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 030-34325/10-01(DNMS) - VA MEDICAL CENTER – CINCINNATI, CINCINNATI, OHIO

Dear Mr. Williams:

On June 9-11, 2010, the U.S. Nuclear Regulatory Commission (NRC) inspectors conducted a routine inspection at your VA Medical Center - Cincinnati facility located in Cincinnati, Ohio. The inspection results were discussed with Chris Rauf, Radiation Safety Officer (RSO), 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 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 Pelke, Chief
Materials Licensing Branch

Docket No. 030-34325
License No. 03-23853-01VA
Permit No. 34-00799-03

Enclosure:
Inspection Report No. 030-34325/10-01(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. 34-00799-03

Enclosure:
Inspection Report No. 030-34325/10-01(DNMS)

DISTRIBUTION (w/encl):
E. Ullrich, Region I
S. Reynolds, Region III
P. Louden, Region III
P. Pelke, Region III
Docket File

DOCUMENT NAME: Y:\DNMSIII\Work in progress\IR - VA CINCINNATI.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	09/02/10		09/02/10		09/03/10			

OFFICIAL RECORD COPY

INSPECTION RECORD

Region III
Inspection Report No. 030-34325/10-01(DNMS)
License No. 03-23853-01VA
Docket No. 030-34325
Permit No. 34-00799-03

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: VA Medical Center - Cincinnati
3200 Vine Street
Cincinnati, Ohio

Licensee Contact: Chris Rauf, Radiation Safety Officer
Telephone No. 513 425-6969

Priority: 2 **Program Code:** 02110_____

Date of Last Inspection: October 15-16, 2008
Date of This Inspection: June 9-11, 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 9/02/2010
Cassandra Frazier, Senior Health Physicist

Approved: /***RA***/By Kevin G. Null for Date 9/03/2010
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 – Cincinnati, Cincinnati, Ohio is a permittee of the Department of Veterans Affairs (DVA) Master Materials License (MML)

2. INSPECTION AND ENFORCEMENT HISTORY:

On October 15-16, 2008, the U. S. Nuclear Regulatory Commission (NRC) conducted an announced reactive inspection of the VA Medical Center-Cincinnati in Cincinnati, Ohio to review the circumstances that led to the seven reported medical events involving the prostate brachytherapy program. There were no violations identified that were associated with the medical events.

The National Health Physics Program (NHPP) inspected the permittee on October 16-17, 2008 and June 30 - July 1, 2009, with a focus on the prostate brachytherapy program. Two violations were identified during NHPP's inspection involving the failure to: (1) inventory sealed sources as required by Title 10 Code of Federal Regulations (CFR) 35.67(g); and (2) record post-implant information on a written directive as required by 10 CFR 35.40(b)(6).

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. Specifically, the CAL included a commitment that involved developing and implementing standardized procedures for prostate cancer treatments at all DVA hospitals. The inspectors determined that on October 22, 2009, the permittee implemented the new DVA approved standard operating procedures and supplemented these procedures with additional requirements.

The CAL included a commitment to conduct an inspection to confirm that all necessary corrective actions have been taken prior to restarting any suspended prostate brachytherapy program, and to notify the NRC when a suspended brachytherapy program restarts. The VA Cincinnati suspended their prostate brachytherapy program in October 2008. The NHPP conducted an inspection on June 30 through July 1, 2009, prior to the restart of the suspended prostate brachytherapy program. No violations were identified during the NHPP's inspection. The NHPP provided notification to the NRC on February 16, 2010, that the VA Cincinnati planned to resume its prostate brachytherapy program. On March 30, 2010, the permittee resumed its brachytherapy treatment program. The inspectors verified that the permittee implemented all requirements of the CAL for the restart of the brachytherapy program as of October 22, 2009. The permittee has completed 10 cases involving the brachytherapy treatment program to date. These cases were reviewed by an independent DVA expert and no medical events were identified.

3. INCIDENT/EVENT HISTORY:

No additional events have been reported since the last NRC inspection on October 15-16, 2008. The permittee suspended their brachytherapy program from October 2008 to March 30, 2010.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Gary Williams- Director, National Health Physics Program
Linda Smith- Medical Center Director, Cincinnati, Ohio facility
Chris Rauf, Radiation Safety Officer, Cincinnati, Ohio facility

The Department of Veterans Affairs Medical Center, Cincinnati, Ohio (permittee) was authorized by the VA Master Material License No. 03-23853-01VA (licensee) to possess a medical and research license. The facility is a 116 bed general hospital approved for diagnostic and therapy medical procedures authorized in 10 CFR 35.100, 35.200, 35.300 and 35.400. The permittee is also authorized for research and development as defined in 10 CFR 30.4, including animal studies, instrument calibration, student instruction, and in vitro studies. Staff from the DVA NHPP accompanied the NRC inspectors during this inspection.

