE 2	DPM SAMPLE 3	DPM SAMPLE 4
228900	232600	227800	228500

LOT: 7xxxxx C DATE: 1-SEP-1999 SINGLE PHOTON: D2,C2,B2,A2 SQP(I)=100

1204-438 TRITIUM / SINGLE PHOTON CALIBRATION STANDARD

DET 1/POS D1	DET 2/POS C1	DET 3/POS B1	DET 4/POS A1
DPM SAMPLE 1	DPM SAMPLE 2	DPM SAMPLE 3	DPM SAMPLE 4
232600	228900	248400	233100

LOT: 7xxxxx D DATE: 1-SEP-1999 SINGLE PHOTON: D2,C2,B2,A2 SQP(I)=100

1204-438 TRITIUM / SINGLE PHOTON CALIBRATION STANDARD

DET 1/POS D1	DET 2/POS C1	DET 3/POS B1	DET 4/POS A1
DPM SAMPLE 1	DPM SAMPLE 2	DPM SAMPLE 3	DPM SAMPLE 4
231100	225600	237200	234700

LOT: 7xxxxx E DATE: 1-SEP-1999 SINGLE PHOTON: D2,C2,B2,A2 SQP(I)=100

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**1204-438 CALIBRATION STANDARD for
1204 BS BetaPlate**

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**1204-438 CALIBRATION STANDARD for
1204 BS BetaPlate**

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1204 BS BetaPlate**

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**1204-438 CALIBRATION STANDARD for
1204 BS BetaPlate**

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TEST PLATE
for Envision's 2100 Luminescence Adjustment Plate

Product No. 60000774

Lot No. 1468366

CERTIFICATE

Product description

60000774 Test plate is a service tool which includes four luminescence samples containing labeled [^{14}C] palmitic acid in an inorganic fluorescence powder in a sealed capsule.

The total Carbon-14 activity of the luminescence sample is less than 250 kBq

Specification

The samples are made of inorganic fluorescent powders, some of which mixed with a non-fluorescent material in order to attenuate the photoluminescence signal. This batch was tested using a reference VictorTM X5 Multilabel Reader. The signal levels of each sample are strongly instrument dependent; therefore, any universal signal levels cannot be defined. Nor can the samples be compared to any of the known reference standards. Because the plate will be delivered along with an instrument, the plate will be measured at the factory with the appropriate instrument, and an individual signal data sheet will be attached to this certificate. For other instruments, the signal levels will be determined by measuring the plate at the customer's site.

Product use

The 6000074 test plate is restricted to EnVision service purposes only. The luminescence sample is intended to use with EnVision for the calibration of the plate carrier straightness. For specific instructions on use of luminescence sample with Envision, the service manual should be consulted.

Precautions for storage and use

The Luminescence Adjustment Test Plate should be kept inside the package except while measuring. The package should be stored in a dry place at room temperature.

Handle the plate with care. If the plate breaks down and some of the inorganic powder is released from the samples, be aware that the powders might be harmful if inhaled or swallowed.

Radioactive Material – Not for Human Use. Introduction into foods, beverages, cosmetics, drugs, or medicinal, or into products manufactured for commercial distribution is prohibited. Exempt quantities should not be combined.

Approved by: _____

Date: _____



TEST PLATE
for Envision's 2100 Coordinate Adjustment Plate

Product No. 60000128

Serial No.

CERTIFICATE

Product description

60000128 Test plate is a service tool which includes two luminescence samples in positions (B4, green) and (T15, red), containing labeled (^{14}C) stearic acid in an inorganic fluorescence powder in a sealed plastic capsule.

The total Carbon-14 activity of the luminescence sample is less than 250 kBq

Specification

60000128 Test plate luminescence samples were tested using a VictorTM X5 Reader. The plate id number and individual luminescence sample Lot. No. are attached on the test plate label.

Product use

The 60000128 test plate is restricted to EnVision service purposes only. The luminescence sample is intended to use with EnVision for the calibration of the mirror block, the emission slide, the aperture slide, the PMT voltage, the TR excitation filter slide, and for testing the luminometer. For specific instructions on use of luminescence sample with Envision, the service manual should be consulted.

