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Kurt A. Barwis, FACHE
President & Chief Executive Officer

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REGION 1
2010 DEC 13 PM 12:16

December 9, 2010

Lester Tripp, M.S.
Health Physicist
Region 1
475 Allendale Road
King of Prussia, PA 19406

Dear Mr. Tripp:

Enclosed please find the corrective/preventive action plan documentation from Bristol Hospital's Brachytherapy Program to include as requested:

- Authorized user Radiation Oncologist performing Brachytherapy procedures.
- The minutes from the Brachytherapy collaborative addressing the training of personnel on the definition of a medical event and reporting requirements found in 10CFR Part 35.
- The Quality Improvement Plan and annual audit of the Brachytherapy program with objective monitoring measures.
- Results of the post procedure evaluation of patients done in January 2010 and September 2010.

Please contact us if you have additional questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Kurt Barwis".

Kurt A. Barwis, FACHE
President & Chief Executive Officer

A handwritten signature in black ink, appearing to read "Pat Caruso RN".

Pat Caruso, RN, BSN
Quality Consultant



a SAINT FRANCIS Care Partner

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Summary of Event:

The event resulted from a miscommunication between the dosimetry planning and the radiation oncologist. These were the first implants being performed with a new planning team and the radiation oncologist. The seed supplier can load the seeds either with a seed or a spacer at the end or base of each strand. In the case in question the seeds were base loaded but manually retracted when implanted. Retraction resulted in a displacement of some seeds by approximately 2 to 3 mm from the intended plan. Comparison of the radiographs of the strands supplied with the shipment from the manufacturer and the treatment plan would have shown that the implant was planned with base loads not retraction.

CORRECTIVE ACTIONS:

A procedure checklist has been developed to be accomplished prior to the start of any procedure. A copy of this checklist is attached. Included in this is review of the manufacturer's radiographs of the strands and a comparison of them with the treatment plan by the radiation oncologist. Any discrepancies will be resolved before the start of the procedure.

The reportable event included two patients on the same day. Patient #1 was evaluated by the radiation oncologist who determined that additional radiation was unnecessary. Patient #2 received a lesser dose and has been scheduled for an external radiation boost. Both patients will be followed.

The hospital has initiated a Prostate Cancer Brachytherapy Collaborative with Lynne Ramer RN, Director of Per-Operative Services as its Chair. The Collaborative consists of:

- Radiation Oncology
- Radiology-Radiation Safety Officer
- Nuclear Physicist from Oncology Medical
- Independently Contracted Nuclear Physicist
- Nursing Directors from:
 - Radiology
 - Cancer Care Center
 - Peri-Operative Services
 - Operating Room Staff RN Representative
 - Quality Improvement Department RN

The program (attached) stipulates a post plan evaluation for all implants. It also includes outcome limits that will be used to initiate an internal investigation to determine if there could be a reportable event. If the possibility of a reportable event exists then there are defined steps which must be followed by appropriate staff and includes reporting requirements.

Bristol Hospital Brachytherapy Collaborative
November 2, 2010

Attendees: Dr. J Ravalese, Dr. D Ferguson, Dr. W. Walker, Jack Sloan, Jerry Randall, Lynne Ramer, Barbara Nawrocki, Pat Caruso, Marie Marciano, Greg Brown

Absent: Dr. P. D'Addario

Topics of Discussion and Plan of Action:

- The evaluation of the number of seeds implanted and the treatment volumes for the two patients in question from January of 2010 has been completed by Dr. Percarpio and Pat Caruso has that evaluation.
- The evaluation of the most recent seed implants will be done within the next 2-3 weeks by Dr. Ravalese.
- From this point forward Oncology Medical in partnership with the Quality Department will oversee/facilitate addressing concerns to clinical personnel and the NRC.
- Oncology Medical will prepare a flow chart/algorithm for the flow of patient planning/treatment and the exchange of information to include a process for evaluating outlying patients – i.e. those patients in whom the plan does not match the outcome. This algorithm will be sent to both Lynne Ramer and Pat Caruso upon its completion within the next two weeks and will become a part of the Brachytherapy Policy after approval.
- To ensure that our current institutional policy is in accordance with regulations, Lynne will send this policy to Dr. Walker for review.
- Jack Sloan will send an electronic version of the Brachytherapy Checklist to Lynne to incorporate into the policy.
- Both Dr. Percarpio and Dr. Ravalese's names will be left on our license per our discussion and the advice of Jerry Randall.
- Committee members will meet bi-annually to evaluate/audit the care provided to the brachytherapy patient population. Lynne will arrange those meetings.
- Jerry Randall reviewed the regulations as it relates to reportable events.
- Lynne passed out the regulations for reference.
- Patient isotope cards are being created. Lynne will look into their readiness.
- All of the above noted information will be sent from Kurt Barwis' office with his signature in accordance with the NRC requirements. Pat Caruso will coordinate this.

