



710 Bridgeport Avenue  
Shelton, CT 06484  
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December 29, 2008

Licensing Assistant Section  
Nuclear Materials Safety Branch  
U.S. Nuclear Regulatory Commission, Region 1  
475 Allendale Road  
King of Prussia, PA 19406-1415

*Brz*

2009 JAN -2 PM 12:32

RECEIVED  
REGION 1

*030 03776*

RE: Materials License #06-02135-08

Enclosed is PerkinElmer's submission for amendment of our Materials License #06-02135-08. This amendment is being requested to remove the incorrect statement "For research and development as defined in 10 CFR 30.4" in section 9A. In addition, I am removing Bart Rasmussen from section 11A.

I have reviewed and updated the Thomas Thompson email from 2006 since it is still applicable.

I have enclosed the following supportive documents:

1. NRC Form 313
2. NRC Form 313 items 5 through 11
  - a. Various procedures and documents
3. February 10, 2006 reply to NRC operational questions
4. Current licensed marked up with requested changes

If there are any further questions concerning our renewal application, please contact me at 203-402-5219 or Email [john.widomski@perkinelmer.com](mailto:john.widomski@perkinelmer.com).

Sincerely,

John Widomski  
RSO

*143172*

NUCLEAR MATERIALS 002

**NRC FORM 313**  
(4-2008)  
10 CFR 30, 32, 33,  
34, 35, 36, 39, and 40

**U.S. NUCLEAR REGULATORY COMMISSION**

**APPROVED BY OMB: NO. 3150-0120**

**EXPIRES: 10/31/2008**

Estimated burden per response to comply with this mandatory collection request is 1.4 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@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.

**APPLICATION FOR MATERIALS LICENSE**

**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:**

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY  
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS  
U.S. NUCLEAR REGULATORY COMMISSION  
WASHINGTON, DC 20555-0001

**ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:**

**IF YOU ARE LOCATED IN:**

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

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

**IF YOU ARE LOCATED IN:**

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

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

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

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

03003776

**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 **06-02135-08**
- C. RENEWAL OF LICENSE NUMBER

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

**PerkinElmer LAS**  
**710 Bridgeport Ave**  
**Shelton, CT 06484**

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

**710 Bridgeport Ave**  
**Shelton, CT 06484**

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

**John Widomski**

TELEPHONE NUMBER

**(203) 402-5219**

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

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

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

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

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

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

FEE CATEGORY      AMOUNT ENCLOSED \$

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

SIGNATURE

DATE

**FOR NRC USE ONLY**

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

APPROVED BY

DATE

**Supplement to:** APPLICATION FOR MATERIALS LICENSE  
 AMENDMENT TO LICENSE  
 #06-02135-08

5) **RADIOACTIVE MATERIAL**  
 Sealed Source

Radionuclide --Nickel 63  
 Form --Foil  
 Manufacturer --NRD (Nuclear Radiation Development Corp)  
 2937 Alt Boulevard  
 Grand Island, NY 14072  
 Mfg part # --Model N1001  
 Source Registration # --NR-536-D-110-B  
 Source Activity --15 millicuries max

6) **PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED**  
 N (Ion Generator, Chromatography)

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

<u>PSO</u>	<u>Training</u>	<u>Training Duration</u>	<u>On the Job</u>
John Widomski Operations Mgr.	PerkinElmer	1 years	Yes
		3	Yes
<u>AU</u>	<u>Training</u>	<u>Training Duration</u>	<u>On the Job</u>
Jeanne Raccio Mfg. Supervisor	PerkinElmer Packard Bioscience	23 years 5 years	Yes Yes
Rosario Mannino QA Engineer/R&D	PerkinElmer	11 years	Yes
Barton Rasmussen R&D	PerkinElmer	1 year	Yes
Dave Bodwell Service	PerkinElmer	23 years	Yes



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[www.perkinelmer.com](http://www.perkinelmer.com)

- 8) TRAINING FOR INDIVIDUAL(S) WORKING IN OR FREQUENTING RESTRICTED AREAS**  
Not applicable – no restricted areas -- only sealed sources received from supplier, NRD

**9) FACILITIES AND EQUIPMENT**

Sealed sources are shipped/stored in anti-tamper source housing, model #N610-0133, N610-0063, N610-0134. Sealed sources are stored in a locked cabinet.

