



**BON SECOURS CANCER INSTITUTE**  
Bon Secours Richmond Health System

March 3, 2009

Nuclear Regulatory Commission  
Region I  
475 Allendale Road  
King of Prussia, PA 19406-1415

*03032638/2009001*

Subject: Corrective Action per February Visit of  
License # 45-25187-01

Dear NRC:

This letter is to address the recent minor violation found upon recent inspection at the St. Francis location of license #45-25187-01. The door interlock and daily QA was found to be incomplete on one day during the morning warm up procedure.

The following Corrective Actions were discussed during the exit interview and deemed acceptable: the physicist performing the morning checks will be re-educated on the morning warm-up procedures and the requirements for thorough documentation. Additionally, the QA records will be reviewed during the quarterly Radiation Safety Committee Meetings.

Any questions regarding the above matter should be directed to, Nirmal Sakthi, MS, R(T)(T), CMD, DABR e-mail nirmal@yennes.net or cell phone (804) 243-4365.

Sincerely,

Teresa L. Crist, CMD  
Director, Radiation Oncology

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2009 MAR -9 PM 12:39

**NMSS/RGNI MATERIALS-004**

**Bon Secours Virginia HealthSource**  
**Diagnostic & Therapeutic Services**

Policy/Procedure

<b>Topic:</b> Quality Assurance program for High Dose Rate remote afterloading brachytherapy	<b>Policy No.:</b> GP-35a	<b>Date:</b> 6/2008
<b>Area:</b> Richmond Radiation Oncology Center		
<b>Approved By:</b> _____		
<b>Administrative Director:</b> _____		
<b>Medical Director:</b> _____		

**POLICY**

It is the policy of Richmond Radiation Oncology Center to maintain a program to ensure that the operations are carried out and comply with the Center's NRC materials license.

**PROCEDURE**

1. The operating procedures are maintained to include without exception that the ~~microSelectron high-dose-rate~~ afterloading device and system will not be overridden except by written authorization by both the Authorized User and the Radiation Safety Officer/Medical Physicist.

Bon Secours Virginia HealthSource  
Diagnostic & Therapeutic Services

Policy/Procedure

Topic: High Dose Rate remote afterloading  
Brachytherapy Treatment Protocol – Error-  
Message

Policy  
No.: GP-35a

Date: 6/2008  
Revised: 712008

Area: Richmond Radiation Oncology Center, Inc.

Approved By:

Administrative Director: *Jeresa L. Crist*

Medical Director: *George A. Truett, M.D.*

**POLICY**

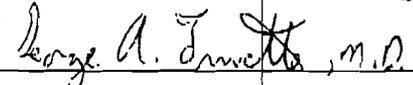
It is the policy of Richmond Radiation Oncology Center, Inc. to provide HDR treatments that are delivered in accordance with the written directive and treatment plan.

**PROCEDURE**

Upon occurrence of an HDR error message the Authorized User (AU) and Authorized Medical Physicist (AMP) will jointly investigate and correct the cause of the error before proceeding. Obstructions will be checked in the transfer tubes and applicators and a check wire ran to manually recheck the catheter length. Any changes will be agreed upon by both the AU and AMP and independently checked by two authorized individuals before proceeding. If the cause for the error cannot be identified and resolved, we will not proceed with the treatment. The vendor will be contacted immediately for maintenance.

**Bon Secours Virginia HealthSource****Diagnostic & Therapeutic Services**

## Policy/Procedure

Topic: Quality Assurance program for High Dose Rate remote afterloading brachytherapy	Policy No.: GP-35	Date: 1/93 Reviewed: 2/03, 6/08
Area: Richmond Radiation Oncology Center		
Approved By:		
Administrative Director:		
Medical Director:		

**POLICY**

It is the policy of Richmond Radiation Oncology Center to maintain a program to ensure that the operations are carried out and comply with the Center's NRC materials license.

**PROCEDURE**

1. The quality management program is maintained and adhered to as defined in attached written directives.
2. The operating procedures are maintained and adhered to as defined in attached procedures.
3. The model procedure for leak testing sealed sources is adhered to as defined in attached written directives.
4. The procedures for receiving and opening radioactive material are maintained and adhered to as defined in written directives.
5. The procedure for High Dose Rate double check is adhered to and maintained as written in attached directive.

