UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

October 07, 2022

Edwin M. Leidholdt, Ph.D. Director
National Health Physics Program (115 HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
Building 101
North Little Rock, AR 72114

SUBJECT: NRC INSPECTION REPORT 03034325/2022013(DNMS) – VA MEDICAL CENTER, SHREVEPORT, LOUISIANA

Dear Dr. Leidholdt:

On August 2, 2022, the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at the VA Medical Center, Shreveport, Louisiana. The inspection was limited to a review of activities authorized under Permit Number 17-12273-01. The inspectors conducted an exit meeting with the management and staff at the facility at the completion of the inspection.

The inspection was an examination of activities conducted under the Permit as they relate to radiation safety and to compliance with the Commission's rules and regulations. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, independent measurements, and observation of activities in progress. Within the scope of the inspection no violations of NRC requirements were identified; therefore, no response to this letter or the enclosed NRC Form 591M is required.

In accordance with Title 10 of the Code of Federal Regulations (CFR) 2.390 of the NRC's "rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or the NRC's Agencywide Documents Access and Management System (ADAMS, accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Should you have any questions concerning this inspection or the enclosed report, please contact Bryan Parker of my staff at 678-828-7050.

Sincerely,

Joseph L. Nick Digitally signed by Joseph L. Nick
Date: 2022.10.07 13:43:44 -04'00'

Joseph Nick, Acting Chief
Materials Licensing Branch
Division of Radiation Safety and Security

Docket No. 030-34325
License No. 03-23853-01VA
Permit No. 17-12273-01

Enclosure:
IR 03034325/2022013

NRC FORM 591M
(04-2022)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Report

1. Licensee/Location Inspected:	2. NRC/Regional Office
Department of Veterans Affairs Under Secretary of Health Washington, D.C. 20420 Location Inspected: Shreveport, LA **Report Number(s)** 2022-013	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	03-023853-01VA	August 2, 2022

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. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.

A. 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, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.
(Non-cited violation(s) was/were discussed involving the following requirement(s)

B. The following violation(s) is/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 AND DATE
LICENSEE'S REPRESENTATIVE		
NRC INSPECTOR	Janine F. Katanic, PhD, CHP	Bryan A. Parker Digitally signed by Bryan A. Parker Date: 2022.10.06 17:11:25 -04'00'
BRANCH CHIEF	Joseph Nick, Acting Branch Chief, MLB	Joseph L. Nick Digitally signed by Joseph L. Nick Date: 2022.10.07 13:38:03 -04'00'

Add Continuation Page

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Department of Veterans Affiars	030-34325	03-23853-01VA

4. Report Number(s):	5. Date(s) of Inspection:
030-34325/2022-013	August 2, 2022

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Janine F. Katanic, PhD, CHP; Kyle Bischoff	3614	2	IP 87130

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Anil Ramachandran, MD, RSO	Anil.Ramachandran@va.gov	318-990-5082

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial ☐ Routine ☑ Announced ☑ Non-Routine ☐ Unannounced	☐ Main Office ☑ Field Office ☐ Temporary Job Site ☐ Remote	NA ☐ Normal ☐ Extended ☐ Reduced ☑ No change

16. Scope and Observations:

Per guidance to conduct independent inspections of DVA facilities, the inspection was announced with the DVA NHPP staff. Because of Covid-19 considerations, the inspection was also announced and scheduled with the permittee. This was an inspection of DVA MML Permit No. 17-12273-01, Overton Brooks VA Medical Center, located at 510 East Stoner Avenue, Shreveport, Louisiana, 71101.

The last NRC independent inspection of this facility was on December 19, 2013, with no violations identified. The last DVA NHPP inspection of this facility was June 3, 2021, with no violations identified.

The permittee was authorized for 10 CFR 35.100, .200, and .300 activities, along with authorization to possess gadolinium-153 sealed sources associated with imaging equipment, and strontium-90 and cesium-137 sealed sources in storage pending disposal. The Permit RSO was Dr. Ramachandran, who had an office just down the hall from the nuclear medicine and PET/CT areas, and thus had daily interaction with the staff which helped facilitate overall radiation safety oversight. The nuclear medicine and PET/CT supervisor was Alan Fraser, who handled day-to-day radiation safety oversight. At the time of the inspection, there were six technologists that covered nuclear medicine and PET/CT.