Precautions for storage and use

The Luminescence Adjustment Test Plate should be kept inside the package except while measuring. The package should be stored in a dry place at room temperature.

Handle the plate with care. If the plate breaks down and some of the inorganic powder is released from the samples, be aware that the powders might be harmful if inhaled or swallowed.

Radioactive Material – Not for Human Use. Introduction into foods, beverages, cosmetics, drugs, or medicinal, or into products manufactured for commercial distribution is prohibited. Exempt quantities should not be combined.

Approved by: _____

Date: _____



Test Plate
for VICTOR™ Multi Label reader
Product No. 1420-442

Lot No.

CERTIFICATE OF RADIOACTIVITY

Product Description

1420-442 Test plate is a service tool which includes one luminescence sample in position B4 containing labeled [1-14C] stearic acid in inorganic fluorescence powder in a sealed plastic capsule.
The Carbon-14 activity of the luminescence sample is less than 250 kBq

Specification

1420-442 Test plate luminescence sample was tested using a reference Victor™ X5 Multilabel Reader. The plate id number, an individual luminescence sample Lot. No. and signal data is attached on the test plate label.

Product Use

The 1420-442 test plate is restricted to VICTOR service purpose only. The luminescence sample is intended to use with VICTOR for the calibration of the mirror block, the emission slide, the aperture slide, the PMT voltage, the TR excitation filter slide and for testing the luminometer. For specific instructions on use of luminescence sample with VICTOR, the service manual should be consulted.

Precautions for storage and use

The Test Plate should be kept inside the package except while measuring. The Package should be stored in a dry place at room temperature.

Handle the plate with care. If the plate breaks down and dome of the inorganic powder is freed from the samples, notice that the powder might be harmful if inhaled or swallowed.

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.

Approved by: _____
Chemist

Date: _____



CERTIFICATE OF RADIOACTIVITY

Internal Standard Kit for Liquid Scintillation Counting

^3H FOR ORGANIC SOLVENTS ($^3\text{H-O}$)

Product No. 1210-120

This kit includes 40 internal standard capsules containing a tritium-labeled organic compound in solid form. The labeled compound, $[1,2-^3\text{H(N)}]$ -cholesterol is produced by PerkinElmer Life and Analytical Sciences.

The absolute activity of the capsule is calibrated by comparison with the reference standards of tritiated toluene supplied by the National Institute of Standards and Technology (NIST), USA. The Standard Reference Material (SRM) No. 4947C is certified to have an estimated accuracy of $\pm 1.2\%$.

The mean value of the absolute activity having a $\pm 0.5\%$ error in relation to NIST SRM No. 4947C and the % C.V. of the distribution of activity among the capsules are based on results of a 5% random samples of the capsule batch.

Activity: 203700 DPM (0.092 μCi or 3.40 kBq)
% C.V.: 0.46 %
Reference Date/Lot No.: April, 1, 2010

The total activity of the kit is 3.67 μCi (135.8 kBq)

Precautions on Storage and Use

The chemical stability of the tracer compound and the press-through package provide stability better than 1% of the absolute activity for at least one year from the date of calibration. Expiry Date: April 2012.

The contents of these standards are exempt from NRC or Agreement State licensing requirements. "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."

Approved By: _____



CERTIFICATE OF RADIOACTIVITY

Internal Standard Kit for Liquid Scintillation Counting

^3H FOR AQUEOUS SOLVENTS (^3H -W)

Product No. 1210-121

This kit includes 40 internal standard capsules containing a tritium-labeled organic compound in solid form. The labeled compound, D-[5- ^3H (N)]-Glucose is produced by PerkinElmer Life and Analytical Sciences.

The absolute activity of the capsule is calibrated by comparison with the reference standards of tritiated toluene supplied by the National Institute of Standards and Technology (NIST), USA. The Standard Reference Material (SRM) No. 4947C is certified to have an estimated accuracy of $\pm 1.2\%$.

