

June 17, 2013

US Nuclear Regulatory Commission
TWFN-8 E24
11545 Rockville Pike
Rockville, MD 20852-2738
Attn: Margie Kotzalas, Branch Chief, FSME, DMSSA, LB

Re: PerkinElmer, Inc. – Addendum to Amendment Request to Radioactive Material Exempt Distribution License #20-00320-14E; Ba-133 Source Description

Dear Ms. Kotzalas,

PerkinElmer is submitting this addendum to our amendment request dated June 3, 2013 for our Exempt Distribution Radioactive Material License No. 20-00320-14E. This addendum provides information concerning the requested authorization for distribution of a Ba-133 exempt sealed source installed in a Tri-Carb Liquid Scintillation Counter. This exempt source is also identified in a current Use and Possession amendment request with the State of Massachusetts for License #56-0683.

Enclosed is supplemental information and applicable attachments describing the source design and Tri-Carb device.

This amendment was developed in accordance with 10 CFR 32.14, 32.15, and 32.16, Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct, and the additional guidance provided in NUREG-1556 Vol. 8, Program-Specific Guidance About Exempt Distribution Licenses.

Please let me know if you have any questions, concerns, or items that need to be addressed.

Sincerely,

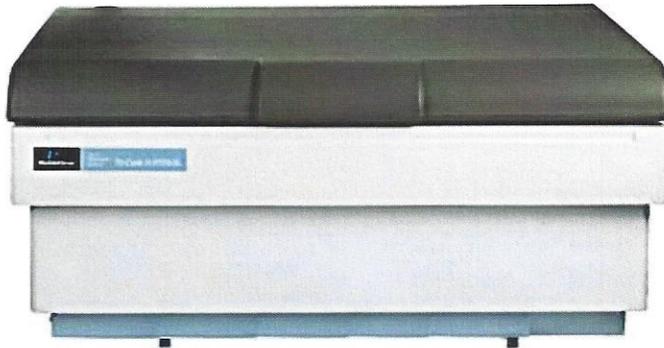


William R. Hoey
RSO and Radiation Protection Manager
PerkinElmer
617 350-9068

Item 6 – Purpose(s) For Which Licensed Material will be used.

Summary

Perkin Elmer (Tri-Carb) Liquid Scintillation spectrometer, containing Ba-133 sealed capsule source (nominal 1.0 μ Ci) manufactured by Eckert & Zeigler Strahlen. Details of source design are described in Attachment A of this application. The specified device model the B3180XX.



Tri-Carb “B” Series

The Hopkinton facility will function as the U.S. representative responsible for the exempt distribution of a liquid scintillation counter (LSC) that contains the B-133 radioactive material identified in Item 5 of the original amendment communication. Distribution reporting for this equipment will be through this E-Distribution License. The State of Massachusetts license # 56-0683 is currently being amended to authorize the possession of the Ba-133 sources installed in the liquid scintillation counter.

This device is manufactured by;

PerkinElmer Singapore PTS LTD
28 Ayer Rajah Crescent #04-01/08
Singapore 133359

PerkinElmer Health Sciences, Inc of Hopkinton, MA will act as the initial importer and distributor in the United States for the device described below. This exempt reference sources installed in the liquid scintillation counting equipment will be received from the Singapore manufacturing facility under the State of Massachusetts specific possession license #56-0683. The exempt sources will then be distributed under this exempt distribution license to persons exempt under 10 CFR Part 32. Records and processes will be maintained to ensure that the sources subsequently transferred back to the U.S. for distribution from the Hopkinton facility are the same product as described in this original distribution license application and amendments.

This activity of reference source contained in this device is below the criteria requiring leak testing per NUREG-1556, vol. 3 §5.1.1.

10.2 Conditions of Use

The intended users of this product are specific licensees and persons exempt from licensing. These devices are used for counting samples for radioactivity using a liquid scintillation cocktail solution. The devices will typically be used in a laboratory environment.

The external standard radioactive source is placed adjacent to a sample to produce scintillation in the sample for the purpose of monitoring the sample's quench level. The Tri-Carb instrument uses an exempt quantity Ba-133 source for this purpose.

The devices receive routine maintenance and evaluation by PerkinElmer field engineers on a periodic basis. This is typically done yearly, but the frequency can be extended based on usage and operating conditions.

10.3 Construction of the Product

The general design and source configuration are shown in Appendix A. The Ba-133 source is a registered source (#CA0510S117S). It is a stainless steel construction attached to a spring delivery system to position the source for reference measurements prior to counting samples.

