



030-38390

October 19, 2010

RECEIVED

OCT 25 2010

DNMS

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

Gentlemen,

Medical Packaging Corporation hereby submits the attached, 4 page application for an exempt distribution materials license (E license).

The Carbon 14 sources involved (designated Model PSC0025) are presently distributed for us, to persons exempt from Regulatory authority, by Eckert & Ziegler Isotope Products under the terms of an E license held by them.

Last week, medical Packaging also submitted the required application for possession and use to the Radiologic Health branch of the California Department of Public Health.

We enclose a check for \$10,100 to cover the Materials Application Fee.

Your timely attention to our application is very much appreciated.


Sincerely,

Fredric L. Nason
President/CEO
Medical Packaging Corporation/Hygienea LLC

573840

NRC FORM 313
(3-2009)
10 CFR 30, 32, 33,
34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 3/31/2012

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 Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects.resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

OFFICE OF FEDERAL & STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

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IF YOU ARE LOCATED IN:

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

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

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

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

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

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

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

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- A. NEW LICENSE
- B. AMENDMENT TO LICENSE NUMBER _____
- C. RENEWAL OF LICENSE NUMBER _____

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

Medical Packaging Corporation
941 Avenida Acaso
Camarillo, CA 93012

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

941 Avenida Acaso
Camarillo, CA 93012

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Peter Knapp

TELEPHONE NUMBER

(949) 498-3662

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 3I AMOUNT ENCLOSED \$ 10,100.00

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

FREDRIC L. NASON PRESIDENT/CEO

SIGNATURE

F. L. Nason

DATE

10/19/10

FOR NRC USE ONLY

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

Medical Packaging Corporation – Attachment to NRC Form 313

Item 5 – Radioactive Material

Carbon 14, no single source to exceed 12 μCi
Eckert & Ziegler Isotope Products Model PSC0025

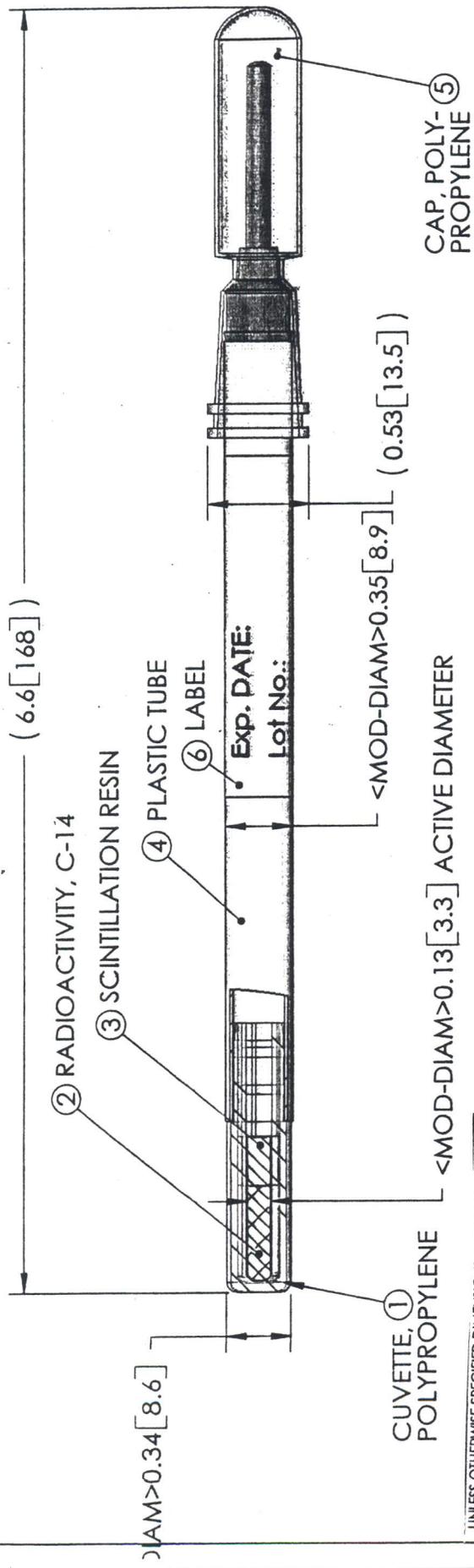
Maximum amount possessed at any one time = 9mCi

Each source consists of no more than 12 μCi of Carbon 14 uniformly mixed into approximately 0.5 mL of scintillation plastic resin which is subsequently hardened into a solid. The resin is contained within a polypropylene cuvette which has 0.04 inch thick walls and bottom. The top of the cuvette is force fitted into a sealed plastic tube with 0.014 inch thick walls. See attached drawing

Each source is labeled in a form such as that shown in the attached drawing. Each label bears the information shown in the drawing.

