Virginia Urology

November 13, 2005

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555
Copy to Regional Administrator

Reply to a Notice of Violation

Enclosed you will find a written statement and corrective actions related to the Notice of Violation from November 14, 2005 based on the NRC Inspection of Virginia Urology Center radiation program dated October 19, 2005.

Docket Number. 03035941
License No. 45-25582-01

If you have any further questions or comments, please let us know.

Thank you,

Traci L. Badin, RN
Director Surgical Services

Terry Coffey
Virginia Urology Administrator

Enclosures/tlb

IE07

9105 Stony Point Drive, Richmond, VA 23235 (804) 287-6100

Virginia Urology

December 13, 2005

During the NRC Inspection conducted on October 19, 2005, one violation of the NRC requirements was identified. The violation and corrective actions are addressed as follows:

A. 10 CFR 20.1101 © requires each licensee to periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, the licensee did not at least annually review the radiation protection program for content and implementation. Specifically, no program review was conducted since the first use of the licensed material on June 2002.

Reply to Violation;

Included in this summary you will find a copy of a survey that was performed in June of 2003. This covered the first year of use of the licensed material. From that date, until the inspection, there have been no annual reviews held.
Since the date of the inspection on October 19, 2005, this has been rectified by the review of the content and implementation of the program from August 2003 to October 2005 performed by the medical physicist as stated in our policy. (Noted in Document 1 enclosed)
A copy of the annual review is enclosed. (Document 2).
To prevent this from occurring in the future, an annual review and update with signature of the policy books has been activated.

Compliance of this violation was achieved on November 9, 2005.

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December 13, 2005

B. 10 CFR 35.41 (a) states, in part, that for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Contrary to the above, as of October 19, 2005, the licensee did not have a written procedure to provide high confidence that: each administration is in accordance with the written directive. Specifically, the licensee did not develop written procedures for verification that the brachytherapy seed activity was in accordance with the treatment plan and written directive.

Reply to violation:

Since the date of the inspection, our medical physicist has developed a written policy and procedure which addresses the verification process of the brachytherapy seed activity in relation to the treatment plan and written directive.

Enclosed is the policy and procedures relating to the total seed activity implanted on the date of surgery and the written directives.

Compliance was obtained and dated on December 13, 2005.

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Virginia Urology Center
8228 Meadowbridge Road
Richmond, VA

2003 Quality Management Program Review Report
Radiation Oncology

Review Date: 6/3/03

The Quality Management Program (QMP) review is required under our NRC license and is a requirement under the Code of Federal Regulation, Title 10, Part 35 (10 CFR 35.32). This is the first year of operation and first performance analysis. The QMP was reviewed to insure consistency with the adopted QMP and it's revisions. With regard to brachytherapy procedures, we analyzed records to investigate any possibilities of medical events, that doses have been properly prescribed, any recordable events were properly identified and the written directives were properly prepared and executed. Specific definitions for medical events, prescriptions, recordable events and written directives are indicated in the current QMP.

Brachytherapy Program

Brachytherapy procedures performed during 2002-3 involved the implantation of both I-125 and Pd-103 radioactive seeds within the prostate gland under ultrasound guidance.

QMP Review

The QMP review was performed on June 3, 2003 by Michael D. Rutstein, MS, DABR, Cherie Snead, RT. A total of 62 patients were administered prostate implants using both I-125 and Pd-103. Thirty-six (36) patients were administered with Pd-103 and twenty-six (26) with I-125 during 2002. There were two (2) cancelled implants in which the radioactive seeds were returned to the vendor. The records of six patients were reviewed, resulting in an evaluation of 10 percent of the patient administrations. Each patient's chart was examined to insure that a written directive was properly prepared, dated and signed by an authorized user; that the patient was properly identified by at least two means; that prior to administration, the final plans of treatment, including the radioisotope, number of sources and implant dose, were in accordance with the written directive; that all the brachytherapy dose calculations were checked before administering the prescribed dose; that following administration, an individual under the supervision of the authorized user dated and signed a written record of the administered dose. Each chart was also reviewed for proper patient monitoring following implantation, recovery, and discharge. In addition, the records were examined for any deviations from the written directive and for the existence of any recordable or medical events.

