

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Barnes-Jewish St. Peter's Hospital
Department of Radiology
10 Hospital Drive
St. Peters, Missouri 63376

REPORT NUMBER(S) 2013-001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-17414

4. LICENSE NUMBER(S)

24-18968-01

5. DATE(S) OF INSPECTION

12/11/2013

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:


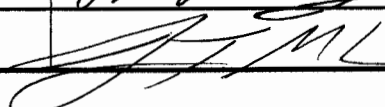
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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 | Bill Lin |  | 12/31/13 |
| BRANCH CHIEF | Aaron T. McCraw |  | 12/31/13 |

Docket File Information

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6. INSPECTION PROCEDURES USED

87130, 87131, 87132

7. INSPECTION FOCUS AREAS

All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02120

2. PRIORITY

3

3. LICENSEE CONTACT

Constance Courtois, M.D., RSO

4. TELEPHONE NUMBER

(314) 495-3438

☒ Main Office Inspection

Next Inspection Date: December 2016

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

The licensee was a small hospital and authorized to use licensed material permitted by Section 35.100, 35.200, 35.300, and 35.400. The nuclear medicine department was staffed with three full-time technologist who performed approximately 20 diagnostic procedures a day which included a full spectrum of studies. The licensee administered approximately 25 plus I-131 treatments for hyperthyroidism and Graves Disease annually (capsule form only). The licensee anticipated that it would expand its use to include I-131 for thyroid carcinoma treatments. The hospital retained the services of a consulting physicist who audited the radiation safety program on a quarterly basis. The licensee's radiation therapy activities were limited to permanent prostate implants using I-125. The patient treatments were performed by one authorized user supported by one medical physicist. The licensee administered approximately 50 I-125 permanent prostate implants each year.

PERFORMANCE OBSERVATIONS

The inspection consisted of interviews with selected licensee personnel; a review of select records; tour of the nuclear medicine and radiation oncology departments; and independent measurements. The inspector observed the administration of several diagnostic nuclear medicine procedures. The inspector reviewed the post-treatment plans for 10 implants with physics personnel. From the randomly selected 10 implants, the NRC inspector identified one patient brachytherapy post-treatment plans where the administered dose appeared to exceed the prescribed dose by more than 20 percent. According to the authorized user, she took a conservative approach in contouring the prostate and treatment site, therefore causing the administered dose to exceed the prescribed dose by 20.48 percent. The inspector reviewed the contour and agree with the authorized user's assessment. The written directives prescribed a dose to the prostate of 110.0 Gy.

In accordance with NRC Interim Enforcement Policy that was issued in the Regulatory Issue Summary (RIS) 2013-10, the one prostate implant where the administered dose was 20.48 percent over the prescribed dose met the criteria for enforcement discretion.

continued on Part 2

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(Continued)

Specifically, the enforcement discretion will apply if the licensee used absorbed dose to compare the dose delivered to the treatment site with the prescribed dose, the doses to normal tissues and structures do not exceed the regulatory dose threshold for reporting Medical Events; and the total dose for the treatment site was expressed in the written directive as absorbed dose. Based on discussion with the staff, a review of treatment documentations, and the NRC RIS, the failure to report the one medical events to the NRC as required by 10 CFR 35.3045 warrants enforcement discretion.

The inspector performed an in-office review of the circumstance around the one post-treatment prostate implants. The inspector performed a final telephone exit with the licensee's radiation safety officer on December 31, 2013.

No violations of NRC Regulatory Requirements were identified.