**10) RADIATION SAFETY PROGRAM**

- a) Twice yearly audit of the ISO-9000 system, of which the control processes of the sealed sources are a component. Procedures below attached.
  - i. Inspection Instructions for ECD cells
  - ii. Radioactive Package Receiving & Survey Instructions
  - iii. Wipe / Rewipe Instructions
  - iv. Stock and Issue Instructions for ECD cells
  - v. Review of Specific License
- b) Formal review of processes every 5 years
- c) Inventories verified quarterly
- d) Survey meter under controlled yearly calibration process
- e) Instruments properly labeled with signage and initial test results
- f) Shipping containers labeled
  - i. Shipping & label document
- g) Receipt and transfer of all devices recorded

**11) WASTE MANAGEMENT**

Not applicable – no waste generated

**STOCK AND ISSUE INSTRUCTIONS FOR ECD CELLS**  
Product Teams: ECD\_3\_002

Approved by: John Widomski

Approval date: 08/03/07  
Review date: 01/30/09

## **STOCK AND ISSUE INSTRUCTIONS FOR ECD CELLS**

### **1. PURPOSE**

To ensure the handling of ECD cells is controlled to NRC guidelines.

### **2. REFERENCES**

10 CFR 20

### **3. DEFINITIONS**

- 3.1 CFR Code of Federal Regulations
- 3.2 ECD Electron Capture Detector
- 3.3 GC Gas Chromatograph
- 3.4 NRC Nuclear Regulatory Commission
- 3.5 RSO Radiation Safety Officer
- 3.6 SAP MRP system used to plan and schedule
- 3.7 SPO Sales Purchase Order

## REVIEW OF CUSTOMER NRC SPECIFIC LICENSE

Product Teams: ECD\_3\_002

Approved by: John Widomski

Approval date: 07/30/07

### 4. PROCESS

A number of specific processes are listed below. Each area should understand the steps necessary to properly handle and control the stocking and issuing of ECD cells. Also, the **NOTES** section of this document should be read before proceeding.

#### 4.1. Receiving, inspection and On-line Stocking

4.1.1. Upon receipt Receiving forward cells to **GC Support Team**.

4.1.2. **GC Support Team** supervisor surveys package per "Radioactive package receiving and survey instructions"

4.1.3. GC Supervisor inspects and stocks cells per "Inspection Instructions for ECD Cells".

#### 4.2. Sub Assembly Detector Cell Issue

4.2.1. Issue cells in ascending numerical order.

4.2.2. On-line stores records SAP Production Order number and subassembly rep's name against cells to be issued.

4.2.3. Subassembly representative verifies serial numbers and count.

#### 4.3. Subassembly Detector Cell Stocking

4.3.1. Subassembly representative returns completed SAP Production Order to On-line cabinet.

4.3.2. On-line verifies part count.

4.3.3. On-line records serial numbers in both the log book and SAP.

4.3.4. Cells are stocked in locked cabinet.

#### 4.4. SPO Issue

4.4.1. Check license type for US shipments - General or Specific - If none available, do not issue cell. Check exempt for international shipment.

4.4.2. Check customer information and address for US shipments - If not available, do not issue cell

4.4.3. Issue cells in ascending numerical order.

4.4.4. Check wipe test date on cell to be issued. Cell must have at least two months left before expiration date. (Cells have a six month wipe test period, therefore, cells should not be issued more than four months after the wipe test date on the box. ECD cells must have at least two months

## REVIEW OF CUSTOMER NRC SPECIFIC LICENSE

Product Teams: ECD\_3\_002

Approved by: John Widomski

Approval date: 07/30/07

remaining on the current wipe test. If the wipe test expiration date is past the allowable time, the cell must be rewiped prior to shipment. Contact the RSO or RSO assistant to have the cells rewiped.)