QMP Review Results

No medical or recordable events were detected. There were a total of two paperwork deficiencies were discovered and reviewed. Each deficiency consisted of minor error in the documentation of the procedure paper work. Each was easily corrected and had no regulator or clinical significance.

Discussion

All of the above incidents were considered minor. Once again, during annual in-service, staff members will be reminded that it is important to take an extra moment to make sure that all paper work is filled in completely and correctly.

Procedural Changes

All procedures were reviewed and found to be appropriate at this time.

Follow-up Action

Annual in-service has been scheduled for June 11, 2003. Seed program is supposed to transfer to the Urology group's new facility this fall. A review of the documentation shows that this issue has already been addressed with the NRC and a new license amendment issued. At this time, a request needs to be submitted to the state for a transfer of permission for the use of Pd-103.

Summary

The QMP review of the brachytherapy program involved a review and evaluation of ten percent (10%) of the prostate implants administered. Six procedures were reviewed. There were no medical or recordable events detected. Two record keeping deficiencies were noted and addressed. This program will be transferred to the VUC Stonypoint facility sometime later this fall.

Michael D. Rutstein, MS, DABR
Medical Physicist

Terry Coffey, MBA
Administative Supervisor

Bernard Tisdale, MD
Radiation Safety Officer

Document 1

VIRGINIA UROLOGY SURGERY CENTER

RADIATION ONCOLOGY TREATMENT SERVICES

POLICY

Radiation oncology treatment services provided by Virginia Urology Surgery Center meet the needs of the patients and are provided in accordance with ethical and professional practices and legal requirements. Radiation oncology treatment services that are available or provided by Virginia Urology Surgery Center include:

- consultation services
- treatment planning
- simulation of treatment
- maintenance of service and radiographic image reports appropriate to the therapy for the time required by applicable laws and policy of Virginia Urology Surgery Center
- clinical treatment management including brachytherapy
- appropriate follow-up care of all patients

Radiation oncology services provided by Virginia Urology Surgery Center are directed by a physician who is qualified to assume professional, organizational, and administrative responsibility for the quality of services rendered.

Radiation safety and quality control policies and procedures are established and are reviewed periodically by a qualified medical physicist.

The radiation oncology treatment services maintains sufficient, adequately trained and experienced personnel who are able to supervise and conduct work of the service, including:

- a radiation technologist certified by the American Registry of Radiation Technology (ARRT) or a state licensed technologist
- dosimetrist
- other appropriately trained health care personnel keeping with the local practice and legal requirements, such as oncology nurses, nutritionists, and medical social workers.

VUSC radiation oncology service has adequate facilities and equipment to provide appropriate treatments and related treatments, which shall include:

- isocentric supervoltage machine of at least 80 centimeters source-axis distance
- access to computerized dosimetry
- simulation capabilities
- access to patient transport.

The VUSC radiation oncology service has policies addressing the quality of care, including:

- A recognized methodology for diagnosis and treatment.
- The performance of therapeutic services on the written order of a radiation oncologist.
- A physician shall be present or immediately available during treatment. In those situations in which the physician is not present but is immediately available, the physician shall have qualified support personnel present.
- Weekly chart and port film review.
- Periodic new patient review.
- Signed informed consent to be obtained prior to treatment as part of the surgical record.
- Photo documentation of treatment setups.
- Access to emergency treatment.

VUSC radiation oncology service has policies addressing the safety aspects of treatment, including:

- The designation of a radiation safety officer that periodically reviews the program and facility
- a program to maintain personnel exposure records
- annual review of the radiation safety program by a qualified medical physicist
- maintenance of the records of machine performance, maintenance and malfunctions
- a program for maintenance and repair of equipment
- regulation of the use, removal, handling, and storage of potentially hazardous materials

VUSC has access to appropriate supporting facilities, including diagnostic laboratories and imaging facilities.

The following characteristics are documented in the VUSC record to indicate good-quality patient care:

- confirmation of the presence of malignancy by histopathology or a statement of benign condition
- definition of tumor location, extent, and stage
- definition of treatment volume
- selection of dose
- selection of treatment modality
- selection of treatment technique
- dosimetry calculations
- supervision of treatment and record of patient progress and tolerance
- summary of completion with statement of follow-up plan

Document 1

VIRGINIA UROLOGY SURGERY CENTER

RADIATION ONCOLOGY
TREATMENT SERVICES

VUSC RADIATION ONCOLOGY SERVICE POLICY

A designated radiation safety officer periodically reviews the program and facility.