The device includes error messages for Source positioning.

Ext Std in

The external standard mechanism has not sensed that the source has traveled to the in position. *See the Elevator drive section* for testing motors and sensors and jam conditions.

Ext Std out

The external standard mechanism has not sensed that the source has traveled to the out position. *See the Elevator drive section* for testing motors and sensors and jam conditions

The elevator is driven by two stepper motors, two lead screws, and two blocks on the lead screws to raise and lower the vials and the external source (See Elevator Assembly in Appendix A). The motors operate the lead screws that engage the elevator springs. The elevator springs are connected to a block that is driven by the lead screw and a flexible spring that is going through a rod. The spring allows the linkage to be driven from a plane other than vertical plane of the toad tube. The same concept exists for the external standard.

10.4 Labeling

A radioactive material label is placed so that it clearly identifies the source storage/source subassembly, the manufacturer of the product, the name of the radionuclide and the quantity of activity.

In addition to the required labeling of the product, the accompanying product brochure/manual will state the following;

- That the contents are exempt from the NRC or Agreement State licensing,
- Bear additional wording "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",
- Although the quantities of radioactive material contained in these products is extremely small, the basic radiation principles of time, distance, and shielding should be practiced as effective methods for minimizing exposure,
- This Exempt quantity licensed device containing radioactive material should be used only as intended by PerkinElmer and in accordance with the instructions provided with the product,
- All radioactive materials should be securely stored when not in use in accordance with the product design, and the radioactive material should not be accessed by other than authorized personnel, and
- This exempt distribution device may be disposed of in regular waste without regard to their radioactive content providing the customer is *not* a specific licensee and all radiation symbols have been removed or defaced. If the customer (laboratory/academic institution) receiving the exempt quantity *is* a specific licensee, then the customer is subject to the requirements of 10 CFR Part 20 in areas where 10 CFR 30.18 is silent (e.g., waste disposal).

10.5 Prototype Testing

These devices have a long history of operations with no significant problems identified for source degradation or failure.

10.6 Radiation Profiles

The radiological hazard posed by the encapsulated Ba-133 (1.0 μ Ci) source is minimal. The dose rate at one foot from this source is at background levels. The only potential hazard is from direct handling of the source, with dose rates to the finger tips of about 2 mrem/hr for the Ba-133 source. The sources cannot be accessed without dismantling the devices, and ignoring localized labeling warning against accessing the sources. During normal use of these devices, there is no radiological hazard from these devices.

Internal exposure to the radioactive material is not considered feasible. However even in that eventuality, the maximum internal dose to an individual would be significantly less than the annual limit for a member of the public in 10 CFR Part 20.

10.7 Quality Assurance and Quality Control

PerkinElmer Health Services, Inc of Hopkinton, MA is responsible for ensuring that configuration control and quality control is maintained for these devices. In accordance with ISO 9001:2008, the quality program review inputs will include the following aspects to assure compliance with these license application disclosures:

- Review of PerkinElmer Singapore Internal Audit Reports for potential impact to quality of products being produced;
- Review of Field Engineer discrepancy reports from field service activities,
- Customer Feedback;
- Review of applicable preventative or corrective actions from the manufacturing processes;
- Follow-up review to audit recommendations and corrective actions; and
- Review of production records associated with the Singapore manufacture of the device identified above.

The Singapore PerkinElmer Quality Assurance Manual has been reviewed against ISO 13485:2001, Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes; and ISO 9001:2008, Quality Management Systems – Requirements. Independent Audits of Singapore facility will be initiated by PerkinElmer Health Sciences, Inc. for adverse manufacturing quality discrepancies identified during Field Engineer maintenance and repair activities, or customer feedback.

In addition, a specific audit using Appendix G from NUREG-156, Vol. 3 was used to assess the readiness of the Singapore facility, and to ensure that the products provided under this possession and manufacturing license will meet expected safety standards of the Nuclear Regulatory Commission. All corrective actions for this audit are tracked internal to PerkinElmer, Hopkinton.

An assessment of the Singapore operations will be performed by PerkinElmer, Hopkinton of the Singapore Facility on a three year recurrent basis. This assessment may include on-site assessment as well as review by independent third party assessments.

10.8 Installation, Servicing, and Instructions to Users

During installation by the field service engineer, the ES (External Standard) spring assembly is inspected for operation and wear. If worn on one side, the source in the spring is rotated 90 degrees. This inspection is also done during periodic field service checks (ref; Preventative Maintenance Check List). The action of the external standard as it moves in and out of the counting chamber may cause wear on one side of the source.

