



**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

November 12, 2012

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

Dear Ms. Simmons:

In accordance with our recent telephone conversation, Pharmacia & Upjohn Company LLC (P&U) is requesting a correction/amendment to the recently approved NRC license amendment dated October 22, 2012 (NRC byproduct material license 21-00182-03 amendment no. 71). Specifically, a new license condition no. 17 was added requiring the licensee to conduct a physical radioactive material inventory every six months. This condition did not previously exist in the license other than for the physical inventory of sealed sources and devices containing radioactive materials.

As part of P&U's NRC license application dated December 21, 2004 referenced in the tie-down letters in condition no. 18 of the current license and in accordance with NUREG-1556 Vol. 11, P&U described its radioactive material receipt and accountability program. A copy of that pertinent section from the application is attached. In these procedures, P&U committed to maintain a radioactive material inventory log and to update the radioactive material inventory to reflect usage and new acquisitions at least once per quarter. P&U utilizes an electronic database to maintain this inventory log and actually requires its users to update the inventory on a much more frequent basis than quarterly.

The addition of condition no. 17 to P&U's license requiring a physical radioactive material inventory every six months is unnecessary in terms of what P&U has already committed to in the license application. Furthermore, the addition of this condition limits the broad scope license operational flexibility previously granted the licensee by the NRC to change these administrative procedures through the oversight of its Radiation Safety Committee. Therefore, the licensee requests that condition no. 17 be removed from the license.

Please feel free to contact me should you require any additional information regarding this request.

Sincerely,

Timothy L. Popp  
Radiation Safety Officer

RECEIVED NOV 13 2012

TLP12026

**Radiation Safety Program**  
**Receipt & Control of Radioactive Material Administrative Procedures**

5.11 Receipt and Control of Radioactive Material

5.11.1 Purchase of radioactive materials shall require the approval of the radiation safety staff.

**Note: RSO approval serves as an indication that P&U is licensed to possess the materials solicited, and that the materials, once received, will be incorporated into the routine surveillance and accountability program.**

5.11.2 Incoming packages, known or suspected to contain radioactivity at levels significantly higher than background, shall be monitored for exposure rate and removable external contamination, pursuant to 10 CFR 20.1906.

5.11.3 Radioactive material shall be marked as such to ensure proper handling and storage.

**Note: Markings may include tags or stickers indicating "Radioactive Materials".**

5.11.4 Items identified as radioactive materials shall be maintained in a radioactive material storage area established for this purpose within a restricted area.

5.11.5 Samples of radioactive material received by P&U shall be:

5.11.5.1 Entered in a radioactive material inventory log; and

5.11.5.1.1 The log shall be maintained to assure compliance with maximum possession limits established in the USNRC license.

5.11.5.1.2 The radioactive material inventory shall be updated at least once per calendar quarter to reflect usage and new acquisitions.

5.11.5.2 Assigned to an ARI.

5.11.6 Sealed sources of source, by-product or accelerator-produced material received by P&U shall be:

5.11.6.1 Entered in a sealed source log;

5.11.6.2 Assigned to a Sealed Source Owner; and

5.11.6.3 Tested for leakage and/or removable contamination at the frequency shown in Attachment 2.

5.11.7 Revisions to Receipt and Control of Radioactive Material

5.11.7.1 Administrative controls and provisions relating to material control, accounting, and security may be changed without amendment to our NRC license with completion of the following:

5.11.7.1.1 Initial review and approval of the RSO to confirm that the change meets the requirements of 10 CFR 20.1906 and intent of Appendix P in NUREG 1556, Vol. 11;

5.11.7.1.2 Review and approval by the RSC; and

5.11.7.1.3 Documentation of the specific change in the RSC meeting minutes, including a summary of the reason for the change and the safety matters considered in the approval process.

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

Origin ID: HAIA



Ship Date: 12NOV12  
ActWgt: 1.0 LB  
CAD: 103269545/INET3300

Delivery Address Bar Code



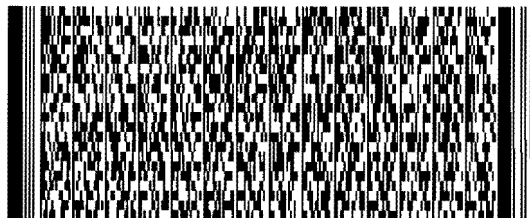
SHIP TO: (630) 829-9842  
**Toye Simmons**  
**US NRC, Region III**  
**2443 WARRENVILLE RD**  
**STE 210**  
**LISLE, IL 60532**

**BILL SENDER**

Ref # NRC Lic Amend  
Invoice #  
PO #  
Dept #

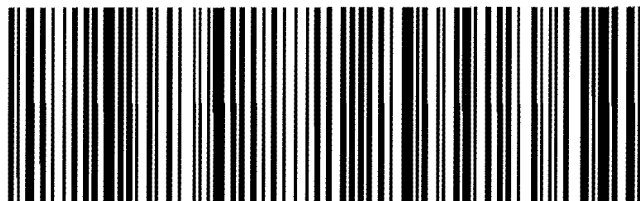
**TUE - 13 NOV A1**  
**STANDARD OVERNIGHT**

TRK# 7940 5101 7363  
0201



**XH ENLA**

**60532**  
IL-US  
**ORD**



515G3/EE3B/AA44

**After printing this label:**

1. Use the 'Print' button on this page to print your label to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

**Warning:** Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com. FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$1,000, e.g. jewelry, precious metals, negotiable instruments and other items listed in our ServiceGuide. Written claims must be filed within strict time limits, see current FedEx Service Guide.