



Pfizer Inc
Environmental, Health & Safety

Timothy L. Popp
7000 Portage Road
Kalamazoo, MI 49001-0199
Tel (269) 833-9364 Fax (269) 833-9400
Email timothy.l.popp@pfizer.com

July 30, 2012

U.S. Nuclear Regulatory Commission, Region III
Nuclear Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Dear Sir:

Pharmacia & Upjohn Company LLC (a subsidiary of Pfizer Inc.) requests a new NRC byproduct material license for its manufacturing facility located at 7000 Portage Road, Kalamazoo, Michigan. This facility is presently authorized to use radioactive materials under NRC byproduct material license number 21-00182-03 along with three other Pfizer facilities located in the nearby area. Pfizer has announced plans to divest its animal health holdings in the near future. As part of that divestiture, the Pharmacia & Upjohn Company LLC facility located at 7000 Portage Road, Kalamazoo, Michigan will remain a subsidiary of Pfizer Inc. However, the other three facilities listed in NRC license number 21-00182-03 (333 Portage Street and 2605 East Kilgore Road, Kalamazoo, and 5300 N. 28th Street, Richland) will be divested.

Pfizer would like to separate the 7000 Portage Road facility from the current NRC license (21-00182-03) by requesting a separate new license for the 7000 Portage Road facility, thus simplifying separating these facilities, and their respective licenses, when Pfizer decides to divest the animal health holdings in the future. Upon approval of this new license request, Pfizer will request an amendment to license 21-00182-03 in order to remove the 7000 Portage Road facility from that license. As required by 10 CFR 30.34(b) and as soon as information is available about the diversified company legal entity, Pfizer will notify and obtain NRC's prior written consent before transferring control of license 21-00182-03.

The facility located at 7000 Portage Road, Kalamazoo, Michigan only uses fixed nuclear gauges for the purpose of measuring level or density of materials used in the manufacturing of pharmaceuticals. These gauges have been authorized under NRC license 21-00182-03 for at least twenty years. At least until the animal health business is divested, the same Radiation Safety Officer and radiation safety program controls will be utilized under the new NRC license as is presently utilized under the existing NRC license.

TLP12016

RECEIVED JUL 31 2012

Attached please find a completed NRC Form 313 "Application for Materials License" along with supplementary pages addressing the additional information requested in Items 5 through 11 of the application form requesting a new NRC materials license for the 7000 Portage Road, Kalamazoo, Michigan facility. Please feel free to contact me should you require any additional information or clarification regarding this request.

Sincerely,

A handwritten signature in black ink, appearing to read "Timothy L. Popp". The signature is fluid and cursive, with a long horizontal stroke at the end.

Timothy L. Popp
Radiation Safety Officer

TLP12016

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.

<p>1. THIS IS AN APPLICATION FOR (Check appropriate item)</p> <p><input checked="" type="checkbox"/> A. NEW LICENSE</p> <p><input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____</p> <p><input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____</p>	<p>2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)</p> <p>Pharmacia & Upjohn Company LLC 7000 Portage Road Kalamazoo, MI 49001</p>
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<p>3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED</p> <p>7000 Portage Road Kalamazoo, MI 49001</p>	<p>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</p> <p>Timothy Popp</p> <table border="1"> <tr> <td>BUSINESS TELEPHONE NUMBER</td> <td>BUSINESS CELLULAR TELEPHONE NUMBER</td> </tr> <tr> <td>(269) 833-9364</td> <td></td> </tr> <tr> <td colspan="2">BUSINESS EMAIL ADDRESS</td> </tr> <tr> <td colspan="2">timothy.l.popp@pfizer.com</td> </tr> </table>	BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER	(269) 833-9364		BUSINESS EMAIL ADDRESS		timothy.l.popp@pfizer.com	
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timothy.l.popp@pfizer.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.

<p>5. RADIOACTIVE MATERIAL</p> <p>a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.</p>	<p>6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.</p>				
<p>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.</p>	<p>8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.</p>				
<p>9. FACILITIES AND EQUIPMENT.</p>	<p>10. RADIATION SAFETY PROGRAM.</p>				
<p>11. WASTE MANAGEMENT.</p>	<p>12. LICENSE FEES (See 10 CFR 170 and Section 170.31)</p> <table border="1"> <tr> <td>FEE CATEGORY</td> <td>AMOUNT ENCLOSED</td> </tr> <tr> <td>3P</td> <td>\$ 1,500.00</td> </tr> </table>	FEE CATEGORY	AMOUNT ENCLOSED	3P	\$ 1,500.00
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3P	\$ 1,500.00				

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.

<p>CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE</p> <p>Gary Spies Director, Environment, Health, Safety</p>	<p>SIGNATURE</p> 	<p>DATE</p> <p>7/17/12</p>
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FOR NRC USE ONLY

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

Items 5 & 6: Materials To Be Possessed and Proposed Uses

Radioisotope	Manufacturer or Distributor Model No.	Quantity	Use As Listed on SSD Certificate	Specify Other Uses Not Listed on SSD Certificate
Cesium-137	Kay Ray Model 7062BP	Not to exceed either the maximum activity per source or maximum activity per device as specified in Sealed Source and Device Registration Certificate	Yes. For use in measuring the fluid level in a process tank	Not applicable
Cesium-137	TN Technologies Model 5200	Not to exceed either the maximum activity per source or maximum activity per device as specified in Sealed Source and Device Registration Certificate	Yes. For use in measuring the fluid level in a process tank or the solids level in a chute at inlet to pump	Not applicable
Cesium-137	TN Technologies Model 5205	Not to exceed either the maximum activity per source or maximum activity per device as specified in Sealed Source and Device Registration Certificate	Yes. For use in measuring the slurry level in a process tank	Not applicable
Cesium-137	Thermo Measure Tech Model 5201	Not to exceed either the maximum activity per source or maximum activity per device as specified in Sealed Source and Device Registration Certificate	Yes. For use in measuring the fluid level in a process tank	Not applicable

Possession of fixed gauges will be limited to quantities not requiring financial assurance.