- 4.4.5. Record customer information (sales order number) and license status in the stock issue log book.
  - 4.4.6. Fill in the electronic CUSTOMER IDENTIFICATION ECD CELL form. File by cell serial number (P:\DEPT\_DIR\GC-PROD-TEAM\ECD Customer Ids) and make three printed copies.
  - 4.4.7. The first copy is filed in the notebook.
  - 4.4.8. SPO representative signs the stock issue log book and keeps the second and third copy. These copies accompany cell to Shipping.
  - 4.4.9. Create certificate using ECD label to accompany cell.
  - 4.4.10. Upon shipment, record the carrier's name and date shipped on the back of the CUSTOMER IDENTIFICATION ECD CELL second copies.
  - 4.4.11. Forward one copy to the ITC representative for listing in the NRC Quarterly Report.
  - 4.4.12. This third copy is forwarded to the RSO for permanent filing.
- 4.5. Instrument Issue -
- 4.5.1. Check license status for US shipments - General or Specific - If none available contact Chrom Production Control or Supervisor. Do not issue cell. Check exempt for international shipment.
  - 4.5.2. Issue cells in ascending numerical order.
  - 4.5.3. Check wipe test date on cell to be issued. Cell must have at least two months left before expiration date. (Cells have a six month wipe test period, therefore, cells should not be issued more than four months after the wipe test date on the box. ECD cells must have at least two months remaining on the current wipe test. If the wipe test expiration date is past the allowable time, the cell must be rewiped prior to shipment. Contact the RSO or RSO assistant to have the cells rewiped.)
  - 4.5.4. Record customer information (sales order number) and license status in the stock issue log book.
  - 4.5.5. Fill in the electronic CUSTOMER IDENTIFICATION ECD CELL form. File by cell serial number (P:\DEPT\_DIR\GC-PROD-TEAM\ECD Customer Ids) and make three printed copies.
  - 4.5.6. Final Assembly representative signs the stock issue log book.
  - 4.5.7. Create certificate using ECD label to accompany cell.
  - 4.5.8. The three printed copies accompany cell to assembly area.
  - 4.5.9. Upon instrument completion, one copy is forwarded to the RSO, the second copy accompanies the cell to Shipping.

## REVIEW OF CUSTOMER NRC SPECIFIC LICENSE

Product Teams: ECD\_3\_002

Approved by: John Widomski

Approval date: 07/30/07

- 4.5.10. Upon instrument shipment, record the carrier's name and date shipped on the back of the second copy.
- 4.5.11. This second copy is forwarded to the ITC representative for listing in the NRC Quarterly Report.
- 4.5.12. The third copy is then forwarded to the RSO for permanent filing.

### 4.6. Non-Conforming Issue

- 4.6.1. Create a "Q2" type notification in SAP
- 4.6.2. Return cell to On-line cabinet to await disposition
- 4.6.3. Upon disposition, record serial number in log and have entry signed and dated by Inspection representative

## 5. TRAINING

- 5.1. Each manager whose department is affected by this procedure will notify the RSO if ECD training is needed by department personnel.
- 5.2. The RSO will offer ECD training as needed.

## 6. NOTES The following notes must be read and followed.

- 6.1. If at any point there are discrepancies, report them immediately to the RSO or RSO assistant.
- 6.2. Do not leave any cells unattended, i.e. on a cart, bench top or skid overnight while stocking. In production, cells are to be kept on the instrument assembly cart or in the area of testing.
- 6.3. In cases where an order is being consolidated in the USA before shipment abroad, log the final destination and the interim (USA) customer in the stock issue log book (sales order number) and CUSTOMER ID form.