Item 6 – Purpose For Which Licensed Material Will Be Used

The source is the single radioactive item in a calibration control kit. The source, referred to as a positive calibration control rod, is intended only to be used to verify the calibration of a device, called the SystemSHURE luminometer, by providing a standardized light output. A copy of the instruction sheet, which is part of each calibration control kit, and which provides instructions on the use, handling and disposal of the source, is attached to this application.



UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCH-SIZES. METRIC UNITS (mm) ARE IN MILLIMETERS.

SEE NOTE 2



POSITIVE ROD (+)

Positive Test Control | Ref. Date:
 Isotope: C-14 | Exp.:
 Activity: 12 µCi | Lot No:
 Positive rod should produce a signal between
 40-70 RLU

Caution: Radioactive Material — Not for drug use.
Not harmful when used correctly.

Calibration Control Kit | Part Number: PCD4000 | Contents: One Positive Rod; One Negative Rod
Calibration Control Kit for verifying calibration of SystemSURE™ instruments.

Description/Intended Use

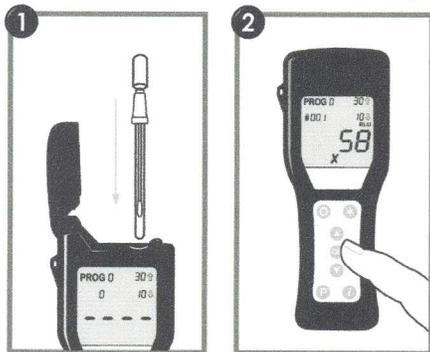
Calibration control rods in this kit are intended to be used to verify calibration of SystemSURE luminometer. Positive Rod consists of C¹⁴ radioactive source that emits very low level of low-energy β radiation in a plastic scintillation matrix. Matrix is configured to give constant light output, within 10% of its original value, at sufficiently high level for up to five years. Negative Rod is used to check for possible background light getting into instrument or light detector not calibrating correctly. Negative Rod produces low-light (0-2) RLU background. It is recommended to verify calibration with Calibration Control Kit each week or every other week depending on use and Quality Control Program requirements. Incorporating Calibration Control Kit into overall Quality Control program will validate instrument is within specifications and operating correctly.

Shelf Life: Five (5) years from date on Positive Rod .

Storage: Store at 15°-25°C (59°-77°F) in box rods were received in or dark container. Store away from light.

Directions for Use:

Positive and Negative Rods are inserted and read in luminometer in the same manner as ATP sample device. Calibrations rods do not need to be activated like the ATP sample device. Do not attempt to activate Positive or Negative Rod.



1. Open sample chamber and insert Positive Rod. Close lid. Let sit for 1 minute.
2. Press “OK” and take reading as normal.
3. Record result. Repeat step 2 another two times and record results. Compute the average of these three readings and enter it in the Positive Rod Reference No. box below. Repeat steps 1 through 3 for each luminometer being checked with this Positive Rod.
4. Repeat steps using Negative Rod.

Positive Rod Reference No.				
Instrument Serial No.	Test 1	Test 2	Test 3	Average

Retain the Positive Rod Reference No.

Interpreting Positive and Negative Control Results

Positive Rod in a correctly calibrated SystemSURE luminometer should read between 40 - 80 RLU. The Positive Rod Reference No. should not vary by more than +/- 20%. If the results from the Positive Rod are outside of the RLU range or vary by +/- 20% from the Positive Rod Reference No. then the machine should be sent in for service. Negative Rod should read between 0 – 2 RLU.

Incorporating the Calibration Control Kit into a Quality Control Program

Calibration Control Kit is designed to be incorporated into a Quality Control Program that monitors and tracks performance of Hygiena equipment and/or devices. When using calibration control rods to verify measurability of a luminometer, it is recommended that a specific program point (e.g. PROG 250) be assigned for results. All results can be viewed directly from luminometer or in the data analysis software.