Bristol Hospital – Prostate Cancer Brachytherapy Quality Improvement Program

The Director of the Brachytherapy program is the Director of Peri-Operative Services. The hospital quality improvement program for prostate seed implants shall consist of the following:

- Post implant evaluation of each implant performed utilizing a post plan performed using CT imaging of the prostate and evaluation by the medical physicist and the attending radiation oncologists. Any prostate seed implant falling outside of the standard implant parameters shall be immediately evaluated utilizing the attached brachytherapy prostate seed evaluation criteria and a determination made as to whether the implant is a “reportable event” to the Nuclear Regulatory Commission (NRC)
- A bi-annual QI committee meeting of the prostate seed implant program will be held with key hospital staff, physicians, radiation safety officer (RSO) and brachytherapy contracted physicist to evaluate the program and the seed implants performed during each 6 month period.

The key program areas for review at bi-annual meeting are as follows:

- Patient implant performance criteria per implant
 - Overall seed implant program success criteria
 - Policy and procedures
 - Any program changes required or recommended
 - Any NRC rule changes, recommendations, or required changes
 - Staff training
- Annual QI Improvement meeting for complete program evaluation:

Key program areas for review at bi-annual meeting:

- Patient implant performance criteria per implant
- Overall seed implant program success criteria
- Policy and procedure review and revision
- Any program changes required or recommended
- Any NRC rule changes, recommendations, or required changes
- Staff training

QI Committee Members shall consist of:

- Director of Peri-Operative Services
- Radiation Safety Officer (RSO)
- Nuclear Medicine representative or department representative
- Primary Radiation Oncologists responsible for the license and program
- Brachytherapy consulting team
- Independently contract Medical Physicist
- Quality Improvement Representative

Implant Evaluation and “Reportable Event” Parameters

Based solely on the final post implant treatment plan completed on each patient, a successful prostate cancer seed implant criteria shall consist of all of the following:

D90 for Prostate > or equal to 80%

V150 for Prostate < or equal 75%

D30 for Urethra is < or equal to 150%

D2cc for Rectum is less than 150%

Any deviation outside of any of these articulated parameters shall require QI action, evaluation, and proper reporting, if required, to the hospital QI committee and NRC.

If any of the measurements are determined to be above the listed parameters, the patient and the implanted dose will immediately be evaluated. If the criteria meets the NCR requirements for a “reportable event” action will be taken. All reporting requirements as determined by any federal, state, or local agencies as stated in current Rules and Regulations governing such treatment at Bristol Hospital will be initiated. Reference: AAPM recommendations on dose prescription and reporting methods for permanent interstitial Brachytherapy for prostate cancer: Report of Task Group 137.

1. The determination of a “reportable event” shall be made promptly and jointly by the following clinical staff:
 - Medical physicist performing the treatment planning
 - Attending Radiation Oncologists
 - Radiation Safety Officer
 - Quality Improvement Department
 - Director of Brachytherapy Program
2. The reporting will be done by the Quality Improvement Department with assistance from Medical Oncology as needed.
3. Should it be determined that a “reportable event” has occurred, the Hospital Program Director shall be immediately notified and the NRC and any other required reporting body will be informed within **24 hours**. This reporting will be done collaboratively between Medical Oncology and the Bristol Hospital Quality Improvement Department.
4. If a “reportable event” has occurred and been reported to the proper agencies, the hospital will call a meeting of the Brachytherapy QI committee to review the implant in detail, determine the cause of the “reportable event”, and immediately report to the NRC its findings, any action taken to correct the current event and any corrective action needed, required, completed, or recommended to prevent future events.

Brachytherapy Implant Review

Action Steps For Determination of a Reportable Event

1. Post plan is completed by medical physicist and evaluated based on implant success criteria and original pre-plan and physician written directive
2. Any deviation of the implant success criteria determined by the medical physicist shall require an initiation of a “reportable event” evaluation form
3. Post plan, medical physicist evaluation, and the initiated “reportable event” evaluation form shall be provided to the attending radiation oncologists for review
4. Attending Radiation Oncologists shall review all documentation of implant:
 - Written directive
 - Pre-implant treatment plan
 - Seed order forms and other seed documentation
 - Prostate contouring on the pre-implant treatment plan
 - Prostate contouring on the post implant treatment plan
 - Prostatic treatment margins on pre and post treatment contours and written directive
5. Attending Radiation Oncologists in conjunction with the medical physicist and hospital Radiation Safety Officer (RSO) shall make a determination utilizing the NRC and standard hospital brachytherapy success criteria on whether a “reportable event” has occurred.
6. If a determination is made that a “reportable event” **has not** occurred, a detailed report will be completed by the radiation oncologists and his/her report, as well as, all review information shall be forwarded to the Hospital Brachytherapy Program Director to be filed for review by the Brachytherapy QI Program Review Committee at its next meeting.
7. If a determination is made that a “reportable event” **has** occurred, the following action shall be taken immediately:
 - The Quality Improvement Department will be notified immediately
 - The radiation oncologists or radiation safety officer (RSO) shall immediately notify the Brachytherapy Implant Program Director of the Hospital
 - The Brachytherapy Program Director, Quality Improvement Department Representative and Medical Oncology shall make an immediate report to the NRC and any other required department of the hospital or outside regulatory agency
 - The radiation oncologists shall notify the attending urologists of the event