The personnel involved in the care of the patient receiving radioactive seed implantation shall wear a film badge to detect any radiation exposure. If the personnel are in direct contact with the procedure of counting or loading the radioactive seeds, these personnel shall wear a ring badge. These badges are exchanged out on a monthly basis and are reviewed by the radiation safety officer.

There is an annual review of the radiation safety program by a qualified medical physicist.

A maintenance record shall be maintained on machine performances, maintenance and malfunctions, as well as repair of the equipment.

Records of machine performance, maintenance, and malfunctions are maintained. These are included in the protocol for maintenance and repair of the equipment.

Periodic testing of sealed sources will be performed and documented satisfying all pertinent radiation regulations.

VUSC has policies regulating the use, removal, handling, and storage of radioactive seed implants.

Document 2

McComas Enterprises Inc.

Van H. McComas, MS, DABR,

Medical Physics Consultant

* 2005 Quality Management Program Review Report for Virginia Urology at Stony Point

NCR License #: 45-25582-01 **Expires: 4/30/2012**

Review Date: November 9, 2005

A review of the Radiation Safety Program, Compliance to the NRC Regulations concerning the Byproduct Material License and the Quality Management Program for Virginia Urology at Stony Point (VUSP) was conducted by the consulting medical physicist. The inspection was an examination of the activities conducted under the NRC license as they relate to radiation safety and in compliance with the Nuclear Regulatory Commission's rules and regulations (Code of Federal Regulation, Title 10, Part 35), for the use of radioactive materials. This report deals only with activities in prostate seed implants.

Audit History:

Annual audits were conducted in accordance with 10 CFR Part 20.1101(c) with the exception to the calendar year 2004. The last annual review was conducted June 3, 2003. This report covers all activities from August 2003 through October 2005. There is no further action required. The records of annual audits were maintained for three years in accordance with 10 CFR Part 20.2102. There is no further action required. There were no recommendations for the year 2006.

Brachytherapy Compliance with 10 CFR Part 35.

There were 273 procedures using sealed source brachytherapy (I-125 or Pd-103) performed at VUSP from August 2003 until October 2005. All treatments were handled in accordance with 10 CFR Part 35 and documented in each patient's chart. Post Radiation Safety surveys were conducted in accordance with 10 CFR 35. Radioactive material receipt and decay-in-storage of radioactive material were handled in accordance with (10 CFR 71.5(a) and 49 CFR 171-189). Patient's charts were reviewed by this physicist at the respective oncology center, either Richmond Radiation Oncology Center, 5711 Staples Mill Road, Richmond or Commonwealth Cancer Institute, 1109 West Marshall Street, Richmond. Documentation of pre-implant written directives as well as post-implant written directives were in accordance with 10 CFR Part 35.

Personal Monitoring Devices Results and Radiation Safety Training

All records of exposures are properly documented and maintained in accordance with 10 CFR Part 20 Regulations. Radiation Safety Training was conducted in August 2004 and again in October 2005 in accordance with 10 CFR Part 20 and 35.

Conclusion

The annual review of the Quality Management Program for Virginia Urology Center at Stony Point was acceptable. There were no medical events or recordable events detected. This report is in accordance with 10 CFR Part 35.22(b) (6).

Van H. McComas, MS,
Consulting Medical Physicist

Terry Coffey, MBA
Administrative Supervisor

Bernard Tisdale, MD
Radiation Safety Officer

Document 13

VIRGINIA UROLOGY SURGERY CENTER
Policy and Procedures

RADIATION ONCOLOGY TREATMENT SERVICES

Virginia Urology at Stony Point

Prostate Brachytherapy Seed Implant Procedure

This protocol is implemented to establish uniform procedures throughout Virginia Urology concerning Prostate Brachytherapy Seed implants using either iodine-125 or palladium-103. Completeness, communication, quality and efficiency should be enhanced. Documentation of deviations is expected.

