September 3, 2010

Mr. Gary Williams, Director
National Health Physics Program (115 HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, AR 72114

SUBJECT: NRC INSPECTION REPORT 030-34325/10-02(DNMS) G.V. (SONNY) MONTGOMERY VA MEDICAL CENTER, JACKSON, MISSISSIPPI

Dear Mr. Williams:

On June 14-17, 2010, U. S. Nuclear Regulatory Commission (NRC) inspectors conducted a routine inspection at your G.V. (Sonny) Montgomery VA Medical Center facility located in Jackson, Mississippi. The inspection results were discussed with Michael Smith and you during a final telephonic exit briefing conducted on August 25, 2010. The enclosed report presents the results of this inspection.

This inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. 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 this inspection no violations of NRC requirements were identified.

In accordance with Title 10 Code of Federal Regulations (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from 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, please contact Cassandra Frazier of my staff at (630) 829-9830.

Sincerely,

/RA/ By Kevin G. Null Acting
For/

Patricia J. Pelke, Chief
Materials Licensing Branch

Docket No. 030-34325
License No. 03-23853-01VA
Permit No. 23-08786-01

Enclosure:
Inspection Report No. 030-34325/10-02(DNMS)

Should you have any questions concerning this inspection, please contact Cassandra Frazier of my staff at (630) 829-9830.

Sincerely,

/RA/ By Kevin G. Null Acting
For/

Patricia J. Pelke, Chief
Materials Licensing Branch

Docket No. 030-34325
License No. 03-23853-01VA
Permit No. 23-08786-01

Enclosure:
Inspection Report No. 030-34325/10-02(DNMS)

DISTRIBUTION:
E. Ullrich, RI
S. Reynolds, RIII
P. Louden, RIII
P. Pelke, RIII

DOCUMENT NAME: G:\Work in progress\IR - VA JACKSON_LTR2.docx
☒ Publicly Available ☐ Non-Publicly Available ☐ Sensitive ☒ Non-Sensitive
To receive a copy of this document, indicate in the concurrence box "C" = Copy without attach/encl "E" = Copy with attach/encl "N" = No copy

OFFICE	RIII DNMS	C	RIII DNMS	C	RIII DNMS	C		
NAME	DGWiedeman: jm		CFFrazier		PJPelke KGN for			
DATE	09/01/10		09/02/10		09/03/10			

OFFICIAL RECORD COPY

INSPECTION RECORD

Region III
Inspection Report No. 030-34325/10-02(DNMS)
License No. 03-23853-01VA
Docket No. 030-34325
Permit No. 23-08786-01

Licensee (Name and Address):
National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, AR 72114

Location (Authorized Site) Being Inspected: G.V. (Sonny) Montgomery VA Medical Center
1500 East Woodrow Wilson Dr.
Jackson, Mississippi, 39216

Licensee Contact: Michael Smith, M.S., Radiation Safety Officer
Telephone No. 601 946-6518

Priority: 2 **Program Code:** 02110

Date of Last Inspection: November 9, 2000
Date of This Inspection: June 14-17, 2010

Type of Inspection: ( ) Initial ( ) Announced (X) Unannounced
(X) Routine ( ) Special

Next Inspection Date: NA

Summary of Findings and Actions:
(X) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
( ) Non-cited violations (NCVs)
( ) Violation(s), Form 591 issued
( ) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspector: ***/RA/*** Date 09/02/2010
Darrel Wiedeman, Senior Health Physicist

Inspector: ***/RA/*** Date 09/02/2010
Cassandra Frazier, Senior Health Physicist

Approved: ***/RA/*** By Kevin G. Null for Date 09/03/2010
Patricia J. Pelke, Chief, Materials Licensing Branch

Enclosure

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

NA-The VA Medical Center, Jackson, Mississippi is a permittee of the Department of Veterans Affairs (DVA) Master Materials License (MML).

2. INSPECTION AND ENFORCEMENT HISTORY:

On October 8-9, 2008, the U. S. Nuclear Regulatory Commission (NRC) conducted an announced reactive inspection of the G.V. (Sonny) Montgomery VA Medical Center in Jackson, Mississippi to review the circumstances that led to the ten reported medical events. Two apparent violations were identified concerning the permittee's failure to: (1) have written procedures that provide high confidence that the administered dose is in accordance with the written directive as required by Title 10 Code of Federal Regulations (CFR) 35.41(a)(2); and (2) verify that the administration is in accordance with the treatment plan and written directive as required by 10 CFR 35.41(b)(2). On August 23, 2010, the NRC issued one Severity Level III violation involving the failure to develop, implement, and maintain written procedures that addresses methods to verify that administrations were in accordance with the written directive as required by 10 CFR 35.41(a)(2) and 35.41(b)(2).