## 7. SPECIAL DISTRIBUTION

- 7.1. Supervisor, Receiving and Stores
- 7.2. Supervisor, Chromatography Final Assembly and Test
- 7.3. Supervisor, Warehouse Operations
- 7.4. Manager, International Trade and Compliance

## REVIEW OF CUSTOMER NRC SPECIFIC LICENSE

Product Teams: ECD\_3\_002

Approved by: John Widomski

Approval date: 07/30/07

### 8. REGISTER OF AMENDMENT

*(Note: History of the older revisions may be hidden from printing to conserve paper. To view the entire register, use Word and TOOLS | OPTIONS | VIEW | HIDDEN TEXT. The total pages in the footer will reflect the page length with text hidden.)*

DOCUMENT CODE	DATE REV.:	REASON / CHANGE	PREPARED BY:
	1996 December 12	Add paragraph 3.5.8 concerning rewipes prior to shipment.	D.DeMent
	1997 August 20	Modify/clarify paragraph 3.4.3 and 3.5.3 with respect to rewipes and sign-off	D.DeMent
	1997 December 29	August revision was never formally released. Changed date and issued	D.DeMent
	2002 August 15	Major revision for Shelton Operations. Add flying P logo	J. Raccio
	2004 June 24	Modify procedure to incorporate the electronic customer ID form	J. Raccio
Stock and Issue Instructions 8_02.doc	2004 July 1	Reformat document	J. Raccio
	2007 August 3	Minor changes throughout	J. Widomski

Approved by: John Widomski

## WIPE / REWIPE TEST INSTRUCTIONS FOR ECD CELL

### 1. PURPOSE

- 1.1. To ensure that incoming ECD cells were properly decontaminated by the subcontractor.
- 1.2. To ensure that customers are shipped ECD cells with at least 2 months remaining on the active wipe test period.

### 2. REFERENCES

10 CFR 20

### 3. DEFINITIONS

- 3.1 CFR Code of Federal Regulations
- 3.2 ECD Electron Capture Detector
- 3.3 RSO Radiation Safety Officer

### 4. EQUIPMENT

- 4.1. Wipe test kit (0009-1667)
- 4.2. Rubber gloves

### 5. PROCEDURE

- 5.1. Remove one envelope containing a filter paper from the test kit.
- 5.2. Stamp the following information on the filter paper envelope:

PerkinElmer

P/N \_\_\_\_\_

S/N \_\_\_\_\_

Date \_\_\_\_\_

Initial \_\_\_\_\_

- 5.3. Record the cell information on the coin envelope. For cells that are being rewiped, place an *R* before the serial number i.e. Rxxxx.
- 5.4. Wipe the surface of the cell body and entrance/exit fittings with the filter paper.
- 5.5. Place the filter paper into its envelope.
- 5.6. Contact Purchasing for shipment to subcontractor for analysis.
- 5.7. Store cells in the quarantine section of the On-line cabinet used to store radioactive materials until the results are recorded by the RSO, RSO assistant or manufacturing supervisor.
- 5.8. For cells that are rewiped, record the new wipe test date on the certificate and restock.

Approved by: John Widomski

**6. NOTES**

- 6.1. Wear disposable rubber gloves while performing the wipe tests on new cells.
- 6.2. Properly dispose of any waste that is suspected to be contaminated. Contact the RSO or RSO assistant for instructions.
- 6.3. Wash hands thoroughly with soap and water after completing tests.
- 6.4. If at any point there are discrepancies, report them immediately to the RSO or RSO assistant.
- 6.5. Do not leave any cells unattended, i.e. on a cart, bench top or skid overnight while stocking. In production, cells are to be kept on the instrument assembly cart or in the area of subassembly and test.
- 6.6. Contact RSO or RSO assistant for waiver to ship an ECD prior to receipt of the wipe test result.

**7. SPECIAL DISTRIBUTIONS**

- 7.1. Supervisor, Chromatography Assembly and Test

**8. AMENDMENT HISTORY**

(Note: Most of the older revisions will be hidden from printing to conserve paper. To view the entire register, use Word and TOOLS | OPTIONS | VIEW | HIDDEN TEXT. The total pages in the footer will reflect the page length with text hidden.)