Field Service Engineers (FSE) are trained and qualified to perform maintenance on the devices described in this license amendment. Initial set up and installation are performed by the field engineers as part of the purchase and sales agreement with the customers. In addition, the Ba-133 source actuation system is only serviced by these FSEs. The radioactive sources cannot be removed or disposed of by Generally Licensed entities. Sources are only removed for disposal by qualified engineers.

ATTACHMANT A
Detailed Design Information of the Ba-133 Source Configuration

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCES
(AMENDED IN ITS ENTIRETY)

NO.: CA0510S117S

DATE: November 18, 2008

PAGE: 1 of 4

SEALED SOURCE TYPE: Calibration Check Source

MODEL: IND1401
IND1403

MANUFACTURER / DISTRIBUTOR: Eckert & Ziegler Isotope Products
dba Isotope Products Laboratories
24937 Avenue Tibbitts
Valencia, CA 91355
(661) 309-1010 (voice)
(661) 257-8303 (FAX)

ISOTOPE: Any radionuclide with atomic numbers 3-83
Cobalt-57

MAXIMUM ACTIVITY: 200 microcuries (7.4 MBq)
30 millicuries (1.11 MBq)

LEAK TEST FREQUENCY: Six (6) months

PRINCIPAL USE: (I) Calibration Source (Activity greater than 30 mCi)

CUSTOM SOURCE: Yes No

DESCRIPTION:

The IND1401 was originally designed to meet the requirements set forth by Packard Instrument Company ("Instrument Manufacturer") for the use in their liquid scintillation counters. The IND1403 is intended for calibration applications where a special threading and a rounded end is not required during normal use. For both the IND1401 and IND1403 configurations, Eckert & Ziegler Isotope Products ("Source Manufacturer") specifies that the activity is absorbed on a ion exchange resin bead ~0.8 mm in diameter. The IND1401 capsule will measure approximately 0.115" in diameter by 0.200" in length with a 0.230" threaded extension making an overall length of 0.200". Both configurations are constructed on either 304 or 316L stainless steel. The active element is loaded and a stainless steel plug is fusion welded into place to complete the containment.

The source activity range shall be +20% and -10% for all models.

LABELING:

The source is engraved with nuclide, nominal activity, and serial number. Due to the dimensional limitations, inherent to the source, "IPL", reference date, and the standard radiation caution symbol cannot be included on the capsule.

The source storage and shipping container is labeled with Eckert & Ziegler Isotope Products, the radiation symbol, isotope, activity, serial number, reference date, and the words, "CAUTION-RADIOACTIVE MATERIAL."

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SEALED SOURCE TYPE: Calibration Check Source

DIAGRAM:

Attachment 1: IND1401 Gamma Source
Attachment 2: IND1403 Gamma Source

CONDITIONS FOR NORMAL USE:

These sources are normally placed inside a shielding housing during normal working conditions or attached to a threaded rod for use and stored in the supplied shielded container when not in use. The source is used under normal laboratory, controlled laboratory, or controlled field conditions. **The calibration check sources** should not be subjected to conditions of normal use which require a higher rating than ANSI N542-1977, classification of ANSI 77C64545. **Other applications of a research and development nature are acceptable provided that the sources are not subjected to environmental conditions exceeding those listed above.** Typical useful life of the line source is dependent on nuclide:

Nuclide	Typical Useful Life
Barium-133	5
Cadmium-109	2
Cesium-137	10
Cobalt-57	2
Gadolinium-153	2
Germanium-68	2
Sodium-22	5

PROTOTYPE TESTING:

Prototype sources of Model IND1401 have undergone testing per ANSI N542-1977 and have been classified as ANSI 77C64545. This exceeds the required rating of ANSI 77C22212 for "Calibration Sources—Activity greater than 30 μ Ci" as defined in ANSI N542-1977 and Packard Instrument Company's testing requirements of ANSI 77C32232. The vibration rating of a "4" was determined based on the test data for the Model IND1050, which has a similar weld area (Refer to previous SS&DR No. CA0510S107S).

