

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Department of Veterans Affairs Under Secretary of Health Washington, D.C. 20420 Location: VA NY Harbor Healthcare System, Brooklyn, NY REPORT NUMBER(S) 03034325/2018003		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
3. DOCKET NUMBER(S) 030-34325	4. LICENSE NUMBER(S) 03-23853-01VA	5. DATE(S) OF INSPECTION August 8, 2018

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	Shawn Seeley		9/4/2018
BRANCH CHIEF	Patricia J. Pelke		9/4/2018

Docket File Information

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7. INSPECTION FOCUS AREAS All			

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03614	2. PRIORITY 2	3. LICENSEE CONTACT Ed Leidholdt, Ph.D., Acting Director	4. TELEPHONE NUMBER (501) 257-1571
<input type="checkbox"/> Main Office Inspection Next Inspection Date: _____			
<input checked="" type="checkbox"/> Field Office Inspection VA NY Harbor Healthcare Sys., Brooklyn, NY			
<input type="checkbox"/> Temporary Job Site Inspection RSO: Esfandir Sarfaraz			

PROGRAM SCOPE

This was an unannounced, routine inspection of a permittee under the Department of Veterans Affairs (DVA) Master Materials License. The permittee was a broad scope medical facility operating under a permit issued by the DVA's National Health Physics Program (NHPP) and authorized for medical diagnosis, therapy (both unsealed and sealed), and research in humans. The permittee is also authorized for research and development, including animal studies, instrument calibration, student instruction, and in vitro studies.

The hospital had a full-time Radiation Safety Officer (RSO). The RSO oversees day-to-day radiation safety activities, including providing radiation safety and hazmat training, instrument calibration, sealed source inventory and leak tests, surveys, and program audits. The Radiation Safety Committee (RSC) oversees the program and meets quarterly.

The nuclear medicine (NM) department was staffed with three nuclear medicine technologists (NMT) working in standard nuclear medicine area medical diagnosis (including PET). The NM department operated Monday through Friday, performing a variety of procedures. Permittee staff typically performed around 8-14 nuclear medicine diagnostic procedures (primarily cardiac studies) daily using unit doses provided by local radiopharmacies. PET studies are only performed Mondays, Wednesday and Fridays, unless a Holiday falls on one of those days, then an alternate day is selected that week. All doses were assayed in the dose calibrator prior to administration. In addition, NM staff performed approximately 12 therapeutic administrations of I-131 (capsule only), and 5-8 Ra-223 Xofigo per year.

In the radiation oncology department, one authorized user performed 3-4 permanent I-125 prostate seed implants per month.

At the time of the inspection, the permittee had no active research labs.



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PROGRAM SCOPE

(cont'd. from previous page)

The inspector toured the facility to evaluate the permittee's measures for materials security, hazard communication and exposure control. The inspector observed permittee staff performing several diagnostic administrations of licensed material including dose preparation and disposal. No therapeutic procedures involving sealed or unsealed material were conducted by the permittee at the time of the inspection. Permittee staff discussed and/or demonstrated various procedures, including package receipt and opening, dose calibrator QA/QC, daily and weekly contamination surveys, and waste handling.

Permittee staff also demonstrated the implementation procedures for the prostate seed implant program.

The inspector performed independent and confirmatory radiation surveys which indicated results consistent with survey records, regulatory limits, and postings. The inspector reviewed a selection of records including program reviews and audits, dosimetry, RSC meeting minutes, written directives and treatment verifications for I-131, Xofigo, and prostate seed implants, leak tests and inventories, instrument calibrations, and dosimetry. The review of dosimetry records indicated no exposures of regulatory concern.

An exit briefing was held with the RSO, the chair of the RSC and representatives of hospital management, to discuss the results of the inspection. Within the scope of the inspection, no violations were noted.