**Revision History for document code: ECD\_3\_003**

REV. DATE:	REASON / CHANGE	PREPARED BY:
1997 June 11	Change 4.8 to reflect organizational changes. Add RSO sign-off statement.	J. Bouse
2002 January 18	Review, and update	J. Bouse
2002 August 16	Update for on-line stocking Add flying P logo	J. Raccio
	Wipe Rewipe Instructions 8_02.doc	
2004 October 22	Reformat document	J. Raccio
	Wipe Rewipe Instructions 8_02.doc	
2007 July 19	Sect 5.7 add mfg supervisor – Reformatted to current doc. template	J. Widomski

**RADIOACTIVE PACKAGE RECEIVING & SURVEY INSTRUCTIONS**

Product Teams: ECD\_3\_004

Approved by: John Widomski

Approval date: 08/02/07  
Review date: 01/30/09

**RADIOACTIVE PACKAGE RECEIVING & SURVEY  
INSTRUCTIONS**

**1. PURPOSE**

To ensure that materials arriving from our radioactive materials supplier are directed expeditiously to the *GC Support Team* for survey to ensure that the material was properly decontaminated by the supplier.

**2. REFERENCES**

10 CFR Part 20.1906 "Procedure for Receiving and Opening Packages"

**3. DEFINITIONS**

- 3.1 CFR Code of Federal Regulations
- 3.2 ECD Electron Capture Detector
- 3.3 GC Gas Chromatograph
- 3.4 RSO Radiation Safety Officer

**4. EQUIPMENT**

- 4.1. RADIATION ALERT MONITOR 4 meter
- 4.2. Gloves
- 4.3. ECD Control Sheet

## REVIEW OF CUSTOMER NRC SPECIFIC LICENSE

Product Teams: ECD\_3\_004

Approved by: John Widomski

Approval date: 07/30/07

### 5. PROCESS

Upon receipt of each lot of ECD cells from the supplier, *Receiving Department* receives and delivers the cells to the *GC Support Team*. *GC Support* will survey the outside packaging, as well as the internal packing material, per the following instructions. Read the entire procedure, including Notes, before proceeding.

- 5.1. Quarantine the package to the GC Production area.
- 5.2. Using a calibrated meter, survey the package as follows:
  - 5.2.1. Set OFF-ON-AUDIO switch to the AUDIO mode.
  - 5.2.2. Set RANGE switch to BATT mode. Dial should move up to the BATTERY portion of the meter. If not, replace battery.
  - 5.2.3. Set RANGE switch to X1, and monitor the normal background level. Approximately 5 to 25 counts at random intervals can be expected every minute from naturally occurring background radiation.
  - 5.2.4. With the ALPHA WINDOW positioned towards the package to be surveyed, slowly approach until 1 to 2 inches from the surface (To avoid possible contamination to the meter, never touch the package). Slowly trace an X on each side, top and bottom. Radiation levels should not increase more than 5X the levels measured in step 4.3.3. If radioactivity is detected, place the package in the cabinet used to store radioactive materials and notify your supervisor and Radiation Safety Officer or RSO assistant immediately. Exercise caution to avoid unnecessary exposure.
  - 5.2.5. If radiation is not detected above, open the package. Repeat survey on contents. If at any time radiation is detected above the 5X level, place the package in the cabinet used to store radioactive materials and notify your supervisor and Radiation Safety Officer or RSO assistant immediately. Exercise caution to avoid unnecessary exposure.
  - 5.2.6. Set OFF-ON-AUDIO switch to the OFF position.
- 5.3. Record at the top of an *ECD Control Sheet* "No Radiation Detected" then initial and date the statement. Use this sheet for logging in the cells.

## REVIEW OF CUSTOMER NRC SPECIFIC LICENSE

Product Teams: ECD\_3\_004

Approved by: John Widomski

Approval date: 07/30/07

- 5.4. Remove ECDs from the shipping package and proceed with the wipe tests per "Wipe/Rewipe Test Instructions for ECD Cells". Upon completion of the wipe tests, quarantine the cells to the cabinet used to store radioactive materials until results are recorded by the RSO.