Nuclear Medicine Program

At the time of this inspection, the permittee had five full-time nuclear medicine technologists and two authorized-user physicians that worked in the department. The permittee conducts approximately 1,800 diagnostic procedures per year; 60-70% of the annual workload is cardiac scans. The remaining workload consists of bone, liver, fluorine-18 and iodine-123 thyroid scans. During 2009, the permittee performed five whole body scans with iodine-131, six hyperthyroid treatments and three thyroid cancer treatments. All use of iodine-131 is in capsule form. The inspectors reviewed a random sample of written directives (Calendar Year (CY) 2008-2009) and did not identify any deficiencies in those records.

During the inspection of the nuclear medicine program the inspectors reviewed a random sample of records for the period of 2007-2010 and discussed the following areas with the nuclear medicine technologists: package surveys, daily/weekly radiation surveys; disposal of radioactive materials; and dose calibrator verifications. The inspectors asked the technologist 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 inspectors reviewed dosimetry records and determined that the highest whole body exposure for the period CY 2007-2008 was 366 mrem and the highest extremity exposure was 2,560 mrem.

Research Activities

The permittee has authorized five researchers to perform research activities with microcurie quantities of phosphorus-32 and sulphur-35 for cell tagging. Two of the researchers currently have active programs and three researchers have inactive programs. The Radiation Safety Officer (RSO) performs periodic contamination wipe tests of the research labs and each researcher performs contamination surveys at the end of each experiment. No significant contamination was identified during the period of 2007-2010.

Prostate Brachytherapy Program

The permittee has two authorized-user physicians that oversee the brachytherapy program. The permittee contracts with the University of Cincinnati for medical physics support. The inspectors reviewed a random sample of patient treatment records for CY 2007 (12 cases), 2008 (13 cases) and 2010 (7 cases). The inspectors identified that the permittee did not perform post-treatment plans to determine that each prostate brachytherapy treatment was in accordance with the written directive as required by 10 CFR 35.41(b)(2). In addition, the VA Inspector General identified that the permittee did not perform post-treatment plans in 2007 and documented its findings in a report dated May 3, 2010.

During the inspection, an authorized-user physician stated that in 2007 to mid 2008 the medical center did not use D-90 (dose to 90% of the prostate) to determine the dose to the prostate, but instead determined the dose using other various methods, e.g., ultrasound imaging, fluoroscopy images during surgery, post surgery radiographs, computerized tomography, PSA levels and activity of the sources to determine that the administered dose was in accordance with the written directive. The inspectors concluded that the process that the permittee used in 2007 for determining dose distribution to the prostate met the requirements in 10 CFR 35.41(b)(2). Beginning in mid-2008, the permittee converted to using D-90 as their method to determine total dose.

In 2008 the permittee reported seven medical events because the D-90 was less than 80% of the prescribed dose. The permittee indicated that the reason that the D-90 was less than prescribed was because of a disagreement between two VA authorized-user physicians regarding the exact size of the prostate during re-contouring and not because of misplaced seeds.

The inspectors identified that the permittee instituted several corrective actions as a result of the reported medical events which include: 1) implemented enhanced VHA Standard Procedures; 2) hired a newly trained medical physicist available to devote additional time to the brachytherapy program; 3) replaced implanting different seed activities with single strength brachytherapy seeds; 4) utilize real-time dosimetry during surgery; 5) perform post-treatment plans within a day of the implant procedure; 6) purchased a treatment planning computer and software; and 7) additional training provided to authorized-user physicians, RSO, and medical physicists regarding standard procedures and medical event identification and reporting.

The inspectors interviewed the authorized-user physician, medical physicist, nuclear medicine technologists 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. All individuals had a good understanding of the definition of a medical event and who to report a medical event to.

2. SCOPE OF INSPECTION:

Record review: During the inspection the inspectors reviewed a random sample of patient treatment records (prostate brachytherapy) for CY 2007 (12 cases), 2008 (13 cases) and 2010 (7 cases). The inspectors reviewed Radiation

Safety Committee minutes, 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, and 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 follow-up on the restart of the suspended prostate brachytherapy program. The permittee restarted its suspended prostate brachytherapy program on March 30, 2010.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspectors conducted independent radiation surveys with a Ludlum Model 2402, Serial No. 157587, calibrated on May 20, 2010. Surveys in and around the hot lab 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 Smith, Medical Center Director
#*@ Chris Rauf, RSO
#*@ Gary Williams, Director, NHPP
* Michael Lamba, Ph.D, Medical Physicist, University of Cincinnati
* Kevin Redmond, M.D., Radiation Oncologist, Barrett Cancer Center, University of Cincinnati
* Howard Elson, Ph.D, Radiological Physicist, University of Cincinnati
@ Tom Huston, NHPP

Use the following identification symbols:
Individual(s) present at entrance meeting
* Individual(s) present at exit meeting
@ Individuals(s) present at the final telecom exit meeting

-END-