

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Department of Veterans Affairs Under Secretary for Health: VA Puget Sound Health Care System 1660 S. Columbian Way, Seattle, Washington REPORT NUMBER(S) 2018-009	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 December 12, 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:

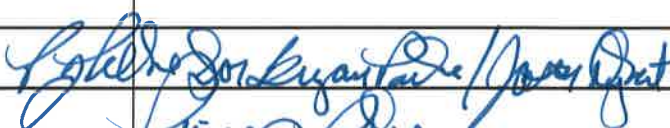
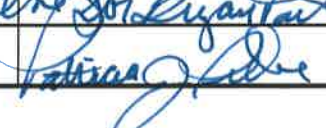
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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	Bryan Parker / Jason Dykert		1/7/2019
BRANCH CHIEF	Patricia J. Pelke		1/7/2019

Docket File Information

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6. INSPECTION PROCEDURES USED 87126, 87131, 87134		7. INSPECTION FOCUS AREAS Manual Chapter 2800, Section 05.01.b.1.(a) through (h) (All)	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02110, 3610	2. PRIORITY 2	3. LICENSEE CONTACT Christopher Peterson, RSO	4. TELEPHONE NUMBER (206) 277-1433
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- Main Office Inspection
 Field Office Inspection 1660 S. Columbian Way, Seattle, WA
 Temporary Job Site Inspection
- Next Inspection Date: n/a

PROGRAM SCOPE

This was a routine unannounced inspection of the Department of Veterans Affairs MML permittee VA Puget Sound Health Care System, licensed for radioactive materials in broad-scope medical and research uses. This inspection focused on activities performed under the permit (46-00990-01) at the Seattle location, including diagnostic and therapeutic nuclear medicine (35.100, 35.200 & 35.300), permanent implant prostate seed brachytherapy (35.400), medical research activities in humans as well as research and development as defined in 10 CFR 30.4. The Radiation Safety Officer (RSO) provides oversight for the radiation protection programs in Tacoma, Spokane, and Seattle. At the time of inspection there was not an Assistant RSO and many of the long-term nuclear medicine staff were retiring. Continuity planning and change management were a priority for the Radiation Safety Committee (RSC) and health care system executive leadership team.

The inspection reviewed compliance with regulations in 10 CFR through examination of security and control of materials, shielding in place including independent radiation measurements, safety practices by personnel, review of records and training, observations of ALARA, dosimetry use and direct observation of work activities, interviews with personnel and management, and observations in nuclear medicine including PET/CT, research labs, radiation oncology brachytherapy, and waste storage areas. A selection of Written Directives were reviewed for brachytherapy and therapeutic nuclear medicine. All pre and post op were signed and dated appropriately with a total activity and number of seeds implanted, and post op imaging with surveys was completed for each seed treatment record.

The most recent permit amendment approved use of Lutetium-177 in nuclear therapeutic medicine. Written directives, patient release instructions and procedures for safe use are in development. Ensuring successful uptake of amino acids co-administrated with Lu-177 is a priority because it reduces median radiation dose to the kidneys and increases isotope clearance time.

The RSC meets quarterly and provided appropriate oversight for the protocols used in current biomedical research and other areas for radiation protection. The RSO interacted with staff in each departments on a daily basis when possible. An exit meeting was held with the Director at VA Puget Sound Health Care System, Michael Tadych, and his staff. No violations were identified.