### 6. **NOTES: The following notes must be read and followed:**

- 6.1. Wear gloves when ever handling the packaging, packaging material, and cell boxes.
- 6.2. Verify the survey meter is in calibration.
- 6.3. If at any point there are discrepancies, report them immediately to the RSO or RSO assistant.
- 6.4. Do not leave any ECD cells on a bench top, cart, or skid overnight while inspecting. Lock them in the cabinet used to store radioactive materials.
- 6.5. Properly dispose of any waste that is suspected of being contaminated. Contact the RSO or RSO assistant for instructions.
- 6.6. If wipe tests are to be performed later, place cells in the cabinet used to store radioactive materials.
- 6.7. Wash hands thoroughly with soap and water after completing tests.

### 7. **SPECIAL DISTRIBUTIONS**

- 7.1. Supervisor, Receiving and Stores
- 7.2. Supervisor, Chromatography Final Assembly and Test
- 7.3. Supervisor, Warehouse Operations
- 7.4. Manager, Purchasing

## REVIEW OF CUSTOMER NRC SPECIFIC LICENSE

Product Teams: ECD\_3\_004

Approved by: John Widomski

Approval date: 07/30/07

### 8. REVISION HISTORY

(Note: Most of the older revisions will be hidden from printing to conserve paper. To view the entire register, use Word and TOOLS | OPTIONS | VIEW | HIDDEN TEXT. The total pages in the footer will reflect the page length with text hidden.)

DOCUMENT CODE	DATE REV.:	REASON / CHANGE	PREPARED BY:
	1997 August 20	Add receiving instructions	D. De Ment
	2002 January 18	Review and Update	J. Bouse
	2002 September 03	Add flying PE logo. Minor updates	J. Raccio
Radioactive Package Survey Instructions 9_02.doc	2004 July 1	Reformat document	J. Raccio
	2007 August 02	Reword --- 5 PROCESS	J. Widomski

**Subject: Amendment of License**

Renewal of your NRC license 06-02135-08 for PerkinElmer LAS Shelton CT

I have reviewed your December 1, 2005 letter and have additional questions as follows:

1. Please provide additional information on the purpose for which licensed material will be used. Do you simply receive gas chromatograph detectors for re-distribution or are they placed in gas chromatograph units, are there other activities that you perform? Your current license indicates manufacturing and testing.

PerkinElmer is a manufacturer of Gas Chromatographs. The licensed devices are part of the options choices that can be built into the unit. The devices are used for the manufacture of new GCs, additions to GCs in the field (add-ons) and for service replacements.

You have requested only NRD Model N1001 detector cells be listed on your license. Please confirm the disposition of any other model detector cells that you may have possessed.

The NRD model N1001 is the radioactive foil that is built into our licensed cells. The license should reference models N610-0063 and N610-0134. These are the currently shipping models. In addition to these models, our service organization continues to service GCs containing models 0330-0119, N600-0113, N600-0030, L413-0127, L413-0128. These models are no longer in production. I believe that all these, both new production and discontinued models, should be on the license.

2. Although you have mentioned radiological surveys that you will conduct in your application, some additional details are needed. Please confirm that leak tests will be evaluated by a facility licensed by NRC or an Agreement State to conduct leak evaluations for outside customers.

Newly manufactured devices received from NRD include both source assay information and wipe test results. These documents are reviewed upon receipt. In addition, all cells are re-wiped and wipes are sent to a third party test facility, currently NLTC (National Leak Test Center) in North Tonawanda, NY for verification of supplied results.

Additionally you have not provided the information requested in Item 8.10.2 of NUREG-1556, Vol. 12 with regard to your survey instrument. That information described under "response from applicant" should be provided.

**RESPONSE:** Radiation monitoring is performed using a model RADIATION ALERT Monitor 4 instrument purchased from S.E. International, Inc. Summertown, TN 38483. "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix K to NUREG-1556, Vol 12. We reserve the right to upgrade our survey instruments as necessary."

3. Please confirm that emergency procedures have been developed in the event a sealed source has leaked.

In the highly unlikely event that a cell has leaked, emergency procedures are in place to quarantine the source that exceeds regulation. In addition, all incoming sources are treated as "hot" and are quarantined.

4. You have requested to add several new authorized users and provided indication of on the job training but have not specified what specific training applicable to performing wipe tests and conducting surveys that has been provided. Please specify what radiation protection related training is provided to those you are requesting to be listed as new authorized users.

