NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Department of Veterans Affairs Under Secretary of Health Washington, D.C. 20420 Location: VA New Jersey Health Care System, E. Orange, NJ REPORT NUMBER(S) 03034325/2018004	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-34325	03-23853-01VA	August 6-7, 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 violations(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		9/5/2018
BRANCH CHIEF	Patricia J. Pelke		9/5/2018

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131, 87134, 87126	All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
03614	2	Ed Leidholdt, Ph.D., Acting Director	(501) 257-1571

☐ Main Office Inspection Next Inspection Date: _____

☑ Field Office Inspection VA NJ Health Care System, E. Orange, NJ

☐ Temporary Job Site Inspection RSO: Venkata Lanka

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 has a full-time Radiation Safety Officer (RSO) and an assistant RSO, and two medical physicists. The RSO and an assistant RSO oversee 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. The NM department operated Monday through Friday, performing a variety of procedures. Permittee staff typically performed around 8 nuclear medicine (primarily cardiac) diagnostic procedures daily using unit doses provided by local radiopharmacies. 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 eight Ra-223 Xofigo per year. They are hoping to get their PET facility up and running by November.

In the radiation oncology department, one authorized user performed 20-24 permanent I-125 prostate seed implants per year. The permittee is authorized for high dose rate remote afterloader (HDR) procedures. However, the last use was in 2016. They are exchanging the source through Nucletron at least quarterly.

At the time of the inspection, the permitee 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 prostate seed implant and HDR programs.

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, HDR procedures, HDR daily QC and spot checks, leak tests and inventories, instrument calibrations, and dosimetry. The review of dosimetry records indicated no exposures of regulatory concern. The inspector discussed with the RSO the importance of documenting the sealed source inventory, especially for the sources in storage and not being used. He is updating the inventory on the NHPP website at least annually. The inspector recommends that the next NHPP inspector follow-up with the permittee in this area during the next routine inspection.

The inspector reviewed the permittee's follow-up to an event that was reported to the NRC on 05/03/17 (Event Notification #52728; NMED # 170236). A Program Manager with the VA National Health Physics Program (NHPP) reported a series of 6 medical events (10 CFR 35.3045(a)) at the VA New Jersey Health Care System, East Orange, NJ where the administered dose was different from the prescribed dose specified on the written directive.

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PROGRAM SCOPE

The medical events were identified by the NHPP Program Manager during a routine inspection on May 2, 2017.

The events occurred between December 2015 and March 2017; four resulted from the use of a pre-printed written directive form where an incorrect dosage unit was selected (millicuries) when the actual prescribed dosage unit was microcuries. In these fours cases, the actual doses administered (prescribed microcurie doses) were correct and the written directives were wrong. The fifth event involved a 121 microcurie dosage of radium-223 Xofigo where the prescribed dose on the written directive stated 211 microcuries, but the correct dosage (121 microcuries) was administered. The physician transposed the numbers on the written directive. The sixth event involved a dosage of 25.9 millicuries of I-131 (which was intended); however, the written directive specified a prescribed dosage of 25 mCi radium-223 Xofigo. In all the events identified, the correct isotope and doses were administered. The events were the result of written directives (WD) that contained inaccurate information.

Immediately after the discovery of these events in May 2017, the permittee initiated a review of the form utilized for the WD. The WD form was revised to clearly delineate which isotope and dosage was being prescribed. Additionally, the permittee implemented its corrective actions outlined in the NHPP letter dated May 18, 2017, and trained all users on the revised procedures and WD form. In addition, the permittee ensured the revised WD and procedures were implemented by instituting a review of all WDs upon completion by the RSO, which includes the date reviewed and RSO signature on the WD, and increasing the review of the nuclear medicine program by the RSO.

There were no issues identified regarding the WDs and RSO oversight at the time of the NRC inspection. Based on this review, NMED #170236 is considered closed.

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 identified.