The mean value of the absolute activity having a $\pm 0.5\%$ error in relation to NIST SRM No. 4947C and the % C.V. of the distribution of activity among the capsules are based on results of a 5 % random samples of the capsule batch.

Activity: 208000 DPM (0.094 μCi or 3.47 kBq)
% C.V.: 0.38 %
Reference Date/Lot No.: January 1, 2010

The total activity of the kit is 3.75 μCi (138.70 kBq)

Precautions on Storage and Use

The chemical stability of the tracer compound and the press-through package provide stability better than 1% of the absolute activity for at least one year from the date of calibration. Expiry Date: January 2012.

The contents of these standards are exempt from NRC or Agreement State licensing requirements. "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."

Approved By: _____



CERTIFICATE OF RADIOACTIVITY

Internal Standard Kit for Liquid Scintillation Counting

^{14}C FOR ORGANIC SOLVENTS ($^{14}\text{C-O}$)

Product No. 1210-122

This kit includes 40 internal standard capsules containing a carbon-labeled organic compound in solid form. The labeled compound, [4- ^{14}C]-cholesterol is produced by Amersham International.

The absolute activity of the capsule is calibrated by comparison with the reference standards of ^{14}C -n-hexadecane supplied by the National Institute of Standards and Technology (NIST), USA. The Standard Reference Material (SRM) No. 4222C is certified to have an estimated accuracy of $\pm 0.81\%$.

The mean value of the absolute activity having a $\pm 0.5\%$ error in relation to NIST SRM No. 4222C and the % C.V. of the distribution of activity among the capsules are based on results of a 5 % random samples of the capsule batch.

Activity: 102900 DPM (0.046 μCi or 1.715 kBq)

% C.V.: 0.45 %

Reference Date/Lot No.: April 2010

The total activity of the kit is 1.85 μCi (68.60 kBq)

Precautions on Storage and Use

The chemical stability of the tracer compound and the press-through package provide stability better than 1% of the absolute activity for at least one year from the date of calibration. Expiry Date: April 2012.

The contents of these standards are exempt from NRC or Agreement State licensing requirements. "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."

Approved By: _____



CERTIFICATE OF RADIOACTIVITY

Internal Standard Kit for Liquid Scintillation Counting

^{14}C FOR AQUEOUS SOLVENTS (^{14}C -W)

Product No. 1210-123

This kit includes 40 internal standard capsules containing a carbon-labeled organic compound in solid form. The labeled compound, $[\text{U-}^{14}\text{C}]$ -Sucrose is produced by Amersham International.

The absolute activity of the capsule is calibrated by comparison with the reference standards of ^{14}C -n-hexadecane supplied by the National Institute of Standards and Technology (NIST), USA. The Standard Reference Material (SRM) No. 4222C is certified to have an estimated accuracy of $\pm 0.81\%$.

The mean value of the absolute activity having a $\pm 0.5\%$ error in relation to NIST SRM No. 4222C and the % C.V. of the distribution of activity among the capsules are based on results of a 5 % random samples of the capsule batch.

Activity: 102,300 DPM (0.046uCi or 1.70 kBq)
% C.V.: 0.66 %
Reference Date/Lot No.: Dec. 2010

The total activity of the kit is 1.84 uCi (68.18 kBq)

Precautions on Storage and Use

The chemical stability of the tracer compound and the press-through package provide stability better than 1% of the absolute activity for at least one year from the date of calibration. Expiry Date: Dec. 2012

The contents of these standards are exempt from NRC or Agreement State licensing requirements. "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."

Approved By: _____



CERTIFICATE OF RADIOACTIVITY

Internal Standard Kit for Liquid Scintillation Counting

^{14}C FOR AQUEOUS SOLVENTS (^{14}C -W)

Product No. 1210-124

This kit includes 10 internal standard capsules containing a carbon-labeled organic compound in solid form. The labeled compound, [U- ^{14}C]-Sucrose is produced by Amersham International.