The nuclear medicine area consisted of four camera rooms, a stress lab with treadmills, an injection/thyroid uptake room, and a hot lab. The PET/CT department had recently moved to its new area. It had previously been located outside of the main hospital, in a separate building on the campus. The new PET/CT facility had started patient imaging the week of July 10, 2022. The new PET/CT area consisted of a room with a PET/CT camera, a console/ staff work area, a hot lab, and four uptake/injection rooms. In advance of the PET/CT relocation, a consultant performed a shielding design for the proposed build-out. A different consultant performed an as-built shielding integrity check on June 24, 2022. The consultant report of the integrity check indicated that the as-built facility appeared to be adequate to meet NRC regulatory limits, with no holes or gaps in the shielding. The inspectors performed independent surveys inside of the new facility with no patients present, and outside of the new facility with a patient being imaged. Measurements were consistent with those documented by the licensee's consultant with no areas of concern.

The nuclear medicine hot lab had a Capintec CRC-15W dose calibrator. Routine quality control including accuracy, linearity, and constancy were performed and documented. They had a backup Capintec CRC-55tR that was available for standby but was not actively used. They also maintained a calibrated Fluke 451P and three calibrated Ludlum 14C survey meters with pancake or side window probes. Additional survey meters were available in storage

but were not calibrated. They also had a Capintec Captus 4000e thyroid probe with well counter. The inspectors reviewed calibration records for this equipment and found that routine efficiency determination and chi square test were performed and documented. At the time of the inspection, the well counter was not working properly so the licensee was using an alternate technique with a survey meter in order to measure wipes for removable contamination.

At the time of the inspection, only sodium iodide I-131 administrations were being performed under 10 CFR 35.300. The inspectors reviewed records of I-131 administrations requiring a written directive going back to July 2021. Since that time, there were only seven administrations requiring a written directive. Written directives were reviewed by the inspectors and found to contain the required information and were signed and dated by an authorized user prior to the administrations. Patient release determinations were on file and appeared adequate. Administrations appeared to be consistent with the written directives and no medical events were identified.

The permittee was considering starting lutetium-177 (Lutathera) administrations and was actively taking steps to engage with the NHPP to put procedures/equipment/training/etc in place to commence these administrations under 10 CFR 35.300.

For PET/CT, the permittee performed imaging using F-18 FDG as well as F-18 Pylarify, F-18 Neuraceq, and Ga-68 dotate. The F-18 FDG was received as a calibrated 30 cc bulk vial that was then placed into Medrad Intego PET infusion system. This system consists of a shielded cart with wheels in which the bulk vial is placed. Based on the calibration data from the vial, and based on an internal dose calibrator measurement, the system decay corrects the vial contents, and then delivers infusions of F-18 FDG to multiple patients throughout the day. To administer the F-18 FDG, the technologists place the IV line into the patient, then hook up the Intego system, which uses disposable single-use tubing to flush the line, infuse the F-18 at the set flow rate, then flush the line again with saline. The system has some internal calibration features and can retain records of infusions. Use of the Intego system results in lower doses to the staff because they are not having to handle syringes and be close to the patient during the infusion of F-18.

Other PET radiopharmaceuticals were received in unit doses (can't use the Intego system), which were the F-18 Pylarify, F-18 Neuraceq, and Ga-68 dotate. Additionally, there were several instances where the permittee did not have a supply of the single-use tubing for the Intego system, so those patient doses had to be hand drawn from the bulk vial, or provided by the radiopharmacy as unit doses in syringes. The PET/CT department had a hot lab with a Capintec CRC-25W dose calibrator. When the dose calibrator was installed in the new hot lab, tests were performed for accuracy, constancy, linearity, and geometry. The geometry test was performed with 3 cc and 5 cc syringes.