The purpose of the Radiation Training Program is to assist PerkinElmer personnel in establishing the minimum acceptable level of knowledge for the proper use of sealed sources containing radioactive Ni63 in accordance with regulatory requirements, materials license requirements, and current standards of safety.

John Widomski, Jeanne Raccio and Rosario Mannino have been in direct control of all sources for the past 15 years. All cells entering the building must first pass through one of the three of us. Each has been trained on surveying the devices and performing wipe tests. Each is knowledgeable about handling, storage and distribution.

Dave Bodwell not in direct contact with devices. Dave works for the service department and supports the field service organization. He has been trained to performed wipe tests and is the first line between field service and the Shelton RSO.

5. Please provide the information requested under " Response from Applicant" Item 8.9 , NUREG-1556, Vol. 12 with regard to your facilities where you handle gas chromatograph detectors.

Attached is a PDF file of the emergency plan. This document references the licensed cells, as well as, shows location of the devices in the building.

6. Although you have provided a program audit schedule you have not provide the information requested under " Response from Applicant" Item 8.10.1, NUREG-1556, Vol. 12. Please address the specific information requested.

Audit program summary for sealed sources follows:

- Objectives of audits
  - o To ensure that procedures are understood and are being followed
  - o To ensure safe handling of the devices
  - o To ensure that employees understand legal requirements for distribution of radioactive sources
- Scope of audits
  - o Audits are part of the ISO-9000 program with visibility to top management
- Qualification of auditors
  - o Auditors are trained under the ISO-9000 program; special training is not required since processes and procedures in place are mature and stable.
- Frequency of audits

- Annual audits are performed. Annual audits are deemed acceptable based on a record of successful audits of both the site specific and general distribution license by internal, state and federal auditors.
  - Last internal audit was Nov 30, 2005. No problems found.
  - Last Connecticut EPA audit was Oct 2005. No problems found.
  - Last NRC audit of the 06-02135-12G general distribution license was March 21, 2005. No problems found.
  - Last NRC audit of the 06-02135-08 license was September 11, 2002. No problems found.
- **Audit Techniques**
  - **Audit history** - no deficiencies identified over years of audits.
  - **Organization & scope of area audited**
    - The organization consists of ECD cell coordinator who controls all cell movements, department supervisor who receives, audits, wipes and quarantines incoming cells from our supplier and the RSO who manages and maintains the program. Both the department supervisor and cell coordinator report to the RSO.
  - **Training, retraining, and instruction to Workers**
    - Training and retraining occurs as part of workers training - crosstraining regiment. Random training courses offered to those not directly involved with handling sealed sources.
  - **Facilities**
    - Site location per license, 710 Bridgeport Ave, Shelton, CT 06484
  - **Materials**
    - Materials as specified on license
  - **Leak Tests**
    - Sources are leak tested; results are archived.
  - **Inventories**
    - Inventory checked quarterly as a minimum; both paper and electronic storage of records.
  - **Radiation Surveys**
    - Survey equipment calibrated yearly - calibration records stored. Only survey of incoming devices made.
  - **Receipt and Transfer of ECDs**
    - Incoming cells are surveyed. Records of surveys, receipt and transfers maintained to 10 CFR.
  - **Transportation**
    - Packages labeled and marked in accordance with DOT requirements.
  - **Personnel Radiation Protection**
    - No monitoring required based on health physics report and over 10 years of monitoring personnel in the 1980s.
  - **Notification and reports**
    - In compliance
  - **Posting & labeling**
    - In compliance
  - **Recordkeeping for Decommissioning**
    - NA
  - **Bulletins**

- Read and filed if appropriate for our device
- **Problems or Deficiencies**
  - Corrected actions part of ISO-9000 audit procedure
- **Records to be Maintained**
  - Records of audits part of ISO-9000 documentation

9. Accountability of materials should be addressed. Although you have provided some procedures which appear to provide control of receipt and distribution of gas chromatograph detector cells, you have not described your overall program to assure you know which detector cells you have present. See "Response from Applicant" Item 8.10.3, NUREG-1556, Vol. 12 and provide the requested information.