On October 8-10, 2008 with continuing review through July 12, 2010, the National Health Physics Program (NHPP) inspectors conducted an inspection at the permittee's facility. The inspection was in response to the medical events involving the prostate brachytherapy program. Two violations were identified during NHPP's inspection involving the failure to: (1) develop and implement written procedures to provide high confidence that the administered dose is in accordance with the written directive as required by 10 CFR 35.41(a)(2) and 35.41(b)(2); and (2) designate an authorizer-user physician for brachytherapy as a member of the Radiation Safety Committee.

A Confirmatory Action Letter (CAL)(3-08-004) was issued to the NHPP on October 14, 2008. The CAL included several commitments to address the problems that led to the reported medical events involving prostate brachytherapy at the DVA hospitals. Prior to issuance of the CAL, the medical center executive management suspended their prostate brachytherapy program on September 18, 2008. On May 4, 2009, the Acting Under Secretary for Health issued an Executive Memorandum to the permittee that permanently terminated their prostate brachytherapy program.

As a result of this inspection, the NRC inspectors identified one unresolved issue pertaining to patient treatment records. In 2008, the permittee was asked to submit ten brachytherapy cases to the VA Puget Sound Healthcare System, Seattle, Washington, for evaluation. Eight of these ten cases were determined to be medical events. The permittee submitted additional cases for review. Subsequently, the permittee was informed that a total of ten cases were determined to be medical events because the administered dose to the treatment site was less than 80 percent of the prescribed dose. The remaining patient cases (81) were submitted to the DVA's National Radiation Oncology Program's technical expert. The technical expert is coordinating an external review of patient records to determine if additional medical events occurred. The patient records are currently being reviewed by an independent medical group. At the time of this inspection the results of these reviews were not available. The NRC will evaluate

any new information the VA identifies regarding the medical events under separate correspondence. Based on the NHPP inspection report dated July 15, 2010, the NHPP indicated that they will issue an addendum to their report or prepare a separate inspection report if additional medical events are identified.

3. INCIDENT/EVENT HISTORY:

On September 25, 2008, the NHPP notified the NRC of seven medical events at G.V. (Sonny) Montgomery VA Medical Center. Since the last NRC inspection on October 8-9, 2008, the NHPP reported three additional medical events on October 8, 2008, October 30, 2008 and December 17, 2008. The NHPP reported a total of ten medical events at the G.V. (Sonny) Montgomery VA Medical Center as of the date of this inspection.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Gary Williams- Director, National Health Physics Program
Linda Watson- Medical Center Director, Jackson, Mississippi facility
Michael Smith, Radiation Safety Officer, Jackson, Mississippi facility

The Department of Veterans Affairs G.V. (Sonny) Montgomery VA Medical Center, Jackson, Mississippi (permittee) was authorized by the VA Master Material License No. 03-23853-01VA (licensee) to possess a broad scope permit. This permittee is approved for diagnostic, therapy and research in humans as defined in 10 CFR 30.4. Staff from the VA National Health Physics Program accompanied the NRC inspectors during this inspection.

Nuclear Medicine Program

At the time of this inspection, the permittee had four full-time nuclear medicine technologists and two authorized-user physicians that work in the department. The permittee conducts approximately ten diagnostic procedures per day. The cardiac scans comprise 60-70% of the annual work load. The remaining workload consists of bone, liver and iodine-123 thyroid scans. During 2009, the permittee performed 7 whole body scans with iodine-131, 18 hyperthyroid treatments and 6 thyroid cancer treatments. All use of iodine-131 is in capsule form. The inspectors reviewed 39 random samples of written directives and identified an administrative error where the nuclear medicine technologist failed to enter the dosage assay on the written directive as required by their internal policy and procedures. The permittee provided documentation to the inspectors that confirmed that the proper dose was administered in accordance with the written directive.

During the inspection of the nuclear medicine program, the inspectors reviewed a random sample of records for the period 2007-2010 and discussed the following areas with the nuclear medicine technologist: training, package surveys, daily/weekly radiation surveys, inventory of radioactive material, disposal of radioactive materials, and dose

calibrator verifications. During the inspection, the inspectors requested the Radiation Safety Officer (RSO) to perform a constancy test on the dose calibrator with the same sealed source (cesium-137) and in the same manner in which it was performed earlier that morning. The constancy test results matched the licensee's records for the test performed earlier that same morning.