The inspectors asked to observe the PET syringe shields. Permittee staff stated that they had not seen or used the syringe shields since the PET/CT department was moved to its new area. They stated that the syringe shields must have gotten lost or misplaced during the move. The inspectors reviewed the administrations that occurred since the new department was opened, and determined that in the three weeks since the department started imaging patients, there were 18 administrations where syringe shields were not utilized for unit doses or syringes: seven F-18 Pylarify, one F-18 Neuraceq, seven F-18 FDG, and three Ga-86 dotate. The administered activities ranged from 5.7 - 13.85 millicuries. These administrations were performed by four different technologists: six administrations for technologist A, six administrations for technologist B, five administrations for technologist C, and one administration for technologist D. The inspectors reviewed the permittee's procedure titled "Administration of Radiopharmaceuticals in Nuclear Medicine." This document had no date. The RSO and nuclear medicine supervisor stated that it applied to nuclear medicine as well as PET. Item 9 stated: "The technologist will wear disposable gloves and use syringe shields when injecting." Although the nuclear medicine technologists stated that they had consistently used syringe shields at the former PET/CT location, no technologist interviewed by the inspectors questioned why there were no syringe shields at the new facility. Furthermore, none of the technologists interviewed informed the nuclear medicine supervisor or the RSO that the syringe shields were missing. It was the NRC inspectors that brought this to their

attention. Once brought to their attention, the nuclear medicine supervisor commenced a search and located the syringe shields in the nuclear medicine hot lab, but not before another F-18 Pylarify unit dose was administered without a syringe shield.

The inspectors acknowledged that these 18 instances of syringe shield non-use over four staff were not likely to result in any extremity or whole body dose above the regulatory limit although the doses were not ALARA. Following the inspection, the permittee, with assistance from the NHPP performed a dose bounding analysis and estimated that the the additional extremity dose lower range was 9 millirem and upper range was 72 millirem. The inspectors' main concern was a lack of questioning attitude by the staff to not question why safety equipment that they had used for years was now suddenly not available or being utilized. It also calls into question a lack of personal accountability of the technologists and questions about work processes, ALARA considerations, and radiation safety practices. The staff failure to bring this matter upward to the supervisor or RSO for resolution calls into question the environment for raising concerns.

Prior to the inspection, on April 21, 2022, the licensee was issued a Confirmatory Order largely addressing corrective actions to be taken by the licensee with regards to safety culture. Being as the licensee had 18 months to complete the actions, there were no specific items that required review during this inspection. The inspectors did, however, discuss safety culture concerns with the permittee and NHPP representatives regarding staff not using syringe shields when handling PET radiopharmaceutical syringes or unit doses since the time that the new PET/CT facility started imaging patients. Following the inspection, the permittee informed the inspectors that the staff, RSO, and supervisor would observe a DVA-wide webinar put on by the NHPP on either August 18 or September 22, 2022, regarding establishing and maintaining a safety culture.

The inspectors observed the licensee's sealed source storage area. This is best described as a room that was part of the main hospital building, but only had a door that was accessible from the exterior of the facility near the loading dock. The inspectors were particularly interested in observing the two sealed sources that were noted on the permit as being in storage pending disposal.

One source was a cesium-137 Model 6810 sealed source that was in a JL Shepherd instrument calibrator. The permittee was unable to specify when the source was placed into storage. The licensee had disposed of the source in January 2019 through Bionomics. At the time of transfer to Bionomics for disposal, the source was estimated to be 100 millicuries. The inspectors asked to see the leak test record of the source prior to it being transferred for disposal. The permittee produced a liquid scintillation counter (LSC) printout from May 2015, showing counts per minute per channel and said that this was the leak test although the report said "contamination surveys." Further inquiry revealed that this LSC printout was from Louisiana State University (LSU). It was pointed out by the inspectors to the permittee that this report in cpm did not constitute a leak test analysis nor was LSU authorized by its State of Louisiana license to perform leak test analysis for other NRC or Agreement State licensees. The inspectors requested that the permittee review their records to see if they could find an actual leak test. Following the inspection, the permittee located an analysis it performed of a wipe of the source on January 15, 2019, prior to transfer for disposal. The analysis was performed using the permittee's well counter with an appropriate MDA, indicating less than 0.005 microcuries of removable contamination. The permittee stated that when they renewed their permit, they would request that this source be removed from the permit.