Item 7: Individual(s) Responsible For Radiation Safety Program And Their Training Experience

7.1 Radiation Safety Officer

The proposed Radiation Safety Officer for this license is Timothy Popp.

Before obtaining licensed materials, the proposed RSO will have successfully completed the training described in Criteria in the section entitled "Individual(s) Responsible for Radiation Safety Program and Their Training and Experience - Radiation Safety Officer" in NUREG-1556, Vol. 4, dated October 1998; **AND** before being named as the RSO, future RSOs will have successfully completed the training described in Criteria in the section entitled "Individual(s) Responsible for Radiation Safety Program and Their Training and Experience - Radiation Safety Officer" in NUREG-1556, Vol. 4, dated October 1998. Within 30 days of naming a new RSO, we will submit the new RSO's name to NRC to include in our license.

7.2 Authorized Users

Before using licensed materials, authorized users will have successfully completed the training described in Criteria in the section entitled, "Authorized Users" in NUREG-1556, Vol. 4, dated October 1998.

Item 8. Training For Individuals Working In Or Frequenting Restricted Areas

Training programs for individuals who in the course of employment are likely to receive occupational doses of radiation in excess of 1 mSv (100 mrem) in a year (occupationally exposed workers) and ancillary personnel need not be submitted with the licensing application.

Item 9. Facilities And Equipment

We will ensure that the location of each fixed gauge meets the Criteria in the section entitled "Facilities and Equipment" in NUREG-1556, Vol. 4, dated October 1998.

Item 10. Radiation Safety Program

10.1 Audit Program

Need not be submitted with application.

10.2 Instruments

We will use instruments that meet the Criteria in the section entitled "Radiation Safety Program - Instruments," in NUREG-1556, Vol. 4, dated August 1998. Each survey meter will be calibrated by the manufacturer or other person authorized by the NRC or an Agreement State to perform survey meter calibrations.

10.3 Material Receipt And Accountability

Physical inventories will be conducted at intervals not to exceed 6 months or at other intervals approved by the NRC, to account for all sealed sources and devices received and possessed under the license.

10.4 Occupational Dose

We will perform a prospective evaluation demonstrating 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 or we will provide dosimetry that meets the Criteria in the section entitled "Radiation Safety Program - Occupational Dosimetry," in NUREG-1556, Vol. 4, dated October 1998.

10.5 Public Dose

Need not be submitted with application.

10.6 Operating And Emergency Procedures

Operating and emergency procedures will be developed, implemented, maintained, and distributed, and will meet the Criteria in the section entitled "Radiation Safety Program - Operating and Emergency Procedures," in NUREG-1556, Vol. 4, dated August 1998.

10.7 Leak Test

Leak tests will be performed at intervals approved by the NRC or an Agreement State and specified in the Sealed Source and Device Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services for other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide leak test kits to other licensees and according to the kit supplier's instructions.

10.8 Maintenance

ROUTINE MAINTENANCE

We will implement and maintain procedures for routine maintenance of our fixed gauges according to each manufacturer's or distributor's written recommendations and instructions.

NON-ROUTINE MAINTENANCE OPERATIONS

The gauge manufacturer, distributor or other person authorized by NRC or an Agreement State will perform non-routine operations such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement, and disposal of sealed sources, alignment, or removal of a gauge from service.

10.9 Transportation

Need not be submitted with application.

10.10 Fixed Gauges Used At Temporary Job Site

This is not applicable to our program. We will not use fixed gauges at temporary job sites.

10.11 Minimization Of Contamination

Need not be submitted with application.

Item 11. Waste Managemt

11.1 Gauge Disposal And Transfer

Need not be submitted with application.

From: (269) 833-9364
Timothy Popp
PFIZER
333 Portage Street
Kalamazoo, MI 49007

Origin ID: HAIA



Ship Date: 30JUL12
ActWgt: 1.0 LB
CAD: 103269545/NET3300

Delivery Address Bar Code



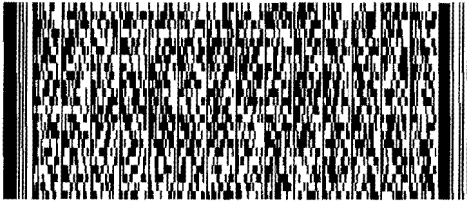
SHIP TO: (630) 829-9500 **BILL SENDER**
Nuclear Materials Licensing Section
US NRC
2443 WARRENVILLE RD
STE 210
LISLE, IL 60532

Ref # PGS NRC Lic App
Invoice #
PO #
Dept #

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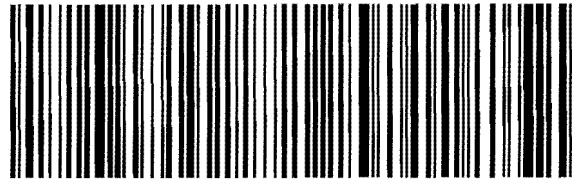
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