

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Pioneer Pharmacy
1968 Innerbelt Business Center Drive
Overland, MO 63114

REPORT NUMBER(S) 12-01

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-38460

4. LICENSE NUMBER(S)

24-32827-01MD

5. DATE(S) OF INSPECTION

January 31, 2012

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, to exercise discretion, were satisfied.

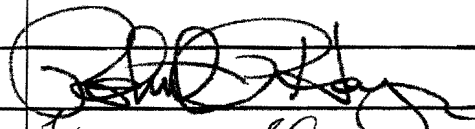

Non-cited violation(s) were discussed involving the following requirement(s):

- ☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited 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 | DATE |
|---------------------------|-------------------|--|---------|
| LICENSEE'S REPRESENTATIVE | | | |
| NRC INSPECTOR | Robert P. Hays |  | 1/31/12 |
| BRANCH CHIEF | Tamara E. Bloomer |  | 2/12/12 |

Docket File Information

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| 3. DOCKET NUMBER(S) 030-38460 | 4. LICENSE NUMBER(S) 24-32827-01MD | 5. DATE(S) OF INSPECTION January 31, 2012 | |
| 6. INSPECTION PROCEDURES USED IP 87125 | 7. INSPECTION FOCUS AREAS 03.01 - 03.07 | | |

SUPPLEMENTAL INSPECTION INFORMATION

| | | | |
|--------------------------------|----------------------|---|---|
| 1. PROGRAM CODE(S) 2500 | 2. PRIORITY 2 | 3. LICENSEE CONTACT Katheryn LeBlanc, Pharmacy RSO | 4. TELEPHONE NUMBER (314) 426-5290 |
|--------------------------------|----------------------|---|---|

☒ Main Office Inspection Next Inspection Date: 01/31/2014

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This nuclear pharmacy employs 2 pharmacists, 1 pharmacy technician, and 4 drivers. Currently the licensee has approximately 10+ customers located in Missouri and Illinois. The licensee prepares and distributes an average of 100 unit doses/day, Tc-99m sestimibi and Tl-201 only. No iodine capsules are compounded. Daily nuclear pharmacy production begins around 3:30 am each morning. The licensee occasionally redistributes xe-133 doses and dose calibrator check sources to clients.

PERFORMANCE OBSERVATIONS

Interviews with licensee personnel indicated an adequate knowledge of radiation safety concepts and procedures provided through recurring training. The inspector observed a generator elution and procedures in progress and the licensee's staff demonstrated/discussed: (1) unit dose prep and safe use procedures; (2) package returns and breakdown procedures; (3) area and contamination surveys; (4) DOT packaging and transportation procedures; (5) unit dose management system; (6) wipe test counting and efficiency procedures; (7) survey instruments and calibrations; (8) dose calibrator tests; (9) sealed source inventory and leak tests; (10) staff training; (11) radiation safety program audits; (12) waste handling; (13) facility security; (14) any events involving licensed material (none); and (15) the highest cumulative weekly and monthly dosimetry records indicated:

2010: 207 mrem DDE (whole body); and 9004 mrem SDE (extremity).
2011: 187 mrem DDE (whole body); and 8643 mrem SDE (extremity) through 12/4/2011

The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.