The other permitted source in storage was a strontium-90 eye applicator, NEN Model NB-1, serial 370. The source was manufactured in October 1980 with a nominal activity of 100 millicuries. The permittee believes that it was received in 1981 and that it was placed into storage at least in 2005 but perhaps prior. The inspectors observed the source container in the permitee's storage room. Radiation surveys indicated the presence of a source. The inspectors did not ask that the container be opened because the licensee could not produce any leak test for the source. The permit requires that sealed sources do not need to be tested for leakage when in storage and not being used, but that no source shall be stored for a period of more than 10 years without being tested for leakage and/or

contamination. The permit also specifies that the leak test shall be capable of detecting the presence of 0.005 microcuries, and the analysis be performed by the permittee or other persons specifically licensed by the NRC or an Agreement State to perform such services. During the inspection, the permittee could not locate any leak test for this source. Following the inspection, the permittee produced the same LSC printout from May 2015 from LSU as described above. As already described, this was merely a printout from a LSC showing cpm in three channels. There was no MDA, no determination of dpm or microcuries, and LSU's license does not authorize it to perform leak test analyses as a service for others. The LSC printout says "contamination surveys" and is not a leak test certificate. However, the permittee considered this to be a leak test and at the time performed a calculation based on this data in an attempt to establish a microcurie quantity and whether the source was leaking. The calculation was reviewed by the inspectors and determined to be inappropriate and does it not meet the criteria for a leak test. The permittee committed to perform a leak test and analyze it properly or have it analyzed by an NRC or Agreement State authorized to perform this service.

Another item discussed with the licensee is that per the DVA MML license (LC 17.A.), permittees are to conduct a physical inventory every six months to account for all sources possessed. This would include sealed sources that are in storage. The permittee's consultant was performing physical inventories of sources that were "in use" but not performing this for sources that were in storage. Prior to the NRC inspection, a nuclear medicine technologist went into the storage room to inventory the sealed sources in storage, which included the strontium-90 eye applicator. The DVA MML license (LC 17.B.) requires that records of physical inventories include the quantities and kinds of radioactive material, manufacturer's name and model numbers, location of the sources and/or devices, and the date of the inventory. The record provided by the permittee did not include the manufacturer's name and model number (some items had no description), or the date of the inventory

A consultant performed quarterly reviews of the permittee's nuclear medicine and PET/CT activities. The reviews appeared effective to identify deficiencies. The consultant also performed inventories and analyzed leak tests of permittee sealed sources that were "in use," but not for the ones that were in storage. The consultant performed leak tests under State of Florida license 4330-1 for LBT Diagnostic Radiation Physics Consulting, LLC. The inspectors reviewed the State of Florida license and did not find any indication that the license authorized leak test analysis for clients, but per an email from the State, this activity was authorized in the license tie downs. Although the consultant was performing the leak test analyses of the "in use" sealed sources, they were not providing the actual documented analysis or leak test certificate to the permittee but rather noting in the audit report that the sources "passed."

The inspectors performed independent radiation surveys using Thermo RadEyeG, serial 30931, calibration due November 12, 2022, and a Ludlum Model 3-IS, serial 257114 with Ludlum 44-9 probe, serial PR287529, calibration due September 8, 2022. Surveys were performed in the hot lab after all daily work activities were completed, in the nuclear medicine imaging rooms without patients present, in the new PET/CT area without patients present, outside of the new PET/CT area with a patient present and being imaged inside of the facility, and at the satellite radioactive materials storage area. No areas of concern were identified.

The preliminary inspection findings were discussed with the representatives of the NHPP, the Permit RSO, nuclear medicine staff, and permittee administration at the conclusion of the on site inspection. At the conclusion of the on site inspection, the inspectors requested specific items for the permittee to follow up and provide additional information to the inspectors. Following the on site inspection the inspectors discussed the preliminary inspection findings with the NRC Project Manager for the DVA MML. The items discussed included the lack of syringe shield use by PET/CT staff, the lack of routine inventory of sealed sources in storage, and the lack of an actual leak test for a sealed source that had been in storage for over 10 years. Based on the information provided by the inspectors and follow up information provided by the permittee and the NHPP, following the inspection it was decided to not cite violations for these issues consistent with the guidance in NRC IMC 2810, Section 6.01.

Partial list of individuals contacted:

Materials Inspection Record (Continued)

Anil Ramachandra; Chief of Imaging, RSO
Alan Fraser, Nuclear Medicine Supervisor
Amber Davis, CNMT
Mark Steger, CNMT
Mark Blake, CNMT
Christopher Duff, CNMT
Clinton Abell, NHPP
Richard Crockett, Medical Center Director
Sevetri Moore-Guillaume, Chief of Staff
Martha Smith, Assistant Medical Center Director
David Williams, Health Systems Specialist
Edwin Mirador, Executive Officer to the Assistant Medical Center Director
Tremelon Steward, Executive Assistant to the Chief of Staff