**RESPONSE** "All shipments of sources entering the facility are checked for quantity and that the serial numbers match the manifest. Sources are stored in a single location; physical inventories are conducted quarterly. Sources are distributed in numerical order. Both hard and electronic records are kept of all sources entering and leaving the site."

10. Please provide the information requested under "Response from Applicant" Item 8.10.4, NUREG-1556, Vol. 12 with regard to occupational dose.

**RESPONSE** "We have done an evaluation and determined that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20."

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select Nuclear Materials; Medical, Industrial, and Academic Uses of Nuclear Material; then Toolkit Index Page. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 137558. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5303.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Thank you.

Duplicate

MATERIALS LICENSE

Duplicate

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

Licensee

*Update*

in accordance with the letter received

August 20, 2005,

1. PerkinElmer LAS

3. License number 06-02135-08 is amended in its entirety to read as follows:

*REMOVE*  
2. 710 Bridgeport Avenue

MS 098

Shelton, Connecticut 06484

4. Expiration date February 29, 2016

5. Docket No. 030-03776  
Reference No.

6. Byproduct, source, and/or special nuclear material

7. Chemical and/or physical form

8. Maximum amount that licensee may possess at any one time under this license

A. Nickel 63

A. Foils (Nuclear Radiation Development N-1001)

A. Not to exceed 15 millicuries per foil and 4 curies total

9. Authorized use:

*REMOVE*  
A. For research and development as defined in 10 CFR 30.4; manufacturing and testing of gas chromatographs, and for distribution to persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses issued by the NRC or any Agreement State.

CONDITIONS

10. Licensed material shall be used or stored only at 710 Bridgeport Avenue, Shelton, Connecticut.

*REMOVE*  
11. A. Licensed material shall be used by, or under the supervision of Dave Bodwell, Rosario Mannino, Barton Rasmussen, Jeanne Raccio, or John Widomski.

B. The Radiation Safety Officer for this license is John Widomski.

12. The licensee is authorized to distribute the following devices:

Device Model Number

Radionuclide

Maximum Activity

Duplicate

Duplicate

Duplicate

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

06-02135-08

Docket or Reference Number

030-03776

Amendment No. 23

Detector Cell Assembly 009-0282	Nickel 63	15 millicuries per foil
Detector Cell Assembly 105-0210	Nickel 63	15 millicuries per foil
Detector Cell Assembly 330-0119	Nickel 63	15 millicuries per foil
Detector Cell Assembly L413-0128	Nickel 63	15 millicuries per foil
Detector Cell Assembly N600-0113	Nickel 63	15 millicuries per foil
Detector Cell Assembly N610-0063	Nickel 63	15 millicuries per foil
Detector Cell Assembly N610-0134	Nickel 63	15 millicuries per foil

13. The following devices are authorized for export only:

<u>Device Model Number</u>	<u>Radionuclide</u>	<u>Maximum Activity</u>
Detector Cell Assembly L413-0127	Nickel 63	15 millicuries per foil
Detector Cell Assembly N600-0030	Nickel 63	15 millicuries per foil

14. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
- B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
- C. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- D. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.
- E. Tests for leakage and/or contamination, limited to leak test sample collection, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. The licensee is not authorized to perform the

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
06-02135-08Docket or Reference Number  
030-03776

Amendment No. 23

analysis; analysis of leak test samples must be performed by persons specifically licensed by U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

- F. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.
15. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.
16. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations
- A. Letter with attachments dated February 10, 2006 except attached letters dated March 25 and April 30, 2003.

For the U.S. Nuclear Regulatory Commission

***Original signed by Thomas K. Thompson***

Date February 15, 2006

By

Thomas K. Thompson  
Commercial and R&D Branch  
Division of Nuclear Materials Safety  
Region I  
King of Prussia, Pennsylvania 19406

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

12/29/2008, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 06-02135-08  
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

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

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

Your action has been assigned **Mail Control Number** 143172.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.