**Bon Secours Virginia Health Source, Inc.****Quality Management Program: High-Dose-Rate  
Remote Afterloading Brachytherapy****Purpose:**

The following program has been established to ensure that the brachytherapy procedures carried out at this facility are of the highest quality and in compliance with Title 10, Code of Federal Regulations, Part 35.41 (10 CFR 35.41).

**Policies:**

- a) Prior to administration, a written directive must be prepared, dated with the current date of the actual treatment delivery and signed by an authorized user for any brachytherapy procedure radiation dose listed under 10 CFR 35.400.
- b) The Authorized User (AU) and Authorized Medical Physicist (AMP) are required to be present in the immediate vicinity of the HDR control console at the initiation and throughout the course of the treatment, with full attention focused on the patient's treatment.
- c) Notification will be made by telephone to the NRC Operations Center no later than the next calendar day after discovery of a treatment error that meets the definition of a medical event. If a treatment deviation occurs and we question whether it meets the definition of a medical event, we will call the NRC Region I for guidance.
- d) Upon the occurrence of an HDR error message, the AU and AMP will jointly investigate and correct the cause of the error before proceeding. For example, for error messages suggesting an obstruction in the source path, we will recheck all connections of the applicator and transfer tube, look for catheter kinks in the applicator and transfer tube, and use a check wire to manually recheck the catheter length. Any changes will be agreed upon by both the AU and AMP and independently checked by two authorized individuals (AUs and/or AMPs) before proceeding. If the cause of the error message cannot be identified and resolved, we will not proceed with treatment.

**Definitions:**

**Medical Events** as defined by the NRC include (but are not limited to):

- a) 10 CFR 35.3045(a)(1): any event (not resulting from patient intervention) in which dose to the target varies by more than 50% from the prescribed dose AND one of the following:
  - a. the total dose differs from the prescribed dose by 20% or more (underdose or overdose), or
  - b. the fractionated dose differs from the prescribed dose for a single fraction by 50% or more (underdose or overdose).
- b) 10 CFR 35.3045(a)(3): A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem and 50% the dose expected from the administration defined in the written directive.

**Written directive** means an order in writing for a specific patient, dated and signed by an Authorized User prior to the administration of a brachytherapy dose containing the following information:

- a) the radioisotope,
- b) treatment site,
- c) dose per fraction,
- d) number of fractions,
- e) actual and tolerance dose to critical tissue/organ,
- f) and total dose.

**Prescribed Dosage** means, for remote afterloader brachytherapy, the total dose and dose per fraction as documented in the written directive,

**Procedures:**

1. Prior to administration, a written directive shall be prepared, dated and signed by an authorized user for any brachytherapy dose from a high-dose-rate remote afterloading device.
2. Prior to each administration, the patient's identity shall be verified as the individual named in the written directive by more than one method. This may be done by asking the patient's name and confirming the name and at least one of the following by comparison with the corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID bracelet or ID card, the name on the patient's medical insurance card or a photograph taken of the patient's face for ID purposes,
3. Prior to administration, the final plans of treatment and related calculations for brachytherapy shall be reviewed by the authorized user or a qualified person under the supervision of the AU to ensure that they are in accordance with the respective written directive. Specifically, the AU or qualified person must confirm the prescribed radioisotope, treatment site, prescribed dose, dose per fraction, and total dose to ensure they are in

accordance with the written directive). A time out will be performed prior to each treatment by the AU and/or AMP or designee which includes verbalizing patient name, treatment procedure, and total dose to be delivered.