EXTERNAL RADIATION LEVELS:

External radiation levels were measured utilizing a calibrated 100 μ Ci Co-57 source in the capsule described. Radiation levels were measured using an Eberline RO-2 Portable Ionization Chamber with a 7 mg/cm^2 window to allow for low energy photon contribution. The source was positioned at distances of 5 cm, 10 cm, and 30 cm as measured from the face of the capsule to the centerline of the ion chamber. The exposure rates in mR/hr for a maximum loading were calculated, as listed below:

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
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SEALED SOURCE TYPE: Calibration Check Source

Co-57 Calibration Sources

Activity	Distance from Source (mR/hr)		
	5 cm	10 cm	30 cm
100 μ Ci	1.8	0.2	Background
30 mCi	240	60	6

QUALITY ASSURANCE AND CONTROL:

Program: The EZIP Quality Manual details the quality control of these sources from raw materials to finished product. The program is designed to satisfy 10 CFR Part 50 (B) and is ISO 9001 and ISO 13485 certified. The program covers design and document control, purchasing, training, calibration records, source numbering, production, incoming raw materials, assay quality control, leak testing, and confirming orders.

Activity: Activity levels are held to within +20%/-10% of nominally desired activity, but will not exceed the maximum limits stated on page 1 of this registry certificate.

Eckert & Ziegler Isotope Products maintains a quality management system program, which has been deemed acceptable for licensing purposes by the California Department of Public Health. A copy of the program is on file with the California Department of Public Health.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- These sources shall be distributed to persons specifically licensed by the U.S. Nuclear Regulatory Commission, an Agreement State, or Licensing State.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.
- The source shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcuries (185 Bq) of removable contamination.
- These sources are designed for use in controlled laboratory conditions and should not be subjected to conditions exceeding their ANSI N542-1977 classification of 77C64545.
- The registration sheet and the information contained within the references shall not be changed without the written consent of the California Department of Public Health.

SAFETY ANALYSIS SUMMARY

Based on a review of the Models IND 1401 and IND 1403 sealed sources, its ANSI classification, and the information and test data cited below, we continue to conclude that the source is acceptable for licensing purposes.

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SEALED SOURCE TYPE: Calibration Check Source

Furthermore, we continue to conclude that the sources would be expected to maintain its containment integrity for normal conditions of use and accidental conditions, which might occur during uses specified in this certificate.

REFERENCES:

The following supporting documents of Models **IND1401 and IND1403** are hereby incorporated by reference and made part of this registry document:

1. North American Scientific, Inc. QA/QC Manual, ASME Nqa-1-1989 Edition (on file with this licensing agency).
2. North American Scientific, Inc. letter dated June 28, 1995.
3. California registry certificate number CA0510S117S dated October 14, 1991 and December 18, 2005.
4. North American Scientific, Inc. letter dated May 10, 1996.
5. **Eckert & Ziegler Isotope Products letter dated 22 September 2008, with attachments thereto.**

ISSUING AGENCY: California Department of **Public Health**

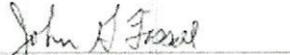
DATE: November 19, 2008

REVIEWED BY:


Bonnie Bessemer

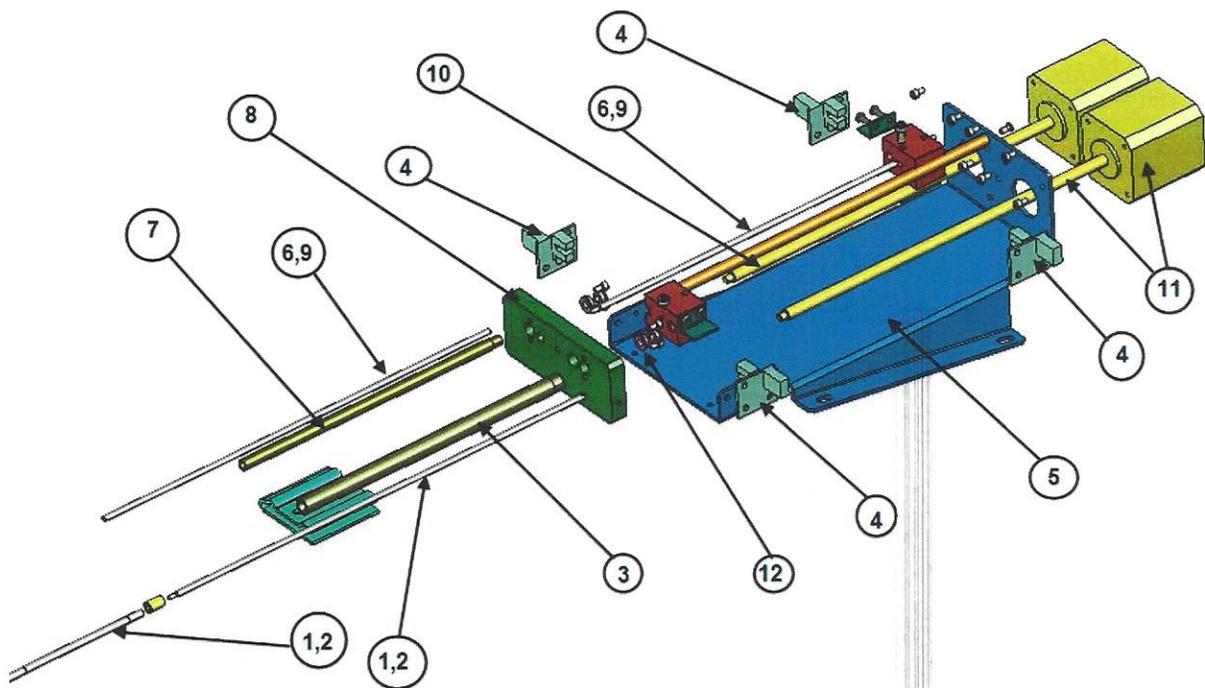
DATE: November 19, 2008

CONCURRED BY:


John Fassell



Elevator Assembly



Item	Part Number	Description
1,2	7400364	SPRING, LIFT - ELEVATOR
3	5085720	TUBE, LIFT - ELEVATOR BODY
4	7101140	INDEX SHUT ELV (qty 4)
5	5085697	CHASSIS, ELEVATOR
6,9	7400366	AES DRV SPRING
7	5085721	TUBE, LIFT - PELLET
8	5085719	PLATE, MTG. - TUBE
10	5085737	SHAFT, GUIDE - DRIVENUT
11	2004240	ASSY, ACTUATOR - LINEAR (qty 2)
12	1648835	BEARING, FLANGED (qty 2)

FedEx Express US Airbill

FedEx Tracking Number

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1 From This portion can be removed for Recipient's records

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Form ID No. 0215

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Company: PERKIN ELMER LIFE SCIENCES

Address: 647 Albany St

City: BOSTON

State: MA

ZIP: 02118-2812

Dept./Room/Station

2 Your Internal Billing Reference

3 To

Recipient's Name: MARGARET KATHAS

Phone: 508 977-0400

Company: 11575 Rockwell Ave

Recipient's Address: 11575 Rockwell Ave

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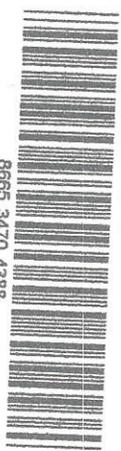
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City: BOSTON

State: MA

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8665 3470 4388

4a Express Package Service

FedEx Priority Overnight
Next business morning, ** Friday shipments will be delivered on Monday unless SATURDAY Delivery is selected.

FedEx 2Day
Second business day, ** Thursday unless SATURDAY Delivery is selected. FedEx Envelope rate applies. Minimum charge: One pound rate.

4b Express Freight Service

FedEx 1Day Freight*
Next business day, ** Friday unless SATURDAY Delivery is selected. Call for Confirmation.

5 Packaging

FedEx Envelope*
Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak.

FedEx Pak*
Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak.

FedEx Box

FedEx Tube

Other

6 Special Handling

SATURDAY Delivery
Not available for FedEx Standard Overnight, FedEx Standard Overnight, Express Saver, or FedEx Priority Overnight. Does this shipment contain dangerous goods? **One line must be checked.**

No

Yes, refrigerated. Shipper's Declaration required.

Yes

Dry Ice
Dry Ice 3, UN 1845

Cargo Aircraft Only

HOLD Saturday at FedEx Location
Not available for FedEx Priority Overnight and FedEx 2Day. Available only for FedEx Priority Overnight and FedEx 2Day to select locations.

7 Payment Bill to:

Sender Recipient Third Party Credit Card Cash/Check

Enter FedEx Acct. No. or Credit Card No. below:

Obtain Resp. Acct. No.

Cash/Check

Total Packages

Total Weight

Your liability is limited to \$100 unless you declare a higher value. See the current FedEx Service Guide for details.

8 Residential Delivery Signature Options

No Signature Required
Package may be left without obtaining a signature or for delivery.

Direct Signature
Someone at the address may sign for delivery. Fee applies.

Indirect Signature
If no one is available at the recipient's address, someone may sign for delivery. Fee applies.

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