The absolute activity of the capsule is calibrated by comparison with the reference standards of ^{14}C -n-hexadecane supplied by the National Institute of Standards and Technology (NIST), USA. The Standard Reference Material (SRM) No. 4222C is certified to have an estimated accuracy of $\pm 0.81\%$.

The mean value of the absolute activity having a $\pm 0.5\%$ error in relation to NIST SRM No. 4222C and the % C.V. of the distribution of activity among the capsules are based on results of a 5 % random samples of the capsule batch.

Activity: 101500 DPM (0.046uCi or 1.69 kBq)
% C.V.: 0.53 %
Reference Date/Lot No.: April 2010

The total activity of the kit is 0.46 uCi (16.9 kBq)

Precautions on Storage and Use

The chemical stability of the tracer compound and the press-through package provide stability better than 1% of the absolute activity for at least one year from the date of calibration. Expiry Date: April 2012.

The contents of these standards are exempt from NRC or Agreement State licensing requirements. "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."

Approved By: _____

A**CANBERRA**

Certificate of Calibration

GAMMA RAY STANDARD

Part Number: 6018503

Radionuclide: Cs-137 **Half-Life:** 30.2 y
Serial Number: E-X-X / XXFXX-X **Type:** 75mm x 12mm Tube

This source has been calibrated with a HPGe detector for which the efficiency has been established with IAEA or NIST traceable standards. The gamma lines listed were measured to determine the stated activity as a weighted average with an uncertainty estimated at 5%.

Calibration Date: 22-Dec-10 **Julian Day: (245)** 5553

Activity: 9 250 Bq 0.2500 μ Cl
Leak tested: 22-Dec-10

Photon Energy (keV)	Intensity (%)	Emission Rate (sec⁻¹)
<u>661.6</u>	<u>85.0</u>	<u>7 860</u>
<u>32.0 Kα</u>	<u>5.8</u>	<u>537 *</u>
<u>36.4 Kβ</u>	<u>1.3</u>	<u>120 *</u>
<u>* calculated</u>		

Certified by: _____ **Date:** _____

CANBERRA INDUSTRIES, INC.

107 Union Valley Road - Oak Ridge, Tennessee 37830-8045, USA - Tel. 865-220-6300 - Fax 865-483-0406



Certificate of Calibration

GAMMA RAY STANDARD

Part Number 6018504

Radionuclide: I-129 Half-Life: 1.6e+07y
Serial Number: E-XX-X / XXFXX-X Type: 75mm x 12mm test tube

This source has been calibrated with a HPGe detector for which the efficiency has been established with IAEA or NIST traceable standards. The gamma lines listed were measured to determine the stated activity as a weighted average with an uncertainty estimated at 5%.

Calibration Date: 22-Dec-10 Julian Day: (245) 5553
Expiration Date: 22-Dec-17
Activity: 1 850 Bq 0.0500 µCi
111,000 dpm

Leak Tested: 22-Dec-10

Photon Energy (keV)	Intensity (%)	Emission Rate (sec ⁻¹)
<u>29.7</u>	<u>57</u>	<u>1 050 *</u>
<u>33.6</u>	<u>10.2</u>	<u>189 *</u>
<u>39.58</u>	<u>7.52</u>	<u>139</u>

*Calculated

Certified by: _____ Date: _____

CANBERRA INDUSTRIES, INC.

107 Union Valley Road - Oak Ridge, Tennessee 37830-8045, USA - Tel. 865-220-6300 - Fax 865-483-0406

Item 5c
Radioactive Material Packaging Label



DO NOT SHIP AFTER: May 24, 2011

ULTIMA GOLD LOW LEVEL QUENCHED STANDARD (15 mL)

6010704 - TRITIUM SERIES (SET OF 8)

LOT NO. = ASSAY DATE: Nov. 24, 2010

EXPIRATION DATE: May 24, 2013

SERIAL NO. 12

sample

CAUTION: RADIOACTIVE MATERIAL
STORE AT 4°C



PerkinElmer®
precisely.

MARK KRACIAN

PerkinElmer Life and Analytical Sciences

549 Albany Street

Boston, MA 02118

7006 3450 0000 8113 6907



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