4. All unintended deviations from a written directive must be identified and evaluated, and appropriate actions taken (see policy for medical events).
5. If at any time a worker needs guidance or is unclear as to how a written directive is to be carried out, he/she should seek advice from the authorized user rather than continue with the procedure.
6. Radiographs or other comparable images (e.g., computerized tomography images) will be used to verify the position of nonradioactive "dummy" markers and will be used in calculating the administered brachytherapy dose before inserting the sealed source(s).
7. All brachytherapy dose calculations must be checked before administering the prescribed brachytherapy dose. An authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist) who did not make the original calculations should check the dose calculations. The responsibilities and conditions of supervision as contained in 10 CFR 35.27 will be followed. Methods for checking the calculations include the following:
  - a. Computer-generated dose calculations should be checked by examining the computer printout to verify that correct input data for the patient were used in the calculations (e.g., source strength and positions).
  - b. The computer-generated dose calculations for input into the brachytherapy afterloading device should be checked to verify correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times).
  - c. An AMP or designee (other than the person who created the plan) will perform an independent calculation of dose to a point for the particular treatment.
8. Visual and audio contact will be maintained with the patient throughout the duration of the treatment. The patient should be able to speak with the operators at any time during the treatment.
9. The AU and AMP must be present at the HDR Treatment Control Station (i.e., direct line of sight with attention to the treatment of the HDR patient), until the treatment is completed in accordance with 10 CFR 35.615 (f) (2) (i) and (ii).
10. After completing the treatment, note that the microSelectron control panel lights, the treatment vault light by the door, and the radiation monitor mounted inside the room all indicate the sealed source has returned to its shielded position.
11. A survey meter shall be used to perform an area radiation survey of the treatment vault, including the patient and microSelectron high-dose rate afterloading device.
12. Immediately after administering the brachytherapy treatment, the authorized user or a qualified person under the supervision of the authorized user, shall date and sign or initial a written record that documents the radionuclide, treatment site, dose per fraction, and the

total dose in the patient's chart or in another appropriate record. These records shall be kept for three years after the date of administration. If this is the actual treatment record, we keep it until 5 years after the death of the patient.

13. Acceptance testing shall be performed by a radiation physicist on each treatment planning or dose calculating computer program that could be used for brachytherapy dose calculations when using high-doserate remote afterloading devices. Acceptance testing shall be performed before the first use of the treatment planning or dose calculating computer program and shall be assessed according to the Center's specific needs and applications.
14. An annual review of the quality management program will be performed by the Radiation Safety Officer or his designee. The RSO or designee should not review their own work independently. If this is not possible, they should review the program with another person as a team. The review should include:
  - a. A representative sample of patient administrations based on the 10% table of lot tolerance percent defects in 10 CFR 32.110 (b)(8). If a Medical Event is uncovered during this review, *the* number of cases reviewed shall be expanded in accordance with Regulatory Guide 8.33,
  - b. An evaluation of all Medical Events to *verify* compliance with all aspects of the quality management program.
  - c. For each case reviewed, the reviewer should determine whether the administered dose was in accordance with the written directive.
  - d. A record of each review, including the evaluations and findings of the review, will be reported to the Radiation Safety Committee and will be kept for a minimum of three years. The report should identify deviations from the written directive, the cause of the deviation(s), and the action(s) necessary to prevent recurrence. The action(s) may include new or revised policies, new or revised procedures, additional training, or increased supervisory review of work.
  - e. Each of these reviews will be evaluated by the Radiation Safety Committee to determine the effectiveness of the quality management program and, if required, the committee will make modifications to meet the objectives of the program.

**Physicist's Final Chart Review  
Richmond Radiation Oncology Inc.**

Patient: \_\_\_\_\_ RT #: \_\_\_\_\_ Date: \_\_\_\_\_

Unit: Nucletron HDR Unit

Items Reviewed	Applicator: _____	OK	Not OK	NA
<b>Patient Identification</b>				
Written name on chart		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Identified by two means		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Written Directive</b>				
Written directive initial by physician		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Specifies total dose		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Specifies dose per fraction		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Specifies treatment site		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Specifies total number of fractions		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Written Record</b>				
Each treatment is recorded and dated		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Each treatment is initialed		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Each treatment has recorded time		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Each treatment has recorded daily dose		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Each treatment has recorded accumulated dose		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Dosimetry Review</b>				
Timely second check of calculations		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Calculations initialed by physician		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Isodose treatment plan initialed by physician		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Computer plan initialed by physicist		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Computer plan has a manual check of dose to a point		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Treatment Delivery</b>				
Correct site was treated		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Correct dose per fraction was delivered		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Correct total dose was delivered ( $\pm 5\%$ )		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Performed by: \_\_\_\_\_

Medical Physicist



**Bon Secours Virginia Health Source, Inc.  
HDR WRITTEN DIRECTIVE  
Vaginal Cylinder Treatments**

Patient Name: \_\_\_\_\_ SSN: \_\_\_\_\_

Pre-Implant Order: Isotope: Ir-192 Activity: \_\_\_\_\_ Ci Supplier: Nucletron

Modality:  HDR  LDR External Beam Radiation:  Yes  No

Treatment Site: Vagina

Dose: \_\_\_\_\_ cGy/fx Rx: \_\_\_\_\_ fractions Total Dose: \_\_\_\_\_ cGy

Rx prescribed \_\_\_\_\_ cm from cylinder surface Dwell Positions: # \_\_\_\_\_

Organ at Risk: Rectum Tolerance Dose: 6500 cGy (EBRT +Brachy)  
Bladder Tolerance Dose: 7000 cGy (EBRT +Brachy)

Authorized User: \_\_\_\_\_ Date: \_\_\_\_\_  
\_\_\_\_\_, MD.