The previous routine NRC inspection on November 9, 2000, identified two apparent violations of NRC requirements: (1) 10 CFR 35.60(c) for failure to use syringe shields, and (2) License Condition No. 23, for failure to properly wear extremity dosimeters. During this inspection it was observed that the permittee routinely uses syringe shields and the technologists were properly wearing extremity dosimetry. These issues are now considered closed. The highest whole body exposure for the period Calendar Year (CY) 2008-2009 was 437 mrem and the highest extremity exposure was 2,990 mrem.

Research Activities

The permittee authorized nine researchers to perform research activities with microcurie quantities of carbon-14 and/or hydrogen-3. Four of the researchers are currently active and five are inactive. The NRC conducted independent radiation surveys in ten research laboratories and did not identify any contamination or unusual/unexpected radiation levels. The RSO performs periodic wipe tests and the researchers perform surveys at the end of each experiment in the research labs looking for removable contamination. No significant contamination events were identified during the period of 2007-2010.

Prostate Brachytherapy Program

On May 4, 2009, the permittee permanently terminated its authorization to perform any further prostate brachytherapy implants and does not plan to re-activate the program. The inspectors reviewed a random sample of patient treatment records for CYs 2005 (6 cases), 2006 (4 cases), 2007 (6 cases), and 2008 (4 cases). The inspectors identified that during CY 2007, post-treatment plans were not performed in accordance with the permittee's procedures as required by 10 CFR 35.41(b)(2). Subsequently, this apparent violation was corrected by the permittee. No new medical events were identified.

This licensee previously (2008) reported seven medical events because the D-90 was less than 80% of the prescribed dose. The permittee indicated that the medical events were due to a disagreement between two VA physicians regarding the exact size of the prostate during re-contouring and not due to misplaced seeds.

The inspectors interviewed the authorized-user physician, dosimetrist, a researcher, nuclear medicine technologist and the RSO regarding their understanding of the definition of a medical event, who to report the medical event to and how they determine if a medical event occurred. The RSO, researcher and nuclear medicine staff had a good understanding of the definition of a medical event and who to report a medical event to. Regarding the authorized-user physician (radiation oncologist) and dosimetrist, these two individuals still had some confusion regarding the definition of a medical event and who to report these events to. The RSO provided additional guidance to these individuals at the time of the inspection.

2. SCOPE OF INSPECTION:

Record review: During the inspection, the inspectors reviewed a random sample of patient treatment records (prostate brachytherapy) for CY 2005 (6 cases), 2006 (4 cases), 2007 (6 cases), and 2008 (4 cases). The inspectors reviewed Radiation Safety Committee minutes, incidents reports, annual audits of the radiation safety program, written directives, package receipt records, training records, survey records, leak test records, waste disposal records, and dosimetry records.

Inspection Procedure(s) Used: 87131, 87132, 87134

Focus Areas Evaluated: 03.01 through 03.07

The purpose of this inspection was to conduct a routine inspection of the permittee's use of license material and to follow-up on the suspended prostate brachytherapy program.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspectors conducted independent radiation surveys with a Ludlum Model 2402, Serial No. 157587, calibrated on May 5, 2010. The inspectors conducted surveys in and around the hot lab and the research labs. The inspector's surveys were consistent with the permittee's survey results. Surveys in unrestricted areas were at background (0.02-0.05 mR/hour). No unusual or unexpected radiation levels were identified.

The NRC inspectors concluded that no worker or member of the public received a dose of radiation in excess of the limits specified in 10 CFR 20.1201 or 20.1301.

4. VIOLATIONS, NON-CITED VIOLATIONS, AND OTHER SAFETY ISSUES:

No violations of NRC requirements were identified.

5. PERSONNEL CONTACTED:

#	Linda Watson Medical Center Director
#*@	Michael Smith, RSO
@	Gary Williams, Director, NHPP
#*	Edward Leidholdt, Jr., Ph.D, Program Director, NHPP
*	Kent Kirchner, M.D., Chief of Staff
@	Tom Huston, NHPP

Use the following identification symbols:

#	Individual(s) present at entrance meeting
*	Individual(s) present at preliminary exit meeting
@	Individual(s) attending the final exit telephone conference

-END-