NRC FORM 591M PART 1
(4-2008)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Michael E. DeBakey VA Medical Center 2002 Holcombe Boulevard Houston, Texas 77030-4298 REPORT NO.: 03034325/2018-010	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER	4. LICENSE NUMBER	5. DATE OF INSPECTION
030-34325	03-23853-01VA	December 6, 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:

[X] 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) was/were discussed involving the following requirement(s) and Corrective Action(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. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.

Licensee's Statement of Corrective Actions for Item 4, above.

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	Linda M. Gersey Sr. Health Physicist, Region IV		1/3/2019
BRANCH CHIEF	Patricia J. Pelke		1/3/2019

NRC FORM 591M PART 3
(10-2003) 10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. PERMITTEE	2. NRC/REGIONAL OFFICE
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6. INSPECTION PROCEDURES USED	**7. INSPECTION FOCUS AREAS**	**8. INSPECTORS**
87134, 87131, NRC Y-90 guidance	03.01-03.07	Jason VonEhr, Linda M. Gersey

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE	2. PRIORITY	3. PERMITTEE CONTACT	4. TELEPHONE NUMBER
2110, 3610	2	Darita Cunanan, Assist. RSO	

	Main Office Inspection:	Next Inspection Date:
X	Field Office: Michael E. DeBakey VA Medical Center Houston, TX	
	Temporary Job Site Inspection:	

This was an unannounced, routine inspection at the regional Department of Veteran Affairs (VA) hospital in Houston, TX. The hospital is authorized for use of licensed material permitted under 10 CFR 35.100, 35.200, 35.300, and 35.1000 Y-90 TheraSpheres. There was no brachytherapy use and the blood irradiator had been transferred to another site. The inspection covered the main hospital facility and did not include any clinics at locations identified in VA Permit 42-00084-06 Condition 10. The permittee stated that licensed material use at the nine clinics identified in VA Permit Condition 10 would be limited to evaluating shielding requirements during x-ray machine installations and the use would not begin until 2019.

The radiation safety program was managed by a Radiation Safety Officer (RSO), one Assistant RSO/Technician, and a radiation safety committee (RSC). At the time of the inspection, the RSO was out of the country and the Assistant RSO was performing all radiation safety-related duties. The permittee stated that the current RSO would be leaving the position soon and they planned on posting and hiring a replacement shortly. The RSO was recently selected for a Program Manager position with the National Health Physics Program (NHPP). The RSC consisted of the RSO, the chief nuclear medicine physician, the lead nuclear medicine technologist, the radiotherapy chief, and the safety manager. The RSC is required to meet at a minimum of once per quarter, although the permittee stated they normally met once every two months.

The Nuclear Medicine (NM) facility operated Monday through Friday with nine Nuclear Medicine Technologists (NMT) and one supervisory NMT. The permittee permittee had seven Authorized Users (AU) as of the date of the inspection. The NMTs performed approximately 10 Positron Emission Tomography (PET) studies and 20 general NM procedures each day. On a regular basis, the permittee receives unit doses, bulk F-18, and bulk Tc-99m. Radiopharmaceuticals were obtained from a variety of providers.

The permittee used Ra-223 Xofigo on one patient during 2016. The Y-90 TheraSpheres have been used since 2017, with approximately 70 procedures conducted by two AUs, as of the date of the inspection. The permittee used the manufacturer's form to generate the written directive.

The permittee stated that use of I-131 requiring a written directive was infrequent and most patients were released in accordance with 10 CR 35.75. If an in-patient I-131 procedure was necessary, the permittee had identified specific rooms for use. In addition, prior to any in-patient I-131 treatment, training was given to each nurse and other staff member that may work on the floor where the patient was located.

The permittee monitors radiation occupational exposure received by approximately 500 hospital personnel, of which 17 are NM staff. The dosimetry program includes whole body badges and ring dosimeters obtained by a NVLAP certified vender. During 2017, the highest occupational exposure was 1662 millirem, received by an interventional radiology physician. The highest 2018 year-to-date occupational exposure was 853 millirem, also assigned to an interventional radiology physician.

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SUPPLEMENTAL INSPECTION INFORMATION

The inspectors noted that students working in the NM department for short periods of time were being monitored for occupational exposure by the school, not the permittee. The inspectors discussed the potential for the students to receive occupational radiation exposure at other facilities, making it difficult to distinguish how much exposure was received during work at the permittee's facility. The permittee stated they would work with the school to improve tracking student exposure received at the hospital.

The permittee has two low level radioactive waste (LLRW) storage locations, which were adequately secured from unauthorized entry. The majority of the LLRW was being held for decay before disposal in the municipal waste. Two 55-gallon barrels of C-14 and H-3 liquid scintillation waste and several small sealed sources were awaiting disposal through a LLRW broker. The permittee had calibrated survey meters in reserve to use while other survey meters were non-functioning or out for calibration.

The permittee contracted Idaho National Laboratory to remove and ship the blood irradiator to another licensed recipient. A checklist was generated for the removal of the blood irradiator. The checklist included the results of the source leak-test, external contamination surveys on the unit, a close-out survey of the location it had been occupying, notifications for shipping, and confirmation of receipt.

The inspectors interviewed the NM staff and the Assistant RSO, observed package receipt, dose preparation, injections of PET pharmaceuticals, security of material, surveys, and waste disposal. Independent radiation measurements were made in the hot lab, injection areas, and the waste disposal areas using a Ludlum Model 2401EC (NRC No. 2117G, calibration due date of 11/5/19). All radiation measurements were within regulatory requirements. The following records were reviewed: written directives, audits and program reviews, exposure reports, radiation safety committee minutes, training, instrument calibration, and paperwork related to the transfer of the blood irradiator. No violations or open items were identified by the inspectors.

The inspectors held an exit meeting with hospital staff at the end of the inspection. Within the scope of this inspection, no violations were identified.