**Post-Implant Order: Isotope: Ir-192**

Rx: See Treatment Below Site: Vagina Total Dose: \_\_\_\_\_ cGy

Authorized User: \_\_\_\_\_ Date: \_\_\_\_\_  
\_\_\_\_\_, MD.

**Treatment Record**

**Post treatment radiation survey**

Tx. #	Date	Time	Fx Dose	Accum Dose	Accum Bladder Dose	Accum Rectum Dose	Patient mR/hr	Bkg mR/hr	Phys. Initials	M.D. Check
EBRT										
1										
2										
3										
4										
5										
6										

Survey Meter: Victoreen 451P SN:2133 Cal:3/08

\_\_\_\_\_  
Physicist/ Dosimetrist

\_\_\_\_\_  
Date

**Bon Secoun Virginia Health Source, Inc.  
HDR WRITTEN DIRECTIVE  
Tandem and Ovoid Treatments**

Patient Name: \_\_\_\_\_ SSN: \_\_\_\_\_

**Pre-Implant Order: Isotope: Ir-192 Supplier: Nucletron Form: HDR**

Activity: 10 Ci decayed

Rx: \_\_\_\_\_ fractions Treatment Site: Cervix For Dose: \_\_\_\_\_ cGy/fx

Total Dose: \_\_\_\_\_ cGy Rx specified st Points A & B

Organ at Risk: Rectum Tolerance Dose: \_\_\_\_\_ cGy total insertion

Organ at Risk: Bladder Tolerance Dose: \_\_\_\_\_ cGy total insertion

Authorized User; \_\_\_\_\_ Date: \_\_\_\_\_

**Post-Implant Order: Isotope: Ir-192**

Rx: See Treatment Below Site: T&O For Dose of: \_\_\_\_\_ cGy/fx

Authorized User: \_\_\_\_\_ Date: \_\_\_\_\_

Treatment Record							Post treatment radiation survey			
Tx. #	Date	Time	Daily Dose	Accum Dose	Accum Rectum Dose	Accum Bladder Dose	Patient mR/hr	Bkg mR/hr	Phys. Initials	M.D. Check
1										
2										
3										
4										
5										
6										

Survey Meter: Victoreen 451B SN: 706 Cal:7/08

\_\_\_\_\_  
Physicist / Dosimetrist

\_\_\_\_\_  
Date

**Bon Secours Virginia Health Source, Inc.  
HDR WRITTEN DIRECTIVE  
GYN Cylinder Treatments**

Patient Name: \_\_\_\_\_ SSN: \_\_\_\_\_

**Pre-Implant Order:** Isotope: Ir-192 Supplier: Nucletron Form: HDR

Activity: 10 Ci decayed

Rx: \_\_\_\_\_ fractions Treatment Site: **Vaginal Wall** For Dose; \_\_\_\_\_ cGy/tx

Total Dose: \_\_\_\_\_ cGy Rx specified at \_\_\_\_\_ cm from cylinder surface.

Organ at Risk: Rectum Tolerance Dose: \_\_\_\_\_ cGy total insertion

Organ at Risk Bladder Tolerance Dose: \_\_\_\_\_ cGy total insertion

Authorized User: \_\_\_\_\_ Date: \_\_\_\_\_

**Post-Implant Order:** Isotope; Ir-192

Rx: See Treatment Below Site: **Cylinder** For Dose of: \_\_\_\_\_ cGy/tx

Authorized User: \_\_\_\_\_ Date: \_\_\_\_\_

**Treatment Record**

**Post treatment radiation survey**

Tx. #	Date	Time	Daily Dose	Accum Dose	Accum Rectum Dose	Accum Bladder Dose	Patient mR/hr	Bkg mR/hr	Phys. Initials	M.D. Check
1										
2										
3										
4										
5										
6										

Survey Meter: Victoreen 451B SN: 706 Cal: 7/08

\_\_\_\_\_  
Physicist / Dosimetrist

\_\_\_\_\_  
Date