- The radiation oncologists shall notify the patient of the event and circumstances and recommend any clinical corrective action required
- A meeting of the hospital Brachytherapy QI Program Review Committee shall be called as soon as possible. This meeting may be performed via conference call or video conferencing
- The attending radiation oncologists shall make a full report to the Brachytherapy QI Program Review Committee
- If it is determined that program and/or policy/procedure changes are necessary, needed, or recommended, the Brachytherapy QI Program Review Committee shall make those changes to the program and/or policies and procedures.
- A full follow up report shall be made to the NRC following the NRC reporting guidelines as outlined in the Rules and Regulations on the “reportable event” with full disclosure
- Brachytherapy QI Program Review Committee will review the “reportable event” again at its regularly scheduled meeting and any and all program and/or policy and procedural changes that may have been made for improvement to the brachytherapy implant program to ensure viability of those changes and overall improvement to the implant program

VariSeed: Study Summary Report [Page 1]

Oncology Med Inc. · Variseed Tower · 11/5/2010 10:39:03 AM

Name: [REDACTED] PID: 000260405 Dept. ID:	Study: Post-Op Variation: Default Images: 19	Source: I-125 (IAI-125A) [NIST 00] Comment: Sources: 81 Anisotropy: Factors (Point Model) Source Activity: 0.470 U [0.370 mCi]
Procedure Date: 11/2/2010	Prescription Dose: 145.0 Gy	Total Activity: 38.070 U [29.976 mCi]

Study Type: Post-Op

Dose Information

Prostate:

Total Volume:	40.86 cc	
V200:	6.49 cc	[15.88%]
V150:	16.16 cc	[39.54%]
V100:	36.41 cc	[89.12%]
D100:	78.00 Gy	[53.80%]
D90:	142.66 Gy	[98.39%]
D50:	199.53 Gy	[137.60%]

Rectum:

Total Volume:	62.16 cc	
V100:	0.08 cc	[0.12%]
D30:	27.54 Gy	[18.99%]
D5:	76.58 Gy	[52.82%]

Bladder:

Total Volume:	110.91 cc	
D30:	14.22 Gy	[9.81%]
D5:	44.57 Gy	[30.74%]

Urethra:N/A

VariSeed: Study Summary Report [Page 1]

Oncology Med Inc. · VariSeed Tower · 10/28/2010 9:36:07 AM

Name: ██████████
PID: 000065854
Dept. ID:

Study: **post**
Variation: **Default**
Images: 17

Source: **CS-131(CS-1)**
Comment:
Sources: **69**
Anisotropy: **Factors (Point Model)**
Source Activity: **2.000 U [3.135 mCi]**
Total Activity: **138.000 U [216.301 mCi]**

Procedure Date: **10/25/2010**

Prescription Dose: **115.0 Gy**

Study Type: Post-Op

Dose Information

Prostate:

Total Volume:	26.43 cc	
V200:	5.41 cc	[20.46%]
V150:	13.10 cc	[49.57%]
V100:	23.15 cc	[87.61%]
D100:	46.00 Gy	[40.00%]
D90:	107.54 Gy	[93.51%]
D50:	171.85 Gy	[149.44%]

Rectum:

Total Volume:	67.31 cc	
V100:	0.40 cc	[0.60%]
D30:	24.86 Gy	[21.62%]
D5:	69.53 Gy	[60.46%]

Bladder:

Total Volume:	127.56 cc	
D30:	13.33 Gy	[11.59%]
D5:	34.91 Gy	[30.36%]

Urethra:N/A

VariSeed: Study Summary Report [Page 1]

Oncology Med Inc. · Variseed Tower · 10/28/2010 9:30:31 AM

Name: ██████████ PID: 000132820 Dept. ID:	Study: post Variation: Default Images: 18	Source: I-125 (IAI 125A) [NIST 00] Comment: Sources: 63 Anisotropy: Factors (Point Model) Source Activity: 0.432 U [0.340 mCi] Total Activity: 27.216 U [21.430 mCi]
Procedure Date: 10/25/2010	Prescription Dose: 145.0 Gy	

Study Type: Post-Op

Organ Information

Prostate:

Total Volume:	25.64 cc	
V200:	3.27 cc	[12.67%]
V150:	6.86 cc	[26.56%]
V100:	15.50 cc	[59.77%]
D100:	87.49 Gy	[60.34%]
D90:	140.73 Gy	[97.06%]
D50:	183.45 Gy	[120.30%]

Rectum:

Total Volume:	31.39 cc	
V100:	0.00 cc	[0.01%]
D30:	20.95 Gy	[16.55%]
D5:	70.76 Gy	[48.80%]

Bladder:

Total Volume:	170.55 cc	
D30:	22.66 Gy	[13.31%]
D5:	59.94 Gy	[41.34%]

Urethra:N/A