Causes for Inconsistent Calibration RLU Readings

Several factors can cause RLU readings to be outside acceptable range. Possible causes are:

- Dirty or damaged calibration rods. Clean outside of both rods with lint-free cloth that has been dipped in reagent-grade isopropyl or ethyl alcohol. Air dry and repeat reading. Return damaged calibration rods to Hygiena for replacement.
- SystemSURE luminometer contamination. Results that have changed suddenly, especially immediately after a number of sampling devices have been run, can indicate contamination problems. Results from calibration rods can increase or decrease as result of foreign materials disturbing optics chamber of instrument. If contamination is suspected in SystemSURE, remove read chamber and clean. See owner's manuals on how to clean read chamber.
- Scratches on glass bottom do not affect readings.
- Exposure to light. Inconsistent readings arise if calibration rods are exposed to intense light prior to being read. Insert calibration rods into SystemSURE and wait minimum of 2 minutes before taking reading.

Handling and Disposal

To ensure stability and longevity of calibration rods, take following steps:

- Limit exposure to light. Store calibration rods in dark or weak ambient light. Kit box provided is recommended as appropriate dark storage. Do not expose to direct sunlight or intense artificial light for too long before use.
- Handle with care. Avoid crushing, cutting, or dropping calibration rods. Any damage that changes shape or light transmission properties of the Positive Rod can affect assigned values.
- Disposal. For U.S. and Canadian customers: Level of radioactive material in Positive Rod does not require special hazardous waste treatment, per U.S. Federal regulations governing use and transfer of excepted radioactive materials. The contents of the Positive Rod are exempt from NRC or Agreement State licensing requirements. Positive Rod contains extremely small amounts of radioactive carbon-14, completely contained by the outer housing of the device. There are no radioactive emissions on the surface of the device, and no special precautions are needed in handling the device to avoid exposure. Positive Rod is designed for use and storage at room temperature; prolonged exposure to extreme heat or cold should be avoided. Do not use if the scintillator tip of the device is cracked or damaged.
- To dispose of Positive Rod, remove or deface “Caution Radioactive Materials” label on rod. Positive Rod may then be disposed of in trash. For disposal requirements in other countries, check with your national and local supplier. For questions, contact Hygiena at enquiries@hygiena.net or the Hygiena distributor from whom product was purchased.
- Radioactive Material – Not for Human Use – Introduction into foods, beverages, cosmetics, drugs, or medicinal products, or into products manufactured for commercial distribution is prohibited. Exempt quantities should not be combined.

Align top of **FedEx Express Shipping Label** here.

ORIGIN ID: OXRA (805) 388-2383
SHIPPING
MEDICAL PACKAGING
941 AVENIDA ACASO

SHIP DATE: 21OCT10
ACTWGT: 0.3 LB
CAD: 344930/CAFE2470

CAMARILLO, CA 93012
UNITED STATES US

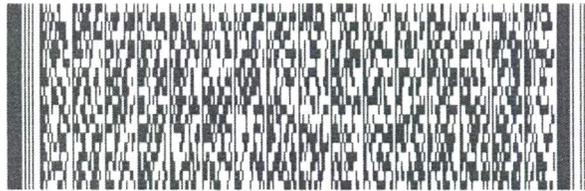
BILL SENDER

**TO NUCLEAR MATERIAL LICENSING BRANCH
NUCLEAR REGULATORY COMMISSION
612 E LAMAR BLVD
SUITE 400
ARLINGTON TX 760114125**

REF: RICHARD CURTIS

PO: FED-EX ENVELOPE

DEPT: DOCUMENTS



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0201

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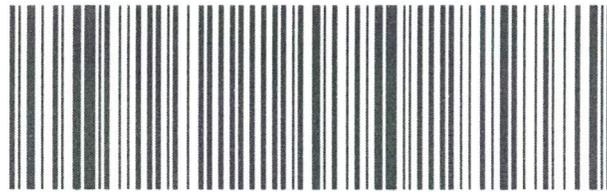
SE FWHA

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Part # 156143-434 NRIT V3 05-09



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