I. Volume Study

A pre-implant volume study will be performed at Virginia Urology at Stony Point by either ultrasound or CT. This volume study will determine the size of the prostate for pre-implant seed orders. The medical physicist along with the radiation oncologist will determine the prostate volume. Using published and inhouse nomograms, the total activity necessary for the prostate volume will be determined and used in the pre-implant Written Directive. Note that the pre-order activity per seed may not match the delivered seed activity however the total activity ordered will be within ± 5%. Any deviation from the total activity will be noted.

II. Seeds received and assayed.

All seeds, either I-125 or Pd-103, will arrive to the Brachytherapy Seed Storage room where they will be inventoried and assayed in accordance with written protocols. The Brachytherapy Seed Tech will verify the total activity and number seeds ordered matches the pre-implant written directive. At least 10% of the the seeds will be assayed. Any deviation from the total activity will be noted.

III. Implant Day

Each patient scheduled for prostate implantation will have another volume study performed in the operating room in the treatment position while under anesthesia. This volume study will be used to determine the total activity needed for the implant. Note that this volume may not match the pre-implant volume study from above. The Post Implant Written Directive will reflect any change in the total activity used. The total activity used for the implant will be determined either by nomograms or implant dosimetry performed in the OR after the volume study.

Van H. McComas

Van H. McComas, MS., D.A.B.R.
Consulting Medical Physicist

December 13, 2005

Radioactive Seed Handling for Prostate Implants
Virginia Urology Center at Stony Point

I. Pre-order of Radioactive Seeds for Preloaded Needles

a. An ultrasound volume study is performed by the urologist two to four weeks prior to the implant. Volume study images are then given to the medical physicist for a pre-implant plan using either palladium - 103 (Pd-103) or iodine - 125 (I-125) radioactive seeds.
b. The images are programmed into the treatment planning computer by the physicist or dosimetrist and a dosimetry plan is performed.
c. The pre-implant treatment plan is then reviewed by the radiation oncologist and the seed order is placed by the Isotope Curator Stony Point.

II. Pre-order of Radioactive Seeds for the Mick Applicator

a. An ultrasound volume study is performed by the urologist two to four weeks prior to the implant. The volume of the prostate is determined and this information is sent to the oncologist and medical physicist. The oncologist determines if either palladium - 103 (Pd-103) or iodine - 125 (I-125) radioactive seeds are to be used for the implant.
b. The volume information is used by the medical physicist to determine the total activity needed in accordance with the appropriate nomogram.
c. The activity needed is then reviewed by the radiation oncologist and the seed order is placed by the Isotope Curator Stony Point.

III. Radioactive Seeds Arrival

a. The radioactive seeds arrive at Virginia Urology Center at Stony Point (VUCSP) typically two days prior to implant.
b. The Isotope Curator then inventories, verify count, and assay 10% of seeds.
c. Typically one day prior to implant the seeds are taken by the Isotope Curator for sterilization.

IV. Operating Room Procedures

a. The urologist and radiation oncologist, working with the medical physicist, places the needles in the patient's prostate according to the pre-implant dosimetry plan.
b. Once all seeds are implanted, the urologist performs a cystoscopy to determine if any seeds are in the bladder and, if so, removes them from the bladder. The Isotope Curator will take charge of any removed seeds and place them back into storage for proper disposition.

c. A urinary catheter is then inserted in the patient.

d. At this time the Isotope Curator will perform a patient and area survey using a thin in window low energy radiation detection device, calibrated for the low energy radiation such as I-125 or Pd-103. The survey will include the prostate needles, the floor around the OR table, the OR table and the exposure rate from the surface of the patient at the level of his pubis.
e. Once the patient is moved from the OR table to the Recovery Room bed or stretcher, the Isotope Curator will again survey the OR table and floor for any loose seeds.
f. A Radiation Safety Survey form (attached) will then be placed in the patient's chart.

V. Post Implant Patient Movement

a. The patient is moved from the OR to the Recovery Room.

b. **Note**: There have been reported cases of seed migration from the prostate; however it is noted that this migration occurs only in a small number of cases and over a period of days or weeks. It is highly unlikely that a seed will migrate from the prostate to the bladder or urethra in the time it takes the patient to leaves the OR and be discharged from the hospital. Since the urologist has performed a cystoscopy and determines that there are no seeds in the bladder or urethra, there is no need to survey the patient or the area the patient has been once he has left the OR.

Van H. McComas, MS,
Consulting Medical Physicist

December 13, 2005