



Materials Inspection Report

1. Licensee/Location Inspected: Pharmacia & Upjohn Company LLC 7000 Portage Road Kalamazoo, MI 49001 Report Number(s) 2022-001	2. NRC/Regional Office Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. Docket Number(s) 030-38566	4. License Number(s) 21-32848-04	5. Date(s) of Inspection November 17, 2022

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. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.
 - A. 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, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.
 (Non-cited violation(s) was/were discussed involving the following requirement(s))
 - B. The following violation(s) is/are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
 (Violations and Corrective Actions)

Statement of Corrective Actions

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 AND DATE
LICENSEE'S REPRESENTATIVE		
NRC INSPECTOR	Ryan Craffey	 <small>Digitally signed by Ryan J. Craffey Date: 2022.12.06 16:36:36 -05'00'</small>
BRANCH CHIEF	Rhex Edwards	 <small>Digitally signed by Rhex A. Edwards Date: 2022.12.14 06:20:24 -06'00'</small>



Materials Inspection Record

1. Licensee Name: Pharmacia & Upjohn Company LLC	2. Docket Number(s): 030-38566	3. License Number(s) 21-32848-04
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4. Report Number(s): 2022-001	5. Date(s) of Inspection: November 17, 2022
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6. Inspector(s): Ryan Craffey	7. Program Code(s): 03121	8. Priority: 5	9. Inspection Guidance Used: IP 87121
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10. Licensee Contact Name(s): Tim Fedewa - RSO	11. Licensee E-mail Address: timothy.j.fedewa@pfizer.com	12. Licensee Telephone Number(s): 269-833-0962
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13. Inspection Type: <input type="checkbox"/> Initial <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input checked="" type="checkbox"/> Unannounced	14. Locations Inspected: <input type="checkbox"/> Hybrid <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote	15. Next Inspection Date (MM/DD/YYYY): 11/17/2027 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change
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16. Location(s) Inspected List:
Main Office - 7000 Portage Road, Kalamazoo, MI

17. Scope and Observations:
Pharmacia & Upjohn Company, a wholly owned subsidiary of Pfizer, was authorized to use fixed nuclear gauges for level indication in active pharmaceutical ingredient manufacturing processes across its 1,300-acre campus in Kalamazoo, Michigan. At the time of the inspection, the licensee had nine specifically-licensed devices containing Cs-137 as well as six generally licensed devices: two drug packaging fill level detectors containing Am-241, two x-ray fluorescence materials analyzers containing Am-241, and two electron capture detectors containing Ni-63. The licensee's RSO was based at the Kalamazoo facility, which is accessed by visitors via Pfizer Circle off Portage Road, just south of the intersection with Romence Road Parkway.

The inspector toured the facility in Kalamazoo. All areas were adequately posted, and all licensed material was adequately secured. The inspector examined almost all specifically and generally licensed devices, and found them to be in good condition. Independent surveys in the vicinity of each found no evidence of exposures in excess of regulatory limits to members of the public in accessible areas. The inspector interviewed plant personnel and the licensee's radiation safety staff to discuss the use and maintenance of specifically and generally licensed devices, including demonstrations of the use of XRF analyzers, discussions of routine maintenance such as leak test collection and shutter checks, and response to abnormal conditions. The inspector also reviewed a selection of records, including semiannual physical inventories, leak tests, and shutter checks of specifically and generally licensed devices, example lock-out/tag-out procedures, and device transfer documentation.

No violations of NRC requirements were identified as a result of this inspection.

Signature and Date - Branch Chief



Digitally signed by Rhex A. Edwards
Date: 2022.12.14 06:19:56 -06'00'