

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Pharmacia & Upjohn Company LLC 7000 Portage Road Kalamazoo, Michigan 49001 REPORT NUMBER(S) 2009-001		2. NRC/REGIONAL OFFICE Region III U.S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532-4351	
3. DOCKET NUMBER(S) 030-04781	4. LICENSEE NUMBER(S) 21-00182-03	5. DATE(S) OF INSPECTION October 26 - 27 , 2009	

LICENSEE:
 The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

1. Based on the inspection findings, no violations were identified.

2. Previous violation(s) closed.


3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

_____ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
 (Violations and Corrective Actions)

Licensee's Statement of Corrective Actions for Item 4, above.

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Geoffrey M. Warren		10/27/09

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6. INSPECTION PROCEDURES USED 87126, 87184		7. INSPECTION FOCUS AREAS 03.01 - 03.07, 03.01 - 03.07	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03610	2. PRIORITY 3	3. LICENSEE CONTACT Timothy Popp, RSO	4. TELEPHONE NUMBER 269-833-9364
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<input checked="" type="checkbox"/> Main Office Inspection	Next Inspection Date: <u>Oct. 2012</u>
<input checked="" type="checkbox"/> Field Office <u>333 Portage St, Kalamazoo; 2605 E. Kilgore Rd., Kalamazoo; 5300 N. 28th St., Richland, MI</u>	
<input type="checkbox"/> Temporary Job Site Inspection	

PROGRAM SCOPE

The licensee was a subsidiary of Pfizer, Inc., employing around 3500 personnel at facilities as describe in the license in and around Kalamazoo, Michigan. Licensee personnel performed research and development for animal pharmaceuticals under a non-medical broadscope license and produced pharmaceuticals for human and animal use. The radiation safety staff consisted of the Radiation Safety Officer (RSO) and a part-time consultant technologist to perform surveys and audits. The radiation safety committee met quarterly to approve research projects and personnel and to discuss issues concerning the use of licensed materials. All licensed materials were received by the RSO before distribution to appropriate areas. The office of the licensee's RSO was located at 333 Portage St. in Kalamazoo.

The licensee performed research using licensed materials, limited to tritium and carbon-14, in approximately 20 laboratories at the 333 Portage St. facility in Kalamazoo and the facility in Richland. In these laboratories, research, including animal research, was performed by around twenty personnel, of whom twelve were Authorized Radioisotope Investigators (ARIs). The RSO considered five of the ARIs to be frequent users of licensed materials.

The remaining facilities were production facilities, using 13 fixed gauges as described on the license to control production processes. Each area where gauges were used had an individual supervisor who was responsible for overseeing their use and safety. The licensee possessed two additional gauges (one generally-licensed) and three nickel-63 gas chromatograph sources in secured storage. In addition, the licensee possessed two generally-licensed portable devices for metal analysis; these devices were used only at the facility at 7000 Portage Rd. in Kalamazoo. The portable devices were kept in secured storage when not under supervision.

Performance Observations

The inspector toured laboratory and radiation safety areas, and observed sixteen of the licensee's twenty fixed and portable gauges. Licensee personnel demonstrated package receipt surveys, survey meter QC, laboratory surveys, and portable gauge use, and described approval of new ARIs, laboratory procedures, lockout/tagout procedures, gauge inventory and testing, training, auditing, and other activities. The inspector noted no issues with these activities. The inspector reviewed radiation safety committee minutes and noted no concerns. Interviews with licensee personnel indicated adequate knowledge of radiation safety practices and concepts. Surveys indicated radiation levels consistent with licensee postings and survey records.

